JMJ

Virgin of the Rosary. Bartolome Esteban Murillo

Legal history of non-regulation of biological products

Whole-of-government public deception campaigns.
Psychological, biological and chemical warfare, communicable disease control and vaccination reporting published at Bailiwick News on Substack, 2022-2025, organized by subject.

Book 1

Authors: Katherine Watt, kgwatt@protonmail.com and Lydia Hazel, lydiahazel@aol.com.

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About the authors

Katherine Watt is a Roman Catholic, American, Gen-X writer, paralegal, wife and mother. She earned a BA in philosophy from Penn State University in 1996 with a minor in natural sciences, and worked as a reporter for small newspapers. In 2003 she earned a paralegal certificate and until 2019, worked for small law firms practicing constitutional, civil rights and environmental law. Since 2005, she has published several independent journalism blogs covering local corporate and government corruption, and food, water and energy security issues. Since 2020, she has investigated changes to US law that have legalized poisoning, mutilation, torture and homicide under public health pretexts. Her primary work product is a timeline called the American Domestic Bioterrorism Program and can be found at her Substack, Bailiwick News. Email: kgwatt@protonmail.com.

Lydia Hazel, a pre-Vatican II Roman Catholic, holds degrees in Latin (BA) and linguistics (MA), with minors and concentrations in mathematics, phonetics/phonology, and philology. Her professional background is teaching English as a Second Language. She raised four children, unvaccinated since 1993, after Hazel investigated vaccines when Hepatitis B vaccines were added to the CDC-recommended childhood immunization schedule. She lives in Illinois and is the author of the Medical Countermeasures Awareness Act posted at Bailiwick in February 2024. Email: lydiahazel@aol.com.

Introduction

This volume contains selected reports from Bailiwick reporting, organized by subject.

Reporting is also collected in annual compilations, organized by date of publication:

- 2022 Bailiwick News Volume 6 Jan. to Dec.[1] (952 pages, 17.9 MB)
- 2023 Bailiwick News Volume 7 Jan. to Dec.[2] (785 pages, 9.5 MB)
- 2024 Bailiwick News Volume 8 Jan. to Dec.[3] (892 pages, 23 MB)

We have assembled an evidence collection documenting changes in statutory, regulatory and other US law before and since the 1944 enactment of the Public Health Service Act, including establishment of programs covering biological products, communicable disease control and quarantine, which serve as the legal foundations for the intentional government-directed sterilizing, sickening and killing programs, which have become more visible through the Covid-19 events that emerged into public view in January 2020.

The essential components of the kill box law evidence collection are public documents available in complete, unredacted and accurate form. The evidentiary package includes dozens of Congressional acts with dated roll call votes and dated presidential signatures; dozens of dated executive orders with presidential signatures; and hundreds of dated regulatory amendments promulgated through Federal Register notices signed by Cabinet secretaries and their delegates.

The basic kill box law evidence (statutes, executive orders and regulations) is supported by corroborating evidence in the form of contracts (often heavily redacted), treaties and treaty-negotiation documents, and other evidence collections.

Other authors who address some of these subjects in their written work include Sasha Latypova (Substack), Mike Yeadon (Substack and Telegram), Debbie Lerman (Brownstone Institute and Substack), Conspiracy Sarah (Substack), Jamie Andrews (Substack), ExcessDeathsAU (Substack), Democracy Manifest (Substack), Paula Jardine (The Conservative Woman UK) and Whitney Webb (The Last American Vagabond and Unlimited Hangout).

[1] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2025/04/2022-bailiwick-news-volume-6-full-corrected.pdf
[2] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/10/2023-bailiwick-news-volume-7-jan.-to-dec.pdf
[3] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2025/01/2024-bailiwick-news-volume-8-jan.-to-dec.-892-p.pdf

Chapter 1

US federal non-regulation of biological products, 1798 to 1972

42 USC 262-263, 42 CFR 22, 42 CFR 73, 21 CFR 273

Part 1 - Federal communicable disease control, quarantine and biological product law, 1798 to 1972; orientation through founding of Marine Hospital Service.

Published Aug. 5, 2024

By Lydia Hazel and Katherine Watt

Research Methods

Covid events have revealed that there are no applicable or enforced federal rules governing production and use of biological products to ensure product identity, purity, safety and efficacy.

To regulate means "to govern or direct according to rule."

Interested in finding the statutory and financial roots of the current pharmaceutical regulatory fraud system — biological product non-regulation that is presented as biological product regulation — we study available records of Congressional laws and appropriations (US Statutes at Large, a collection of laws published in order of the date of passage, starting with the First Congress, 1789-1791) and also within code books that organize laws by subject matter (codification).

The first available codified collection of federal laws was published in 1875 as the Revised Statutes of the United States. After several editions published between 1875 and 1926, Congress replaced the Revised Statutes with the US Code (Code of Laws of the United States of America), for which new editions are printed every six years, most recently in 2018 and revisions between printings are entered into online editions.

We also study federal regulations. Prior to the Federal Register Act (PL 74-220, July 26, 1935), agency regulations were not published as organized collections. Instead, "executive branch agencies and the Office of the President would each publish their own regulations in various separate publications, be they gazettes, bulletins, rulings, digests, pamphlets, notices, codes, certificates, orders, and the like."

Since the Federal Register Act, agency rules have been collected and published in the Federal Register. The Library of Congress maintains an online collection of the editions published between 1936 and 1993. GovInfo.gov maintains an online collection of editions published between 1936 and the present.

Orientation

Between 1798 and the present, US Congress members and American Presidents, through Congressional acts and appropriations, established and funded several federal agencies whose work has been presented to the public as legally responsible for regulating the development, manufacture or propagation, identity, safety, efficacy, purity, distribution and use of biological products and vaccines, allegedly to prevent infection and transmission of bacterial and viral, allegedly-disease-causing pathogens between and among living humans and animals.

In the scientific-medical fields, Edward Jenner allegedly discovered smallpox vaccine in 1796 and published a paper about his work in 1798; Louis Pasteur proposed the germ theory of disease in 1877 and Robert Koch identified the tubercle bacillus as the cause of tuberculosis in 1882.

The term *vaccination* has been traced to a proposal by Louis Pasteur at the 7th International Congress of Medicine, held in London in 1881. (See Early smallpox vaccine manufacturing in the United States:

Introduction of the "animal vaccine" in 1870, establishment of "vaccine farms", and the beginnings of the vaccine industry, Esparza et al, June 19, 2020, *Vaccine*)

During the 1800s, several biological products described as vaccines or analogous products were manufactured (propagated) and used in the United States and other continents, including smallpox vaccine (since 1801), rabies post-exposure vaccine (1885), and diphtheria antitoxin (1895).

These developments are important, because the scientific disciplines of microbiology, bacteriology, virology, immunology, and epidemiology developed in a mutually-reinforcing way with the development of communicable disease, quarantine and biological product law.

Scientific and statistical fraud have historically enabled legal fraud, and legal fraud has historically enabled scientific and statistical fraud.

Among other examples, lawmakers have relied on authoritatively-delivered but false claims made by scientists and statisticians, to build public support for and compliance with federal public health programs and products, from the roots in the late 1700s and early 1800s, through modern global pandemic preparedness and response programs, Covid-19 and the current avian influenza fraud.

When trying to understand the structure of scientific-medical deceptions and how laws and lawmaking acts relate to scientific-medical deceptions, there are several key questions to keep in mind.

1. What are the problems that government officers (Congress members as lawmakers, US Presidents and cabinet secretaries as law executors and civil administrators) claim to be interested in solving? How does the government define problems and the government's role in addressing them?

This corresponds to the "ostensible reason" framing described by Lawrence Dunegan in the Day Tapes: Dunegan's recollection of a lecture given to a group of pediatricians by Dr. Richard Day in March 1969, in Pittsburgh.

Another comment that was repeated from time to time...particularly in relation to changing laws and customs... [Day] said: "Everything has two purposes. One is the ostensible purpose which will make it acceptable to people; and second, is the real purpose which would further the goals of establishing the new system and having it."

The ostensible reason for federal public health, communicable disease surveillance, quarantine, and biological product manufacturing and vaccination programs is communicable disease control. The purported goals are to identify preventable, transmissible diseases, infected people and animals, and measures capable of preventing infection and spread, and then to apply the allegedly preventative measures to human and animal bodies construed as disease vectors.

The real reason, from the get-go, has been to gradually "establish the new system:" a centralized global government engaged in uninterrupted surveillance, control and weakening of human beings and animals, with both humans and animals construed as livestock, and both construed as without free will and immortal souls.

2. What authorizing laws (statutes in the United States) does the government enact to address the problems or goals as defined by the government?

3. What are the public institutions (physical resources such as buildings, workers, equipment, supplies) and programs set up by the government, through the statutes, to address those problems or goals?

4. Who are the public officers assigned responsibility to set up and direct the institutional programs?

5. How do Congress and US Presidents raise money and supply it to the institutes and directors to run the programs?

6. What tasks are assigned to the director and subordinate officers?

Examples in the biological product law context include tasks such as drafting, publishing and enforcement of written regulations; collection, analysis and publishing of scientific, medical and statistical information such as disease surveillance and cause of death data; and design, production and use of medical interventions, such as quarantine and vaccination programs.

7. What non-government organizations and organizational projects support or advance the government's stated problem-solving goals?

Examples in the biological product law context include scientific organizations (universities, research foundations, academic publishers) studying microbiology, bacteriology, virology, immunology and epidemiology; and statistical organizations developing rubrics for classification of diseases and causes of death.

8. What quantitative measures do governments use to assess their progress in solving the government-defined problems?

Examples of quantitative measures in the biological product law context include disease diagnostic (individual) and epidemiologic (population) data, vaccination rates, and cause of death data.

9. Is the government defining problems and measuring the results of government interventions truthfully, or not?

10. If the government is not defining problems or measuring results truthfully, what are the actual, true goals the government is using laws and programs to advance?

11. What observational and analytical measures can the governed public use to distinguish true, real goals from false, ostensible goals?

Working Definitions

The words *virus* and *vaccine* are not defined in physically-verifiable terms in US statutory law, or in US agency regulations (for example, Food and Drug Administration regulations) that derive their legal authority from Congressional statutes, although *virus* entered federal biological product law in 1902 (Biologics Control Act, PL 57-244), and *vaccine* entered federal biological product law in 1970 (Heart Disease, Cancer, Stroke and Kidney Disease Amendments Act, PL 91-515).

The only statutory definition for *vaccine* is a circular or tautological definition, introduced as a part of the tax code in 1987 (26 USC 4132) defining "taxable vaccines" as members of a list of "vaccines containing" components such as diphtheria toxoid and pertussis antigens, at 26 USC 4132(a)(1), and defining "vaccine" non-specifically, in terms of the intention of its designer, as "any substance designed to be administered to a human being for the prevention of 1 or more diseases" at 26 USC 4132(a)(2), originally 26 USC 4132(a)(6). (PL 100-203, Omnibus Budget Reconciliation Act, at 101 Stat 1330-329).

In a 2018 court case, a federal court confirmed that the only statutory definition for *vaccine* is the tax code definition (*Dean* v. *HHS*, No. 16–1245V, 2018 WL 3104388, cited in 86 FR 6249, Jan. 21, 2021).

There is no statutory definition for *virus*.

The 1947 regulatory definition for *virus* [same definition first published in 1919 regulations]:

> "A virus is a product containing the minute living cause of an infectious disease. [42 CFR 73.1(g)(1)]

As of November 1973 and still today, FDA defines *virus* as:

> "A *virus* is interpreted to be a product containing a minute living cause of an infectious disease and includes but is not limited to filterable viruses, bacteria, rickettsia, fungi, and protozos." 21 CFR 600.3(h)(1)

For the purpose of this series, the authors provisionally define *virus* and *vaccine* as follows:

- Virus: An undefined, non-standardized, non-isolated molecule alleged, by government officers, to be transmissible and capable of causing severe, moderate, mild or subclinical (asymptomatic) disease and death in living human or animal hosts.
- Vaccine: An undefined, non-standardized, biologically propagated and/or chemically manufactured compound of molecules alleged, by government officers, to artificially simulate a virus and, upon introduction into a healthy subject, to be capable of causing moderate, mild or subclinical (asymptomatic) disease in living human or animal hosts.

<u>Government sources: How the NIH and FDA describe the history of biological product regulation.</u>

US National Institutes of Health (NIH) - A Short History of the National Institutes of Health: Biologics

> "The Biologics Control Act of 1902...charged the Hygienic Laboratory in Washington D.C. with regulating the production of vaccines and antitoxins, thus making it a regulatory agency four years before passage of the better known 1906 Food and Drugs Act."

US Food and Drug Administration (FDA) - The History of Biologics Regulation.

> "Modern federal oversight of biological products began under the 1902 Biologics Control Act, which the Hygienic Laboratory of the Public Health and Marine Hospital Service carried out. With the creation of the National Institutes of Health from the Hygienic Laboratory, regulatory authority remained at NIH until 1972, when it was transferred to the FDA."

History of federal communicable disease, quarantine and biological product law and appropriations in the United States

In September 1789, the first Congress established the Treasury Department, to be directed by the Secretary of the Treasury. From 1789 until the New Deal in the 1930s, the Treasury Secretary served as the executive branch officer directing most federal executive agencies.

In April 1939, Congress established the Federal Security Agency (PL 76-19, Reorganization Act of 1939) and President Franklin Roosevelt transmitted to Congress an executive branch reorganization plan (Reorganization Plan No. 1).

Roosevelt transferred the Public Health Service and several other federal departments, the PHS Surgeon General, and the PHS communicable disease, quarantine and biological product programs from the Treasury Department, to the new Federal Security Agency, under the control of a new position: the Federal Security Administrator appointed by the President.

President Eisenhower cited the Reorganization Act of 1949 (PL 81-109) as authorization when, in 1953 (Reorganization Plan No. 1 of 1953), he created the Department of Health, Education and Welfare and transferred the authorities of the Federal Security Administrator to the new Secretary of Health, Education and Welfare.

In 1966 (Reorganization Plan No. 3 of 1966), President Johnson transferred the authorities and functions of the Public Health Service and the PHS Surgeon General to the HEW Secretary.

In 1979 (Department of Education Organization Act, PL 96-88), Congress and President Carter created the Department of Education, transferred educational program authority to the new Secretary of Education, and renamed the Department of Health, Education and Welfare as the Department of Health and Human Services (HHS) and its secretary as the Secretary of Health and Human Services.

1798 - Marine Hospital Service founded; first federal health law.

Congress founded the Marine Hospital Service in 1798.

The federal law (Fifth Congress, Ch. 77, p. 605) required the master or owner of every ship arriving from a foreign port into any US port to give the tax collector a count of the number of seamen and pay 20 cents per month per seaman, deducted from the seamen's wages.

The program was an early form of health insurance and the first federal health law.

Tax collectors were authorized to withhold license renewals from ships whose owners failed to provide lists of employed seamen and pay the tax.

Tax collectors forwarded the collected funds quarterly to the Treasury Secretary; and the President was authorized to use the money to provide "for the temporary relief and maintenance of sick or disabled seamen, in the hospitals."

Surplus monies could be invested in the stock of the United States, and used to buy land or buildings to erect hospitals for sick and disabled seamen, and the President was authorized to appoint "directors of the marine hospital," to provide for the "accommodation of sick and disabled seamen" and required the directors to provide quarterly reports to the Treasury Secretary about money received and spent.

Part 2 - 1798-1972 US federal quarantine and biological product law: Marine-Hospital Service; National Quarantine Act; Laboratory of Hygiene

Published Aug. 12, 2024

By Lydia Hazel and Katherine Watt

1802 - Congress began taxing the wages of Mississippi River vessel workers.

In 1802, Congress amended the 1798 "act for the relief of sick and disabled seamen."

Section 1 directed the 20 cents per month tax on seamen's wages into a "general fund," to be used at the discretion of the President to provide hospitals and services, setting aside $15,000 to build a hospital in Massachusetts.

Section 2 authorized the President to spend up to $3,000 from the fund to set up a hospital service at the port of New Orleans.

Section 3 required masters of vessels working on the Mississippi River to provide counts of their employees, classifying them as "seamen of the United States" and authorized a $50 fine for giving false counts, with collected fines to go into the general fund.

Section 4 authorized the President to appoint a director of the marine hospital at New Orleans.

Section 5 authorized the marine hospital directors to admit "sick foreign seamen" if the masters of their vessels requested it, at a charge of 75 cents per day. Tax collectors for each district were authorized to refuse clearance to foreign vessels until the hospital fees were paid. Hospital directors could be fined $50 for failure to properly charge foreign ships for the care of foreign seamen.

Section 6 required the tax collectors to forward the collected money to the Treasury, which would receive commissions on collected money, and Section 7 authorized hospital directors to also take a commission of one percent of money collected.

1813 - First federal vaccination law.

In 1813, Congress passed "An Act to encourage Vaccination."

Section 1 authorized the President to appoint a federal agent (Baltimore physician James Smith, the first National Vaccine Agent) to "preserve the genuine vaccine matter" and to supply "vaccine matter" to applicants "through the medium of the post-office."

The federal vaccine agent was required to swear and file a certificate affirming his intent to preserve the genuine vaccine matter; provide copies of the act to all US post-masters; and provide information about how people interested in getting vaccine matter could apply for it to be delivered, along with instructions about how to use the products on themselves.

Section 2 authorized all packages of vaccine matter under a half-ounce to be carried postage-free by the US postal service, as long as the sending agent labeled the packages with the word "Vaccination" and his signature. Section 2 also authorized a $50 fine on the vaccine agent for sending packages with "any thing relative to any subject other than vaccination."

A 1998 paper by Harvard law student Rohit Singla, Missed Opportunities: The Vaccine Act of 1813, argued the ostensible reason for the 1813 act was to address "the most significant obstacle to effective vaccination...the difficulty of obtaining pure, uncontaminated vaccine when an epidemic threatened. Vaccine was difficult to produce in mass quantities, could only be stored for a short time, and was easily contaminated."

Congress repealed the Vaccine Act in 1822.

According to a 1985 book, *Vaccine Supply and Innovation* (National Academies Press), Congress repealed the Vaccine Act of 1813 in 1822 "after Congress decided that vaccine regulation should be left to local authorities."

In the 1998 Harvard law paper, Singla identified several factors leading to the repeal, including federalist sentiment (state lawmakers angry about federal government interference) and anti-monopoly sentiment (competing physicians angry about Smith's postage subsidy and provision of vaccine directly to consumers); Smith's inability to get sustained federal or state public subsidies other than free US postage; and his inability to raise sufficient money from private subscriptions and donations. The immediate political momentum was provided by the Tarboro Tragedy, when "Dr. Smith accidentally caused an [smallpox] epidemic in Tarboro, North Carolina which eventually killed ten people."

1866 - Authorization for Treasury Secretary to sell marine hospital buildings

In 1866, Congress authorized the Treasury Secretary to sell or lease marine hospital buildings and land and use the proceeds to support the marine hospital system, except for the Cleveland, Ohio and Portland, Maine hospitals, not to be sold, and except for hospitals in municipalities with no other suitable hospital accommodations.

1870 - Reorganization of Marine-Hospital Service

By law passed June 29, 1870, Congress increased the wage tax and reorganized the Marine-Hospital Service.

At Section 1, the per capita wage tax was raised to 40 cents per seaman per month for all US vessels arriving at US ports from foreign ports, and for all "registered vessels employed in the coastal trade."

At Section 2, Congress directed tax collectors to withhold new enrollments or licenses from shipmasters who failed to provide the headcounts and pay the taxes, and authorized a $50 fine on masters who provided false information about the number of employed seamen or duration of their employment, with the collected fines to go into the general fund for the Marine-Hospital Service.

At Section 3, Congress ordered tax collectors to deposit the collected money in the nearest US depository, and submit returns and vouchers to the Treasury Secretary recording the deposits.

At Section 4, Congress ordered the money to be paid to Treasury like other public moneys, "without abatement or reduction" and appropriated the money for the expenses of the Marine-Hospital Service, credited to the Marine-Hospital Fund and its separate accounts.

At Section 5, Congress ordered that the money be used, under Treasury Secretary supervision, "for the care and relief of sick and disabled seamen employed in registered, enrolled and licensed vessels of the United States."

At Section 6, Congress authorized the Treasury Secretary to appoint a surgeon to act as "supervising surgeon" [later known as the Supervising Surgeon-General and then Surgeon-General] of the Marine-Hospital Service, to work with the Treasury Secretary to spend the money, supervise hospital programs and provide medical care.

Congress authorized an annual salary of $2,000 plus travel expenses; and required the Supervising Surgeon to make monthly reports to the Treasury Secretary.

At Section 7, Congress defined "vessel" as "every description of water-craft, raft, vehicle, and contrivance used or capable of being used as a means or auxiliary of transportation on or by water" and repealed all previous acts "inconsistent with or in conflict" with the reorganization act.

1871 - First Supervising Surgeon appointed to direct Marine Hospital Service

In 1871, President Ulysses S. Grant appointed John Maynard Woodworth as the first Supervising Surgeon of the Marine Hospital Service.

1877 - Congress amended the law setting per ton cargo taxes on US and foreign-owned vessels.

By law passed February 27, 1877, Congress updated the tax schedule for cargo brought into US ports from foreign ports; the original tonnage duties act was enacted in 1790.

This is relevant because in 1884, Congress replaced the wage tax with the cargo tonnage tax as the means of financing the Marine-Hospital Service.

For vessels built in the US but owned by foreign subjects, the tax rate was set at 30 cents per ton. For other foreign vessels, the tax was set at 50 cents per ton. For vessels from countries that did not allow US trade vessels to enter, the duty was set at two dollars per ton, until the countries abolished their trade restrictions. See also, RS 4219-4127.

1878 - National Quarantine Act, authorizing Marine Hospital Service supervision of foreign quarantine programs.

On April 19, 1878 Congress passed "An act to prevent the introduction of contagious or infectious diseases into the United States," known as the National Quarantine Act.

State and local laws addressing disease control had already been adopted by many States and municipalities; details of the State and local laws are beyond the scope of this series of reports.

The 1878 quarantine act was the first *federal* law governing disease surveillance, isolation and "disinfection" of passengers and goods on inbound ships, coming from foreign ports, on the pretext of communicable disease control. The alleged infectious diseases mentioned by name in the act were cholera and yellow fever.

Section 1 prohibited vessels from any foreign port or country "where any contagious or infectious disease may exist" from entering US ports "contrary to the quarantine laws of any one of" the States, without following the federal "regulations to be prescribed" under the National Quarantine Act.

Section 2 required the US consular officers to provide weekly reports of the "sanitary conditions" at the foreign ports at which they served.

Consular officers at “infected” foreign ports were ordered to immediately provide information about any vessel leaving the foreign port, carrying passengers or goods and bound for a US port, to the Supervising Surgeon-General of the Marine-Hospital Service, including name of the vessel, date of departure and port of destination.

Consular officers were required to provide the same information to the State or local health officer at the destination port.

Congress charged the Supervising Surgeon-General with carrying out the federal quarantine provisions, under the direction of the Treasury Secretary, and directed him to "frame all needful rules and regulations" subject to the President's approval. Congress directed that federal regulations "shall not conflict with or impair" State or municipal sanitary or quarantine laws in force as of 1878 or enacted later.

Section 3 assigned the medical officers of the Marine-Hospital Service and customs-officers to enforce national quarantine rules established under Section 2, and authorized payment for travel expenses but no additional compensation.

Section 4 directed the Surgeon-General of the Marine-Hospital Service, upon receiving information about vessels departing allegedly infected ports, to immediately notify State, municipal and US officers at the "threatened port of destination," and to send "weekly abstracts of consular sanitary reports" to MHS medical officers, customs collectors, and State and municipal health authorities.

Section 5 authorized officers of State and municipal quarantine systems — where such systems were already in place — to apply for authorization to act as federal quarantine enforcement officers, and to be "clothed with all the power of US officers for quarantine purposes."

Section 5 further authorized the medical officers of the MHS to enforce quarantine measures at the State and municipal level, whenever "in the opinion of the Secretary of the Treasury, it shall be deemed necessary to establish quarantine," so long as the federal MHS officer acts didn't interfere with State or local quarantine laws.

Section 6 repealed all acts or parts of acts inconsistent with the National Quarantine Act.

1879 - Congress established a National Board of Health

On March 3, 1879, Congress passed "An act to prevent the introduction of infectious or contagious diseases into the United States, and to establish a National Board of Health."

Wikipedia reports that the National Board of Health was "to carry out [the National Quarantine Act of 1878] and was "created during a period of emergency, [an alleged yellow fever outbreak in 1878;]...had substantial powers (such as the ability to mandate quarantine)" and "was to effectively strip the powers of quarantine from the Marine Hospital Service, a precursor to the [Public] Health Service which itself would become the CDC."

The National Board of Health operated for four years, but Congress did not reauthorize it in 1883, and then repealed the original authorizing act in 1893, leaving the Marine-Hospital Service to supervise federal quarantine programs.

Section 1 established the board, members to include seven appointed by the President, with advice and consent of Senate, and no more than one from any one State. The state members were to be paid 10 dollars per day for committee work. Members also included three medical officers — one each from Army, Navy and Marine Hospital Service, and one federal officer from the Department of Justice — to be appointed by the secretaries of the departments, to serve on the committee without additional compensation.

Section 1 required the board to meet in Washington within 30 days of the act's passage; choose a board president to convene future meetings; "frame all rules and regulations" and make "special examinations and investigations" at US locations and at foreign ports.

Section 2 authorized the National Board of Health to "obtain information upon all matters affecting the public health," and provide advice to federal government departments, State governors and Washington DC

commissioners.

Section 3 directed the Academy of Science (established by Congress and President Lincoln in 1863) to work with the National Board of Health and State health officers and report to Congress with a plan for a "national public health organization," giving special attention to "the subject of quarantine, both maritime and inland, and especially as to regulations which should be established between State or local systems of quarantine and a national quarantine system."

At Section 4, Congress appropriated $50,000 to pay the salaries and expenses of the board members.

On April 3, 1879, President Rutherford B. Hayes appointed John Brown Hamilton to succeed Woodworth (who had died a month earlier) as the second Supervising Surgeon of the Marine Hospital Service.

1884 - Congress replaced wage tax (hospital tax on seamen) with tonnage tax for funding Marine-Hospital Service

On June 26, 1884, Congress repealed RS 4585 (40 cents per seaman per month wage tax), 4586 (hospital dues of vessels sold abroad) and 4587 (prohibiting vessel enrollment and licensing for failure to provide tax collector with information and collected wage taxes) and established that the cost of maintaining the Marine-Hospital Service would, from that point on, be paid from the receipts on cargo tonnage duties.

The tonnage tax financing system was repealed in 1905, when Congress began making regular appropriations to the institution that was, by that time, called the Public Health and Marine-Hospital Service.

1887 - Supervising Surgeon of MHS set up Laboratory of Hygiene without Congressional authorization.

In 1887, John Hamilton, the Supervising Surgeon of the Marine-Hospital Service, set up a one-room Laboratory of Hygiene at the Marine Hospital in Stapleton, Staten Island, NY, without Congressional authorization.

Hamilton appointed Dr. Joseph Kinyoun to run the lab.

Kinyoun, who had studied under Robert Koch and Louis Pasteur in Europe, called this facility a "Laboratory of Hygiene" in imitation of German facilities; it was later known as the Hygienic Laboratory.

1889 - Congress set up procedures for Presidents to appoint medical officers to MHS.

On Jan. 4, 1889, Congress established a process for Presidents to appoint medical officers of the Marine-Hospital Service, with advice and consent of Senate.

Section 1 required that candidates pass an examination in medicine, surgery and hygiene before a board of MHS medical officers, according to rules drafted by the Supervising Surgeon-General and approved by the Treasury Secretary.

Section 2 set up a rank system, such that appointees would first serve as assistant surgeons, and could, after four years, be promoted to passed assistant surgeon. Upon further exams, passed assistant surgeons could be promoted to surgeons. The act provided for grandfathering: the President could nominate current MHS medical officers for confirmation.

1890 - Congress put Marine-Hospital Service in charge of federal interstate quarantine

On March 27, 1890, Congress passed "An act to prevent the introduction of contagious diseases from one State

to another and for the punishment of certain offenses."

This was the first federal interstate quarantine law, controlling movement of people and goods across State borders within the United States.

At Section 1, Congress established that "whenever it shall be made to appear to the satisfaction of the President that cholera, yellow-fever, small-pox or plague exists in any State or Territory, or in the District of Columbia," the President was authorized to direct the Treasury Secretary to promulgate regulations to prevent the spread of the disease across State borders, and to employ inspectors to enforce such regulations.

Congress directed the regulations to be prepared by the Supervising Surgeon-General of the Marine-Hospital Service and the Treasury Secretary, and authorized fines up to $500 and imprisonment up to 2 years, or both, for civilian violation (criminal misdemeanor) of federal disease control regulations.

At Section 2, Congress authorized fines up to $300 and imprisonment up to one year, or both, for federal officers, or State and municipal public health officers acting as federal officers, found violating quarantine laws and regulations, or violating lawful orders given by superior officers.

At Section 3, Congress authorized criminal misdemeanor fines up to $500 and imprisonment up to two years, or both, for common carriers (public transportation of passengers and goods, such as railroads) and common carrier employees, found to be violating quarantine laws and regulations.

1891 - Laboratory of Hygiene moved to Washington DC; President Benjamin Harrison appointed Walter Wyman as third Supervising Surgeon-General of Marine-Hospital Service.

In 1891, still not Congressionally authorized and still directed and run by Kinyoun of the Marine-Hospital Service, the Laboratory of Hygiene moved to Washington DC.

Effective June 1, 1891, after Hamilton resigned, President Benjamin Harrison appointed Walter Wyman, who had been running the Quarantine Division of the Marine-Hospital Service since 1888, as third Supervising Surgeon General.

1893 - Congress authorized Marine-Hospital Service to exercise additional quarantine powers.

On February 15, 1893, in response to disease outbreaks in the preceding two years that had been attributed, by public health authorities, to infectious transmission of cholera and yellow fever pathogens, Congress passed "An act granting additional quarantine powers and imposing additional duties upon the Marine-Hospital Service."

At Section 1, Congress prohibited any vessel from any foreign port entering any US port, except in compliance with federal, State and municipal quarantine regulations, and established a fine (lien) of up to $5,000 on any vessel, through federal district court proceedings "conducted in accordance with the rules and laws governing cases of seizure of vessels for violation of the revenue laws of the United States."

At Section 2, Congress required vessels seeking access to US ports to obtain a "bill of health" from the consular officer or medical officer at the port, in the form prescribed by the Treasury Secretary.

Each bill of health was required to include the "sanitary history and condition" of the vessel, and affirmation that the vessel had complied with regulations prescribed for "securing the best sanitary condition of the vessel, its cargo, passengers, and crew."

Congress required the consular or medical officer to be satisfied that the statements in the bill of health were true, and authorized those officers to be paid fees for their services.

At Section 2, Congress further authorized the President, in his discretion, to detail federal medical officers to serve in the consular offices at foreign ports to inspect vessels and provide bills of health to masters of vessels. Congress established a fine (lien) of up to $5,000, on any vessel sailing from any foreign port and entering any US port, without a bill of health, through federal district court proceedings under the revenue laws of the United States.

At Section 3, Congress directed the Supervising Surgeon-General of the Marine-Hospital Service to examine the existing quarantine regulations of every State and municipal health board; to "cooperate with and aid" all State and municipal health boards to enforce their State and local regulations and also enforce federal quarantine regulations, "to prevent the introduction of contagious and infectious diseases" into the US from foreign countries, and across State borders within the US.

Congress required the Treasury Secretary to apply federal quarantine regulations uniformly at each port, and to make additional rules and regulations to be enforced in any State or municipality with no quarantine regulations of their own, or where he deemed the State and municipal quarantine regulations to be "not sufficient to prevent the introduction of such disease."

Congress required the Treasury Secretary, when establishing additional regulations, to promulgate them to State and municipal health officials and to ensure that the State and municipal health officials enforced them.

Congress authorized the Treasury Secretary, if State and municipal health officials "fail or refuse" to enforce the regulations, to detail federal medical officers to enforce them.

Congress directed the Treasury Secretary to make "such rules and regulations as are necessary to be observed by vessels at the port of departure and on the voyage," and required him to publish and communicate them to the consular officers at each port.

At Section 4, Congress required the Supervising Surgeon-General of the Marine Hospital Service, under the direction of the Treasury Secretary, to "perform all the duties" related to quarantine and quarantine regulation enforcement, and to gather information about sanitary conditions at foreign ports collected by consular officers at each port, entered onto forms prepared by the Treasury Secretary, and submitted weekly to the Treasury Secretary.

Congress further directed Treasury Secretary to collect information from State and municipal health officers in the US about sanitary conditions at US ports; to write and distribute weekly sanitary reports to all customs officers and State and municipal health officers; to obtain "voluntary co-operation" from State and municipal authorities, public associations and private persons to gather information about "climatic and other conditions affecting the public health; and to make annual reports to Congress with recommendations.

At Section 5, Congress required the Treasury Secretary to "from time to time" send updated regulations to consular officers and medical officers in foreign ports, to be "used and complied with" by vessels, and "observed in the inspection...disinfection and isolation" of the vessel on its arrival at destination ports, and "treatment of cargo and persons on board" to prevent the introduction of cholera, yellow fever or other infectious diseases.

Congress prohibited vessels from entering US ports and discharging cargo or passengers without a "certificate of the health officer" serving at the destination port quarantine station.

Congress required the masters of the vessels to present, to the customs officer, a valid "bill of health" provided at the port of departure, and "certificate of health" from the health officer at the port of entry, and that the signed, sealed documents shall be accepted as evidence in any US court.

At Section 6, Congress authorized the Treasury Secretary to send "infected" vessels that arrived at a port without proper quarantine facilities, on to the nearest "national or other quarantine station" for "disinfection and treatment of the vessel, passengers, and cargo," and, after getting a certificate from the officer that they were "free from infectious disease, or danger of conveying the same," the vessel would be allowed to enter any port named in the certificate. Section 6 also authorized the Treasury Secretary to send infected vessels to State and local quarantine stations for disinfection and certification.

At Section 7, Congress authorized the President to prohibit entry into the US to passengers and cargo from allegedly infected foreign countries, "notwithstanding the quarantine defense."

"...whenever it shall be shown to the satisfaction of the President that by reason of the existence of cholera or other infectious or contagious diseases in a foreign country, there is a serious danger of the introduction of the same into the United States, and that notwithstanding the quarantine defense this danger is so increased by the introduction of persons or property from such country that a suspension of the right to introduce the same is demanded in the interest of the public health, the President shall have the power to prohibit, in whole or in part, the introduction of persons and property from such countries or places as he shall designate and for such period of time as he may deem necessary."

At Section 8, Congress authorized the Treasury Secretary to compensate State and municipal authorities for federal use of buildings and disinfecting apparatus.

At Section 9, Congress repealed the March 3, 1879 act establishing the National Board of Health, and transferred all property held by the National Board of Health, to the Treasury Secretary.

1895 - Marine-Hospital Service Hygienic Laboratory and New York City Board of Health collaboratively producing diphtheria antitoxin.

By 1895, the New York City Board of Health and the Laboratory of Hygiene (later known as the Hygienic Laboratory) of the Marine-Hospital Service, which was not yet Congressionally authorized, were producing and using products they called diphtheria antitoxin.

1901 - Congress provided money and land to MHS Hygienic Laboratory for new building and for purchase of books and journals.

On March 3, 1901, through a funding act and a margin note — "Marine hospitals. Laboratory authorized." — Congress appropriated money and land for the Laboratory of Hygiene that had been in operation since 1887, originally in Staten Island, and had been relocated to Washington DC in 1891.

Congress gave the Marine-Hospital Service $35,000 and authorized transfer of five acres in Washington DC [Old Naval Observatory parcel] from the Navy to the Secretary of the Treasury, "for the erection of the necessary buildings and quarters for a laboratory for the investigation of infectious and contagious diseases, and matters pertaining to the public health, under the direction of the Supervising Surgeon-General."

Congress gave the Marine-Hospital Bureau $500 for "books and journals" to be purchased during fiscal 1902.

Part 3 - 1901-1910: Federal government licensing of virus and toxin propagation establishments; criminalization of traffic in adulterated or misbranded drugs.

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By Lydia Hazel and Katherine Watt

Between 1900 and 1910, more biological products were propagated and used in the United States, added to the smallpox and rabies vaccines and diphtheria and tetanus antitoxins already in use. The new additions included antibacterial antisera, thyroidectomized goat serum, and horse serum (1903 – 1907).

July 1, 1902 - Congress and President Theodore Roosevelt passed "An act to increase the efficiency and change the name of the US Marine-Hospital Service" - PL 57-236

In July 1902, Congress passed "An act to increase the efficiency and change the name of the US Marine-Hospital Service" to the Public Health and Marine-Hospital Service (PHMHS).

The 1902 reorganization and renaming law had nine sections.

At Section 1, Congress changed the name and transferred all the duties of the Marine-Hospital Service — "care of sick and disabled seamen and all other duties now required by law" — to the new PHMHS, still under the supervision of the Treasury Secretary.

At Section 2, Congress set the salary of the PHMHS Surgeon-General at $5,000 per year and dropped the modifier "supervising" from his title.

At Section 3, Congress authorized the Surgeon-General to "detail" commissioned PHMHS medical officers for duty in Washington DC to any of five PHMHS divisions, including marine hospitals and relief; domestic quarantine; foreign and insular quarantine; personnel and accounts; sanitary reports and statistics; and scientific research.

At Section 4, Congress authorized the President, "in his discretion, to utilize the PHMHS in times of threatened or actual war to such an extent and in such manner as shall in his judgment promote the public interest."

At Section 5, Congress established a nine-member advisory board for the Hygienic Laboratory that had been authorized a year before, to consult with the PHMHS Surgeon-General "relative to the investigations to be inaugurated, and the methods of conducting the same."

The advisory board would include three government officers appointed from the Army, Navy and Bureau of Animal Industry by, respectively, the Surgeon-Generals of the Army and Navy and the Secretary of Agriculture; the Hygienic Laboratory director (Milton J. Rosenau at the time); and five people "skilled in laboratory work in its relation to the public health, and not in the regular employment of the Government."

Section 6 authorized the PHMHS Surgeon-General, with the Treasury Secretary's approval, to appoint directors for three Hygienic Laboratory divisions: chemistry, zoology and pharmacology, and referred to the January 1889 law as governing the appointment of a director for the Hygienic Laboratory from among the commissioned medical officer corps.

Section 7 authorized the PHMHS Surgeon-General to organize conventions of state and territorial boards of health, quarantine boards and State health officers, and required him to organize at least one annual

conference.

Section 8 directed the PHMHS Surgeon-General to establish a federal registry for "mortality, morbidity, and vital statistics" and create, distribute and collect forms for state health authorities to complete and return to the PHMHS for use in preparing national health reports, to "secure uniformity."

Section 9 authorized the President to prescribe rules and regulations for the conduct and internal administration of the PHMHS, and required the Treasury Secretary to file annual reports to Congress.

Main points to understand:

In 1902, Congress created a 9-member advisory board for the Hygienic Laboratory to provide input on "infectious and contagious diseases and matters pertaining to public health" (text from the March 1901 funding act authorizing the Hygienic Lab) "relative to investigations...and methods."

Congress did not assign biological product manufacturing regulation drafting or enforcement to the Hygienic Lab advisory board or to the Hygienic Lab employees.

Through the Virus-Toxin law, also passed July 1, 1902, outlined below, Congress assigned biological product manufacturing rule-making to a three-member board of Surgeon-Generals subordinate to the Treasury Secretary, and assigned enforcement to the Treasury Secretary and officers to whom he delegated authority.

In 1902, Congress set up a centralized data-collection system to collect information about births, deaths, diseases and causes of death.

This is important because the false attribution of disease and death to communicable pathogens is the primary means by which public health officers drive public fear of epidemics and pandemics, and thereby drive submission to products that the same government health officers falsely characterize as preventatives for so-called vaccine-preventable diseases.

By centralizing data collection, authorizing the Secretary of Treasury to create the forms to be used by state and local authorities, and funding publication and distribution of reports, Congress gave federal officers control over public perception of falsifiable and routinely-falsified communicable disease threats.

The centralization of information -- enabling government control, coordination and falsification of disease and death evidence -- began in 1902 with the law reorganizing and renaming the Marine-Hospital Service. Government control, coordination and falsification of disease and death data is currently carried out by government officers working at the Centers for Disease Control and Prevention (CDC), one of several federal offices whose functions originated in the Hygienic Lab.

July 1, 1902 - Congress and President Theodore Roosevelt passed "An act to regulate the sale of viruses, serums, toxins, and analogous products," the Virus-Toxin law, also known as Biologics Control Act - PL 57-244

On the same day that Congress reorganized the functions and changed the name of the Public Health and Marine-Hospital Service, Congress also passed "An act to regulate the sale of viruses, serums, toxins, and analogous products in the District of Columbia; to regulate interstate traffic in said articles, and for other purposes."

Passage of the 1902 Virus-Toxin law was ostensibly motivated by the deaths of 22 children in 1901 caused by tetanus-containing diphtheria antitoxin and smallpox vaccines: 13 children in St. Louis, MO who received

diphtheria antitoxin, and nine in Camden, NJ who received smallpox vaccine. (Early smallpox vaccine manufacturing in the United States: Introduction of the "animal vaccine" in 1870, establishment of "vaccine farms" and the beginnings of the vaccine industry, Esparza et al, June 19, 2020, *Vaccine*).

The 1902 Virus-Toxin law had eight sections and went into effect six months from passage: Jan. 1, 1903. The law covered sale in the District of Columbia; interstate commerce in US-propagated products; export of US-made products to foreign countries; and import of foreign-made products into the United States.

Section 1 prohibited international and interstate sale, barter and exchange of "any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention and cure of diseases of man" unless the products had been "propagated and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary of the Treasury."

Section 1 required packages to be "plainly marked with the proper name of the article;" the name, address and license number of the manufacturer; and the "date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results."

Section 1 required the Treasury Secretary to notify the owner or custodian of a product if the establishment license had been suspended or revoked, and if no notice was given, then sale, barter and exchange could continue, even without a license.

Section 2 prohibited falsification or alteration of package labels.

Section 3 provided that Treasury Department officers "may, during all reasonable hours enter and inspect any establishment."

Section 4 established a three-member board comprised of the Surgeon-Generals of the Army, Navy and Marine-Hospital Service, subject to Treasury Secretary approval, and conferred authority to the board "to promulgate from time to time such rules as may be necessary...to govern the issue, suspension and revocations of licenses." Section 4 also conditioned licensing of foreign establishments on the owners allowing the optional inspections authorized by Section 3.

Section 5 authorized and directed the Treasury Secretary to enforce the statute and any regulations issued by the Surgeon-Generals' board; authorized the Treasury Secretary to issue, suspend and revoke licenses; and authorized the Treasury Secretary to assign enforcement duties to other Treasury Department officers.

Section 6 prohibited interference with Treasury Department agents implementing the law.

Section 7 established as punishment for violations, fines not to exceed $500 or imprisonment up to one year.

Section 8 repealed all other Congressional acts inconsistent with the Virus-Toxin law provisions.

Key points to understand:

The 1902 Virus-Toxin law covered "any virus, therapeutic serum, toxin, antitoxin, or analogous product," but did not define any of those terms by measurable physical or chemical attributes.

The products were defined only by the clause: "applicable to the prevention and cure of diseases of man."

Vaccine was not listed as a product class subject to the 1902 Virus-Toxin law.

Congress didn't add the term *vaccine* to federal biological product law until 1970 (PL 91-515), 68 years after the Virus-Toxin law, 26 years after the 1944 Public Health Service Act, and 15 years after the nationwide, Congressionally-funded polio vaccination program began in 1955 (PL 84-377) with vaccines inflicted primarily on children and expectant mothers.

To date (2024), Congress and federal regulatory agencies have still not defined *vaccine* in measurable physical or chemical terms in any statute or regulation.

The 1902 Virus-Toxin law covered licensing of establishments only; it was silent on the licensing of individual products.

The 1902 Virus-Toxin law did not prohibit "manufacture" of viruses, toxins and other biological products without a license; it prohibited "sale, exchange and barter" of such products.

The 1902 Virus-Toxin law did not require labels to contain information about the identity, volume, concentration or purity of any substances or mixtures of substances in product packages.

The 1902 Virus-Toxin law did not set forth physical or chemical compliance standards for product identity, purity, or potency, or direct the Treasury Secretary or the three-member Surgeon-Generals board to establish or enforce compliance with physical or chemical standards.

The 1902 Virus-Toxin law did not define "specific results" and only required package labels to include the proper name of the article.

The 1902 Virus-Toxin law did not prohibit adulteration or misbranding of virus, toxin and serum package contents.

In contrast to the Pure Food and Drug Act passed in 1906 (summarized below), the 1902 Virus-Toxin law did not make reference to the US Pharmacopeia, which had been founded in 1820.

> "...11 physicians came together to take action to protect patients from being harmed by the inconsistent and poor-quality medical preparations of the day. The first standards were "recipes" that guided the preparation of medicines, which were often made in apothecaries relying heavily on botanicals for their therapeutic benefit. As the practice of health and medicine evolved and the modern pharmaceutical industry emerged, USP standards changed from "recipes" to a set of quality specifications for medicines along with analytical tests to be performed to assess quality attributes."

The 1902 Virus-Toxin law did not authorize the three-member Surgeon-Generals board, or the PHMHS Surgeon-General, to enforce the laws, rules and regulations.

The 1902 Virus-Toxin law did not require inspections on any set schedule. It only established the optional right of Treasury Department officers to inspect establishments.

The 1902 Virus-Toxin law did not require manufacturers or sellers to submit specimens of products to federal laboratories for compliance testing; did not establish a federal laboratory responsible for testing of specimens; did not establish procedures for federal investigators to report non-compliant specimens to district attorneys for criminal prosecution of the manufacturers or sellers; and did not impose a duty of prosecution on district attorneys.

Most provisions of the 1902 Virus-Toxin law were incorporated into the 1944 Public Health Service Act

(PHSA, PL 78-410) at Sections 351 and 352, codified currently at 42 USC 262, Regulation of biological products; 42 USC 262a, Enhanced control of dangerous biological agents and toxins; 42 USC 263, Preparation of biological products by [Public Health] Service; and 42 USC 263-1, Education on biological products.

June 30, 1906 - Congress and President Theodore Roosevelt passed "An act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein," also called the Pure Food and Drug Act - PL 59-384

The Pure Food and Drug Act had 13 sections, and went into effect Jan. 1, 1907.

Section 1 prohibited "manufacture" of "any article of food or drug which is adulterated or misbranded" within any Territory or the District of Columbia. Manufacture within States was not mentioned. Violators would be guilty of misdemeanors, subject (for first violations) to fines up to $500, up to one year imprisonment or both.

Section 2 prohibited introduction of any adulterated or misbranded "article of food or drug" into any State, Territory or District of Columbia, from any other State, Territory or the District of Columbia, or to or from any foreign country. Violators who shipped, received, delivered, sold or offered for sale, exported or offered for export "adulterated or misbranded foods or drugs" would be guilty of misdemeanors, subject to fines of $200 to $300 and imprisonment up to one year, with an exemption for food or drugs "prepared or packed" in compliance with the laws of foreign countries, as long as the exempted food or drugs weren't sold or offered for sale domestically in the United States.

Section 3 directed the Treasury Secretary, Agriculture Secretary and Commerce and Labor Secretary to make rules and regulations, including rules governing "the collection and examination of specimens manufactured or offered for sale" in Territories, District of Columbia, States, or passing through ports, exempting food and drugs manufactured and used within one State (those that didn't cross State borders).

Section 4 directed that the Department of Agriculture Bureau of Chemistry would carry out the "examinations of specimens," or at least direct and supervise examinations, to find out if the articles of food and drugs were adulterated or misbranded. Congress directed the Agriculture Secretary to notify the manufacturer if examiners found adulterated or misbranded specimens, and to set rules through which manufacturers could be heard if they wanted to challenge the findings. If, after a hearing, the Agriculture Secretary still believed the articles were adulterated or misbranded, Congress directed him to "certify the facts to the proper US district attorney with a copy of the results of the analysis or the examination...authenticated by the analyst or officer" under oath. Congress directed the regulators (Treasury, Agriculture and Commerce-Labor secretaries) to prescribe rules for the public to be notified of any ensuing court judgment.

Section 5 established the duty of the district attorneys to prosecute violators "in the proper courts...without delay" upon presentation of the certified evidence, to enforce the criminal penalties outlined in Sections 1 and 2.

Section 6 defined the term "drug" as "all medicines and preparations recognized in the United States Pharmacopeia-National Formulary [USP-NF] for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals."

Congress defined "food" as "all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound."

Section 7 defined the term "adulterated." For drugs sold under USP-NF names and monographs, a drug would be deemed adulterated under either of two conditions.

A drug would be deemed adulterated if it "differs from the standard of strength, quality, or purity, as determined by the test laid down" in the USP-NF "official at the time of investigation" but provided that drugs listed by name in the USP-NF would not be deemed adulterated as long as the "standard of strength, quality or purity" was "plainly stated on the bottle, box, or other container" even if the standard differed from the standard determined by the USP-NF test.

A drug would also be deemed adulterated if the product's "strength or purity falls below the professed standard or quality" stated on the package under which it was sold.

Section 7 also defined the term "adulterated" for confectionery and food, but those definitions are not summarized here.

Section 8 defined "misbranded" as applying to all drugs, articles of food, or "articles which enter into the composition of food" enclosed in packages with any statements about the article, ingredients or substances that were "false or misleading in any particular," including false statements about the State, Territory or country in which the article was produced.

Section 8 further defined "misbranded" drugs as those that were "an imitation of or offered for sale under the name of another article" and drugs in packages that had had original contents removed and substituted with other contents, or if the package label failed to list the "quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances."

Section 8 also defined "misbranded" food, and listed exemptions from misbranding, but those definitions and exemptions are not summarized here.

Section 9 provided that "dealers" of food and drug articles could be exempt from prosecution if they had obtained a "guaranty signed by the wholesaler, jobber, manufacturer" or other supplier of the products, asserting that the products were not adulterated or misbranded, as long as the guaranty listed the name and address of the supplier and made clear that the supplier would bear legal responsibility if specimen testing found evidence of adulteration or misbranding.

Section 10 provided "libel for condemnation" procedures, not summarized here.

Section 11 directed the Treasury Secretary to collect and supply "samples of food and drugs" being imported into the US and to provide notice to the owner of such imported products to appear before the Agriculture Secretary and introduce testimony. Section 11 provided for the Treasury Secretary to forbid entry to products found to be adulterated or misbranded, with exceptions covering "penal bonds."

Section 12 defined "Territory" as including the insular possessions of the United States, and "person" as singular and plural, including corporations, companies, societies and associations.

Section 13 set Jan. 1, 1907 as the date of effect.

Key points:

The 1906 Pure Food and Drug Act indicates that Congress members understood the public dangers posed by adulterated and misbranded pharmaceutical products. They were capable of establishing definitions for terms including *drug*, *adulteration* and *misbranding*. They were capable of assigning responsibility for establishing physical and chemical standards, assays and testing methods to a non-governmental organization (US Pharmacopeia-

National Formulary). They were able to establish procedures for collecting and testing specimens and able to designate federal government agencies and officers to collect and test specimens, and testify under oath as to their adulterated or misbranded status. They were able to set up procedures for district attorneys to prosecute violators who manufactured adulterated and misbranded products.

Domestic and foreign manufacturing and foreign and interstate traffic in "virus, therapeutic serum, toxin, antitoxin, or analogous product" were not governed by the 1906 Pure Food and Drug Act.

Viruses, serums, toxins, antitoxins and analogous products were governed by the 1902 Virus-Toxin law, and therefore not subject to physical and chemical standards, specimen collection, specimen testing or criminal prosecution for adulteration or misbranding.

Most provisions of the 1906 Pure Food and Drug Act were incorporated into the 1938 Food Drug and Cosmetics Act (FDCA, PL 75-717), and are currently codified at several sections in Title 21, Chapter 9, Section 301 et seq.

Congressional funding

As laid out in Part 2 of this series, during the 19th century, funding for the Marine-Hospital Service came from taxes levied first on seamen as wage taxes, and then on cargo, through tonnage taxes levied on ship owners. The tonnage tax financing system was repealed in 1905, when Congress began making regular appropriations to the institution that was, by that time, called the Public Health and Marine-Hospital Service. (1904-1943 Congressional funding acts, compilation, at p. 6 of 121 pp. PDF)

In 1878, Congress passed the first federal quarantine law covering quarantine of passengers, crew and goods on ships arriving in US ports from foreign ports.

In 1890, Congress authorized the Marine-Hospital Service to take charge of interstate quarantine — control of people and goods attempting to cross state borders. Congress expanded MHS quarantine powers in 1893.

Between 1904 and 1910, Congress made annual appropriations to the Public Health and Marine-Hospital Service, under Treasury Department appropriations, for several divisions and programs: Office of the Surgeon-General, including medical examinations and treatment at marine hospitals; Quarantine Service; Prevention of Epidemics; printing costs for publishing communicable disease reports (about $500 per year), and money for purchasing books and journals (also about $500 per year)

Through the Prevention of Epidemics section, Congress authorized and funded the President to provide money "in aid of State and local boards [of health]" in case of "threatened or actual epidemics" of named diseases.

> Prevention of Epidemics. The President of the United States is hereby authorized, in case of threatened or actual epidemic of cholera, typhus fever, yellow fever, smallpox, bubonic plague, or Chinese plague, or black death, to use the unexpended balance of the sums appropriated and reappropriated by the sundry civil appropriation Act approved March third, nineteen hundred and three, and one hundred thousand dollars in addition thereto, or so much thereof as may be necessary, in aid of State and local boards, or otherwise, in his discretion, in preventing and suppressing the spread of the same; and in such emergency in the execution of any quarantine laws which may then be in force. (58th Congress, Session II, Ch. 1762, p. 466)

The Prevention of Epidemics program was the forerunner of what became known as the Federal-State Cooperation program in the 1944 Public Health Service Act (PHSA Part B, Section 311 et seq, 56 Stat 693, currently codified at 42 USC 243 et seq., including "public health emergencies" provisions added in 1983 (PL 98-48), repealed and replaced in 2000 (PL 106-505); the "targeted liability protections for pandemic and epidemic products and security countermeasures" (liability exemptions) added in 2005 through the PREP Act (PL 109-148), and many related provisions.

In 1904, Congress appropriated $335,000 for Quarantine Service and $100,000 for Prevention of Epidemics. In 1905, Congress repealed the cargo tonnage tax source of PHMHS funding and directly appropriated $200,000 for the Public Health and Marine-Hospital Service, along with $340,000 for Quarantine Service and $100,000 for Prevention of Epidemics. In 1906, Congress gave Treasury $1,185,000 for the PHMHS, including pay and quarters for officers, pay for all other staff, hospital maintenance costs, medical examination and treatment costs, books and journals, and a line item for the Hygienic Laboratory of $15,000. Congress also gave the Treasury Department $340,000 for Quarantine Service and $200,000 for Prevention of Epidemics. In 1907, Treasury received $1,162,750 for PHMHS, including $15,000 for the Hygienic Lab; $350,000 for Quarantine Service; $200,000 for Prevention of Epidemics. In 1908, Treasury received $1,299,750 for PHMHS, including $15,000 for Hygienic Lab maintenance and $10,000 to equip a new Hygienic Lab building; $400,000 for Quarantine Service; and $500,000 for Prevention of Epidemics. In 1910, Treasury received $1,156,100 for PHMHS, including $15,000 for the Hygienic Lab; $400,000 for Quarantine Service, and authorization for the President to use "unexpended balance of sums...approved March 4, 1909" for Prevention of Epidemics, to fund state and local health board projects to prevent alleged epidemics.

1910 JAMA papers by Milton Rosenau, Director of PHMHS Hygienic Laboratory

In 1910, seven years after the Virus-Toxin law went into effect on Jan. 1, 1903, Milton Rosenau, the second director of the Hygienic Laboratory (1899-1909), published two papers in the Journal of the American Medical Association: The Federal Control of Serums, Vaccines, Etc. and *Vaccine Virus*.

In the first paper, Rosenau described an inspection and licensing program that he claimed was operated by the staff of the Hygienic Laboratory division of pathology and bacteriology, including purchase of samples from manufacturing establishments and "on the open market" for "examination as to potency and purity."

Rosenau further claimed that the licensing process applied to individual products and that "general licenses authorizing the manufacture of any and all biologic products are not issued," even though the 1902 law only addressed the licensing of establishments and did not define or authorize the Treasury department to adopt or enforce product standards.

After describing inspectors inquiring into "methods of manufacture," the "competency" of employees and the "efficiency of the material equipment," Rosenau concluded: "At present every confidence may be had in all biologic products made under government license."

The last section of Rosenau's paper on federal control is titled "Government Guarantee" and states:

> "The government does not guarantee that each vaccine point or each package of antitoxin will produce its full therapeutic effect and be free from all danger. This would be impracticable with the extent and variety of the business in biologic products now carried on in this country and abroad..."

In the second paper, Rosenau described *vaccine virus* as "the specific principle in the material obtained from the skin eruption of calves having a disease known as vaccinia [cowpox]…" and stated "both the pulp and the lymph are mixtures containing epithelial cells, serum, blood, leucocytes, products of inflammation, debris,

bacteria, etc., in varying proportions."

Rosenau admitted "the specific principle of vaccinia [cowpox] is unknown;" stated that "it is impossible to obtain vaccine virus free from the bacteria of the skin;" and stated "the fact that a serum or vaccine is granted a license does not mean that it is a valuable curative or prophylactic; in fact, it may have little or no therapeutic value."

He stated: "it is evidently the province of the medical profession to determine for itself whether a certain substance has therapeutic value or not. The chief concern of the government is to protect the practitioner against sophistications, impurities, faults or mislabeling."

Rosenau did not point out to JAMA readers that the 1902 Virus-Toxin law was silent on identity, purity and labeling of products by physical and chemical composition and ingredients; the 1902 law did not prohibit adulteration and misbranding; and the 1902 law did not establish prosecutorial procedures.

Rosenau ended his paper with an argument for adding *vaccine virus* to the US Pharmacopeia, from which it is possible to infer that US Pharmacopeia officials were resisting such efforts:

> The objection, that vaccine virus is an indefinite substance, the 'active principle' of which is not known, is no longer valid, for the Pharmacopeia contains many such substances, including the ferments, against which similar objection holds.
>
> The objection that vaccine virus cannot be "assayed" [quantitatively and qualitatively analyzed to determine the presence, amount or functional activity of a substance] by the average druggist also lacks force when we recall that the potency and purity of vaccine virus in interstate traffic is cared for by the federal government under the law of July 1, 1902, which relieves the pharmacist of this responsibility…

Again: the words *potency*, *purity* and *vaccine* do not appear in the July 1902 Virus-Toxin law, nor do the words *adulteration* or *misbranding*.

These papers confirm that Rosenau understood that *vaccine virus* was "an indefinite substance" that could not be identified, purified or subjected to any measurable standards for product identity, purity or potency; that no such standards had been established by federal officers or by the US Pharmacopeia acting as a private-sector product quality monitor in partnership with government agencies; that no tests had been developed or were being used by Hygienic Lab workers to test *vaccine virus* specimens for compliance with non-existent identity, purity and potency standards; and that no criminal prosecution of propagation, sale and use of adulterated or misbranded *vaccine virus* was authorized or carried out.

The real purpose of the 1902 Virus-Toxin law was to create initial false public confidence in vaccines.

One of several real purposes for the Hygienic Laboratory and two of its successor organizations today (NIH and FDA) was to serve as front organizations that have never and still do not establish physical or chemical standards, or safety or efficacy standards, for vaccines; have never and still do not conduct product testing to verify manufacturer and public health officer claims as to product identity, purity, potency, safety or efficacy; and have never and still do not support criminal prosecution for manufacture, distribution and use of vaccines and related products.

The Hygienic Lab, NIH and FDA have merely pretended to regulate biological products, to falsely generate and maintain public confidence in vaccines, which were then and are still today, demonstrably heterogeneous, unstable and toxic products.

Since 1902, the biological product regulatory acts that public officials have lied about conducting, they could not and did not conduct in reality.

In the early days, they failed to establish and enforce physical and chemical standards because they lacked the necessary scientific knowledge, methods and equipment, although they demonstrably knew, from anaphylaxis studies, that foreign cells and cell products, especially proteins, when injected into the bloodstream, are inherently harmful to recipients.

In more recent decades, purported regulators did not and do not establish and enforce physical and chemical standards because scientific knowledge, methods and equipment have developed to the point where the results of any tests would disclose the inherent heterogeneity, instability and toxicity of products they need to deceive the public into believing to be pure, stable and beneficial.

Part 4 - 1911-1943: Continued non-existence of legal provisions directing federal agencies to establish and enforce biological product definitions and standards.

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By Lydia Hazel and Katherine Watt

Part 3 Summary:

> The 1902 Virus-Toxin law, also known as the Biologics Control Act, authorized a three-member board (Supervising Surgeon-General of the Public Health and Marine-Hospital Service; Surgeon-General of the Army; and Surgeon-General of the Navy) to promulgate rules addressing licensure of manufacturing establishments only, not products.
>
> Congress was silent as to the identity, purity, potency, safety and therapeutic efficacy of factory-propagated, undefined products including viruses, toxins, antitoxins and serums. Congress was silent as to specimen collection and analysis, and did not designate a laboratory to conduct testing of samples. Congress was silent as to product recall, seizure and destruction procedures.
>
> Congress required labels to contain the proper name of the "article" and the address of the establishment, but did not require labels to contain information about ingredients, volumes, concentrations, or other measurable physical or chemical properties.
>
> Congress did not identify district attorneys, or any other law enforcement officers, or impose a duty to prosecute violators.
>
> Products propagated in virus and toxin establishments were not covered by the provisions of 1906 Pure Food and Drug Act, which defined drugs as "all medicines and preparations recognized in the United States Pharmacopeia-National Formulary [USP-NF] for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals;" required submission of "specimens" to the Department of Agriculture Bureau of Chemistry for analysis; and imposed, upon district attorneys, a duty to criminally prosecute violators.

Part 4 of this series provides summaries of important Congressional, Presidential and Cabinet secretary acts and Supreme Court decisions that took place between 1911 and 1943.

After each summary, we've provided a few key points, and plan to publish further analysis after the five-part series has been published in full.

Readers are encouraged to think about how these earlier forms of scientific, medical and regulatory deception — federally authorized and funded toxin research, federally-licensed toxin manufacturing, and interstate and international trafficking in toxins camouflaged as medicinal products — have been rendered more visible, in their more developed forms, through the fabrication of the Covid-19 pandemic and public health and vaccination programs ostensibly mounted in response to it.

Several other laws enacted during this period are not covered here, but are related to financial, medical, scientific, and legal government-authorized, government-funded criminal enterprises as constructed by Congress, US Presidents, Cabinet secretaries and federal judges. The related statutes, court decisions and executive orders include the 1913 Federal Reserve Act; 1917 Espionage Act; 1917 Trading with the Enemy Act; 1921 Joint Resolution Declaring that certain Acts of Congress, joint resolutions, and proclamations shall be

construed as if the war had ended and the present or existing emergency expired," *excluding* Trading with the Enemy Act and others; 1925 Act to Amend the Judicial Code; 1933 Emergency Banking Act; 1933 House Joint Resolution 192; 1938 *Erie v. Tompkins* Supreme Court decision.

How US government sources describe the effects of the 1902 Virus-Toxin law

Immunize.org Vaccine History Timeline:

> "The standards imposed by the 1902 [Virus-Toxin] Act resulted in bankruptcy for one-third of the companies manufacturing antitoxins and vaccines while benefiting the manufacturers already in compliance. In total, 10 firms held licenses with the Laboratory of Hygiene [in operation since 1887] following the 1902 Act."

NIH history:

> "In 1902 two acts contributed significantly to the emergence of the Hygienic Laboratory as a center for research within the federal government...the act launched a formal program of research by designating the pathological and bacteriological work as the Division of Pathology and Bacteriology and by creating three new components that represented the most fruitful areas for research at that time: the Divisions of Chemistry, Pharmacology, and Zoology. The importance of these new programs was underscored by the provision that the PH-MHS could hire scientist researchers with Ph.D.'s to head them. Up until this time, the professional staff had been limited to physicians..."

Note:

The 1902 Virus-Toxin law did not include the words *pathology* or *bacteriology*. By 1910, Milton Rosenau, the director of the Hygienic Laboratory, referred in a JAMA paper to the 'division of pathology and bacteriology' and made two contradictory claims: that the division's employees examined samples of antitoxins and vaccine virus "for potency and purity" and that "*Vaccine virus* is the specific principle in the material obtained from the skin eruption of calves [1] having a disease known as vaccinia.…This material scraped from the skin eruption is called vaccine 'pulp.' The fluid which exudes after the pulp is taken is called vaccine 'lymph.' Both the pulp and the lymph are mixtures containing epithelial cells, serum, blood, leucocytes, products of inflammation, debris, bacteria, etc., in varying proportions…The specific principle of vaccinia is unknown."

1911 to 1943 - Congress, SCOTUS, Presidents and Cabinet secretaries

From 1911 to 1943, Congress continued funding Public Health Service programs, including research at the Hygienic Lab; treatment of patients at marine hospitals; operation of quarantine stations and medical inspection of aliens arriving on foreign ships at US ports; and federal payments to state and local health boards for "prevention of epidemics." Compilation of Congressional funding acts, 1904-1943.

Funding acts in the timeline below are denoted with double-asterisk** symbols.

**In 1911, Congress funded maintenance of marine hospitals, adding: "Provided, that there may be admitted into said hospitals for study, persons with infectious or other diseases affecting the public health, and not to exceed ten cases in any one hospital at one time."

1911 - Supreme Court ruled, in US v. Johnson, on applicability of 1906 Pure Food and Drug Act misbranding provisions to claims about therapeutic or curative value of drugs. - US v. Johnson, 221 US 488

Between 1907, when the 1906 Pure Food and Drug Act entered into force, and 1910, officers of the US Department of Agriculture and district attorneys applied the law to "nearly 30 cases" in which drug manufacturers falsely claimed their products had curative properties. In each case, "either no defense [was] made, or pleas of guilty had been entered."

One of the manufacturers challenged his prosecution for interstate delivery of packages of medicine "bearing labels that stated or implied that the contents were effective in curing cancer, the defendant well knowing that such representations were false."

The District Court quashed the indictment, prompting the US government to appeal to the Supreme Court.

Johnson didn't dispute that the label statements alleging curative properties were false. He argued that Section 8 of the 1906 Pure Food and Drugs Act "confined" the term 'misbranded' to "representations concerning the identity of the drug, its physical constituents, or chemical ingredients" and did not cover to claims for curative properties.

After a lot of textual analysis, by a 6-3 decision, the Supreme Court held that Johnson and the lower court were correct.

Held:

> "The term "misbranded" and the phrase defining what amounts to misbranding in § 8 of the Food and Drugs Act ... are aimed at false statements as to identity of the article, possibly including strength, quality and purity, dealt with in § 7 of the act, and not at statements as to curative effect; and so *held* that a statement on the labels of bottles of medicine that the contents are effective as a cure for cancer, even if misleading, is not covered by the statute."

The majority opinion and the dissent are worth reading for insights into how federal courts construed "matters of scientific opinion," as addressed in medical treatment contexts and "all health and quarantine laws," and "the constitutional power of Congress to prohibit use of the instruments of interstate commerce to the injury of the public."

Key point:

Viruses, toxins, serums, vaccines and related biological products manufactured or propagated at licensed establishments under the 1902 Virus-Toxin law were not subject to any of the provisions of the 1906 Pure Food and Drug Act. Virus and toxin manufacturers were not required to provide, on package labels, any information about ingredient identity, volumes, weights, concentrations, or effects. Congress was silent on the adulteration and misbranding of virus and toxin products.

1912 - An Act to change the name of the PHMHS to the PHS - PL 62-265

In August 1912, Congress changed the name of the Public Health and Marine-Hospital Service to the Public Health Service; transferred existing PHMHS laws and regulations to the PHS; authorized PHS, including the Hygienic Laboratory, "to study and investigate the diseases of man and conditions influencing the propagation and spread thereof, including sanitation and sewage and the pollution either directly or indirectly of the navigable streams and lakes of the United States;" and authorized PHS to "from time to time issue information in the form of publications for the use of the public."

At Section 2, Congress increased the pay scale for the Surgeon General, Assistant Surgeon General and other

officers.

Key points:

Congress did not define the term *public health*.

Congress did not expand on the 1902 Virus-Toxin law; the terms *viruses*, *toxins*, *serums* and *analogous products* remained undefined. Congress did not transfer responsibility for drafting of biological product regulations from the control of the three-member Surgeon-Generals board Congress had designated in 1902.

Congress did not authorize the PHS Surgeon General or Hygienic Laboratory Director to set or enforce regulations governing virus and toxin product identity, concentration, weights, volumes or other physically or chemically measurable properties, and Congress did not define adulteration or misbranding for virus and toxin products, or authorize criminal prosecution for adulterated or misbranded virus and toxin products.

1912 - An Act to amend section eight of the 1906 Pure Food and Drug Act - PL 62-301

In response to the 1911 *US v. Johnson* Supreme Court ruling, Congress amended the 1906 Pure Food and Drug Act to further define the term *misbranding*.

Congress added a third paragraph to Section 8 of the 1906 law, deeming an article misbranded "If its package or label shall bear or contain any statement, design or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false or fraudulent."

Key point:

The provisions of the 1906 Pure Food and Drug Act, including the 1912 amendment deeming false or fraudulent claims as to curative or therapeutic effect to be misbranding, were not applicable to viruses, toxins and other biological products propagated at establishments licensed under the 1902 Virus-Toxin law.

The 1902 Virus-Toxin law did not address, define or set up procedures to identify and prosecute adulteration or misbranding of biological products.

As of 2024, Congress has still not addressed, defined or set up procedures to identify and prosecute adulteration or misbranding of biological products, nor have any of the federal agencies to which Congress has delegated regulatory authority.

** In 1913, Congress funded the Public Health Service; promoted the director of the Hygienic Laboratory to receive the pay and allowance of a PHS senior surgeon; authorized PHS to conduct "field investigations of public-health matters...diseases of man and conditions influencing the propagation and spread thereof, including sanitation and sewage, and the pollution of navigable streams and lakes;" and funded construction of new buildings at the Hygienic Lab for "research work, disinfection, experiments and housing animals." In 1913, Congress added to the program providing federal payments to state and local health boards, another program for "cooperating with state and local authorities," called "Interstate quarantine service."

1913 - An Act to amend section eight of the 1906 Pure Food and Drug Act - PL 62-419

In 1913, Congress amended the 1906 Pure Food and Drug Act again.

The original act deemed an article misbranded if (among other definitions) "...Third. If in package form, and the contents are stated in terms of weight or measure, they are not plainly and correctly stated on the outside of

the package."

In 1913, Congress added a conditional clause: "Provided, however, That reasonable variations shall be permitted, and tolerances and also exemptions as to small packages shall be established by rules and regulations made in accordance with Section 3 of this act."

Key points:

The provisions of the 1906 Pure Food and Drug Act, including the 1913 amendment authorizing "reasonable variations" in weight and measure of packaged drugs, were not applicable to viruses, toxins and other biological products propagated at establishments licensed under the 1902 Virus-Toxin law.

The 1902 Virus-Toxin law did not address, define or set up procedures to identify and prosecute adulteration or misbranding of biological products.

As of 2024, Congress has still not addressed, defined or set up procedures to identify and prosecute adulteration or misbranding of biological products, nor have any of the federal agencies to which Congress has delegated regulatory authority.

1913 Virus-Serum-Toxin Act, licensing biological products to be used on domestic animals - PL 62-430, 37 Stat. 832

In 1913, as part of an act funding the US Department of Agriculture, Congress set up a licensing scheme prohibiting preparing, selling, bartering or exchanging any "worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals..."

This law was later codified at 21 USC 151-159, and USDA promulgated regulations at 9 CFR Chapter 1, Subchapter E, Parts 101 to 124.

Because it was part of a funding act, the livestock product law was not divided into sections; it was simply a lengthy paragraph.

Condensed:

> ...For...expenses for scientific investigations in diseases of animals...and...for investigations of tuberculin, serums, antitoxins, and analogous products, $78,680...
>
> ...After July 1, 1913, it shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange in the District of Columbia...Territories...or any place under the jurisdiction of the US...or ship or deliver for shipment from one State or Territory or DC to any other State...Territory or DC, any worthless, contaminated, dangerous or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals...
>
> No person, firm or corporation shall prepare, barter, exchange or ship any virus, serum, toxin or analogous product manufactured within the US...unless and until the...product shall have been prepared under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture...
>
> Importation...without a permit...and importation of any worthless, contaminated, dangerous or harmful virus, serum, toxin or analogous product...are hereby prohibited...
>
> Secretary of Agriculture is...authorized to cause the Bureau of Animal Industry to examine and inspect

all...products...which are being imported or offered for importation...to determine whether such viruses, serums, toxins, and analogous products are worthless, contaminated, dangerous, or harmful...and if it shall appear that any such [product] is worthless, contaminated, dangerous, or harmful...the same shall be denied entry and shall be destroyed or returned at the expense of the owner or importer...

Secretary of Agriculture is...authorized to make and promulgate...rules and regulations...to prevent the preparation, sale, barter, exchange, or shipment...of any worthless, contaminated, dangerous or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and to issue, suspend, and revoke licenses for the maintenance of establishments for the preparation of viruses, serums, toxins and analogous products...

Secretary of Agriculture is authorized to issue permits for...importation...of products...which are not worthless, contaminated, dangerous or harmful...

Licenses issued...to establishments where such...products are prepared...shall be issued on condition that the licensee shall permit the inspection of such establishments and of such products and their preparation...

The Secretary of Agriculture may suspend or revoke any permit or license issued under...this Act, after opportunity for hearing has been granted to the licensee or importer, when the Secretary...is satisfied...that such license or permit is being used to facilitate or effect the preparation, sale, barter, exchange, or shipment...or importation...of any worthless, contaminated, dangerous or harmful virus, serum, toxin, or analogous product...

Any officer...of the Department of Agriculture duly authorized...may, at any hour during the daytime or nighttime, enter and inspect any establishment...

Any person, firm, or corporation who shall violate any of the provisions...shall be deemed guilty of a misdemeanor, and...upon conviction...punished by a fine of [up to] $1,000 or by imprisonment [up to] one year, or by both...

There is hereby appropriated...for the purposes and objects of this Act...$25,000...

For construction of buildings at bureau experiment station at Bethesda, Maryland, and bureau experiment farm at Beltsville, Maryland, $16,500...

The Secretary of Agriculture is authorized to prepare and sell at cost such pathological and zoological specimens as he may deem of scientific or educational value to scientists or others engaged in the work of hygiene and sanitation...

Key points:

Congress did not define *virus*, *toxin*, *antitoxin* or *analogous product* in measurable, verifiable physical or chemical terms, and did not cite to or delegate authority to the US Pharmacopeia or National Formulary compendia to define these products in measurable, verifiable physical or chemical terms.

Congress did not define the terms *worthless*, *contaminated*, *dangerous*, or *harmful.*

Congress did not address product labeling or require any information to appear on product labels, did not address or define safety or efficacy, and did not prohibit adulteration or misbranding.

Congress did not require manufacturers to submit product specimens to the Bureau of Animal Industry, and did not require the Bureau of Animal Industry to collect or test specimens, or develop assays (tests) to identify product contents or determine weights, volumes, concentrations, purity, potency or other properties of ingredients.

Similarities between 1902 Virus-Toxin law (human) and 1913 Virus-Serum-Toxin Act (domestic animal):

- Product definition and identity. Both laws were silent on defining products by identity, ingredients and physical or chemical attributes.
- Safety and efficacy. Both laws were silent on defining safety and effectiveness.
- Establishment inspections. Both laws were silent on what intervals, if any, establishments were to be inspected, describing inspections with the optional "may," not the mandatory "shall."
- Specimen collection and analysis. Both laws were silent on the submission, collection and analysis of product specimens.
- Duty to prosecute. Both laws were silent on delegation of duty to report infractions (noncompliance with undefined standards) to any prosecutorial body, and silent on duty to prosecute.
- Sale, barter or governmental purchase, distribution and use. Both laws were limited to products intended for sale and barter, and silent on products intended for governmental purchase, distribution and use.

Differences between 1902 Virus-Toxin law (biologic products for human use) and 1913 Virus-Serum-Toxin Act (biologic products for domestic animal use):

- Terms denoting noncompliance. For human products (1902), the basis of infraction was not defined in measurable physical or chemical terms; instead, the law prohibited products that had been produced in an unlicensed establishment, or bearing a label not containing the proper name of the product, the address and license number of the manufacturer and a "date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results," with no definition of the term *specific results*, or procedures for assessment. For animal products (1913), the basis of infraction was also not defined in measurable physical or chemical terms; instead, the law prohibited (without definition) "worthless, contaminated, dangerous or harmful" products.
- Import permits; licenses. Foreign manufacturers of human products (1902) were to be granted establishment *licenses*. Foreign manufacturers of animal products (1913) were to be granted *permits*.
- Inspectors. The 1902 law designated unidentified agents of the Treasury Secretary as establishment inspectors. The 1913 law designated agents of the Department of Agriculture Bureau of Animal Industry.
- Inspection of imports. Under the 1902 human products law, imported products "may" be inspected at their foreign place of manufacture. Under the 1913 animal products law, all imported animal products were to be inspected at point of entry, not their place of manufacture.
- Hearings. Manufacturers and importers of animal products were entitled to hearings regarding pending permit or license suspension/revocation. Manufacturers of human products were not. However, if Treasury failed to notify a virus or toxin manufacturer that his establishment license had been revoked or suspended, he could continue producing and distributing viruses and toxins.

Similarities between the 1906 Pure Food and Drug Act (non-biologic drug products for human use) and 1913 Virus-Serum-Toxin Act (biologic products for animal use):

- Inspection intervals. The 1906 human drug law and the 1913 animal virus and toxin law were both silent on setting specific intervals for inspection of manufacturing establishments or specimens.

- Bureau tasked with inspection. The 1906 human non-biological drug law named the USDA Bureau of Chemistry as the authorized inspecting laboratory. The 1913 animal products law named the USDA Bureau of Animal Industry as the authorized inspecting laboratory for animal viruses, serums and toxins.
- Products not intended for sale or barter. The 1906 human drug law and the 1913 animal virus and toxin law were both silent as to regulation of products not intended for sale or barter, and not intended to cross state/territory/DC borders for interstate trafficking or import and export across national borders.
- Hearings. The 1906 human drug law and 1913 animal virus and toxin law both provided procedures for hearings for alleged violators to challenge allegations of noncompliance.

Differences between the 1906 Pure Food and Drug Act (non-biologic drug products for human use) and 1913 Virus-Serum-Toxin Act (biologic products for animal use):

- Product definition and identity. Under the 1906 human drug law, drugs were defined by reference to physical and chemical composition and analytical testing procedures published in the US Pharmacopeia-National Formulary compendia. Under the 1913 animal viruses and toxins law, products were not defined by physical or chemical standards or analytical tests.
- Basis for prohibition. For human drugs (1906), the bases for prohibition were that a product was found to be *adulterated* and/or *misbranded*, and both terms were defined. For animal viruses and toxins (1913), the bases for prohibition were undefined qualities of the product, i.e., *worthless* or *harmful*.
- Product regulation; facility regulation. Under the 1906 human drug law, Bureau of Chemistry inspectors were authorized to collect and test specimens of individual products to assess adulteration or misbranding. Under the 1913 animal virus and toxin products law, manufacturing facilities could be inspected by Bureau of Animal Industry officers, but individual products were not subject to specimen collection or analysis.
- State, Territory and DC authority. Under the 1906 human drug law, the health officers for States, Territories and the District of Columbia were authorized to submit specimens collected within their jurisdictions, for analysis by the USDA Bureau of Chemistry. The 1913 animal virus and toxin law was silent on the authority of State, Territory and D.C. officers to collect and submit samples for analysis.
- Rulemaking authority. The 1906 human drug law authorized the Secretaries of Treasury, Agriculture, and Commerce and Labor to promulgate regulations. The 1913 animal virus and toxin law authorized the Secretary of Agriculture to promulgate regulations.
- Criminal prosecution. The 1906 human drug law directed inspectors to report violations to the District Attorney for prosecution, with the Secretary of Agriculture certifying the facts, under oath, as found through specimen examination, and charged the DAs to prosecute. The 1913 animal virus and toxin law was silent on procedures for criminal prosecution of violations.
- Testing imports. The 1906 human drug law authorized the Treasury Secretary to collect and submit samples of imported human drugs for analysis to determine adulteration or misbranding. The 1913 animal virus and toxin law was silent on Secretary of Agriculture authority to collect samples of imported products for analysis to determine if they are worthless or harmful.

**In 1915, Congress funded a special study of pellagra. In 1916, Congress funded "studies of rural sanitation" and added, for the first time, a $10,000 line item for "Biologic products: to regulate the propagation and sale of viruses, serums, toxins and analogous products." In 1917, Congress funded "biologic products" regulation with $20,000 and added "infantile paralysis" to the list of diseases eligible for federal payments to state and local health boards under the *Prevention of Epidemics* program. In 1918, Congress provided $30,000 for the PHS biologic products regulation program.

***1919 - Congressional funding act authorized PHS to "prepare" curative and diagnostic biological products*

In 1919, Congress funded a new PHS Division of Venereal Diseases (authorized by Act approved July 9, 1918) and provided $20,000 for purchase of equipment and furniture for new Hygienic Lab buildings.

In 1919, Congress added influenza to the list of diseases eligible for federal payments to state and local health boards under the *Prevention of Epidemics* program, and added to the "biologic products" regulation line item ($35,000 that year), the phrase: "and for the preparation of curative and diagnostic biologic products."

Key points:

From 1919 to the present, the Public Health Service has been Congressionally-authorized to "prepare" viruses, toxins and related biological products within federal facilities, referring to the products as being "curative" and "diagnostic."

These PHS products are prepared under the 1902 Virus-Toxin law and its successor statutes and regulations, which have never established physical or chemical standards for product identity, purity or other measurable attributes; have never defined adulteration or misbranding or set measurable standards for safety and efficacy; have never prohibited preparation and use of adulterated, misbranded, toxic products; have never established or enforced specimen collection and testing procedures; and have never established or enforced product recall, seizure, analysis, destruction or prosecutorial procedures.

**In 1920, Congress authorized PHS officers to be credited with service in the Army, Navy, Marine Corps and Coast Guard in computing longevity pay, and prohibited the PHS from using money for "advertising in newspapers, magazines or periodicals for any purpose other than the procurement of bids." In 1921, Congress added "arsphenamine" to the list of biologic products. By 1921, the annual biologic product appropriation for regulation of licensed establishments and preparation of products by PHS Hygienic Lab employees was $50,000.

1921 - Sheppard-Towner "act for the promotion of the welfare and hygiene of maternity and infancy." PL 67-97

In 1921, Congress passed "An Act for the promotion of the welfare and hygiene of maternity and infancy." It was a precursor to Title V of the Social Security Act of 1935 (*Grants to states for maternal and child welfare*), and conditioned federal grants to State governments on State government participation in federal programs.

Due for renewal in 1926, the Act faced opposition from several different organizations, was extended for two years, and expired in June 1929.

Summary:

Section 1 - Congress authorized annual appropriations to be given to the States, "for the purpose of cooperating with them in promoting the welfare and hygiene of maternity and infancy."

Section 2 - Congress authorized $480,000, followed by $240,000 per year for five years, to be "equally apportioned," plus $1 million per year for five years, apportioned at $5,000 per state, with the balance "in the proportion which their population bears to the total population" and conditioned the population-based money on the State legislatures appropriating equal sums.

Section 3 - Congress created a Board of Maternity and Infant Hygiene, comprised of the Chief of the Children's Bureau of the Department of Labor, Surgeon General of the Public Health Service, and

Commissioner of Education, and assigned administration of the Maternity and Infant Hygiene programs to the Chief of the Children's Bureau, whose duties included "to make or cause to be made such studies, investigations and reports and will promote the efficient administration of this Act."

Section 4 - Congress required participating States to have their legislatures accept the federal act provisions, and designate or authorize creation of State agencies with which the federal Children's Bureau could cooperate. Congress further authorized governors of States whose legislatures didn't pass state laws to accept (by executive act) the federal provisions and designate or create corresponding State agencies, while "awaiting legislative action."

Section 5 - Congress authorized up to 5 percent of annual additional appropriations to be spent by the Children's Bureau for administrative expenses.

Section 6 - Congress authorized the Children's Bureau to employ assistants, clerks and other staff from the Civil Service Commission, and to purchase supplies, equipment, and incur travel expenses.

Section 7 - Congress required the Children's Bureau to apportion the additional money -- by population -- within 60 days after each Congressional funding act, to report estimates to the Treasury Secretary and to certify the apportioned amounts to the Treasury Secretary and the State treasurers.

Section 8 - Congress required States "desiring to receive the benefits" to submit detailed compliance plans to the Children's Bureau, with a provision that State plans should forbid State officers "entering homes, etc." to remove children "over the objection of the parents."

Section 9 - Congress forbade Children's Bureau officers from entering any home "over the objection of the owner thereof, or to take charge of any child over the objection of the parents," and added "Nothing in this Act shall be construed as limiting the power of a parent or guardian...to determine what treatment or correction shall be provided for a child or the agency or agencies to be employed for such purpose."

Section 10 - Congress charged the Children's Bureau to monitor the State appropriations and certify to the Treasury Secretary the State contributions and the federal money apportioned to each State. The certificate was to record that the State legislature and/or governor had accepted the provisions of the federal Act; that the State agency had submitted plans for carrying out the federal Act's provisions; the amount appropriated by the State legislature; and the amount of federal money to which the population of the recipient State was entitled. The Children's Bureau certificate would trigger the disbursement, by the Treasury Secretary, of the federal payments to the States.

Section 11 - Congress required State agencies to provide reports to the Children's Bureau about their operations and expenditures and authorized the Children's Bureau board to withhold the certificates (described in Section 10) from any State whose agency "has not properly expended the money paid to it," provided that the Children's Bureau gave notice to the State agency stating the State's specific compliance failures.

Section 12 - Congress prohibited use of the money for purchasing, building or repairing buildings or equipment, or for purchase or rental of buildings or lands, and prohibited use of the State-appropriated money for "the payment of any maternity or infancy pension, stipend or gratuity."

Section 13 - Congress required the Children's Bureau to perform the duties under the supervision of the Secretary of Labor, and required the Labor Secretary to provide annual reports to Congress.

Section 14 - Congress stated that the Act should be "construed as intending to secure to the various States

control of the administration of this Act within their respective States, subject only to the provisions and purposes of this Act."

Key points:

The Sheppard-Towner maternity and infant hygiene act of 1921 linked State receipt of federal money to State compliance with federally-directed programs, and to State collection and reporting of detailed population and birth rate information to federal authorities.

The Sheppard-Towner Act was an important step in the undermining of federalist principles: separation of powers between federal and State governments. The Sheppard-Towner Act and the Social Security Act of 1935 both used bribery to entrap families and State governments brought to financial instability through inflation-deflation, boom-bust cycles orchestrated by central bankers through monetary policy decisions, but attributed to natural economic forces.

**In 1922, Congress added Rocky Mountain spotted fever to the list of diseases eligible for federal payments to state and local health boards under the *Prevention of Epidemics* program. In 1923, Congress authorized the Immigration Service to permit the PHS to use Ellis Island Immigration Station hospitals for care of PHS patients. In 1924, Congress authorized the PHS to spend money under the *Prevention of Epidemics* program for "purchase of newspapers and clippings from newspapers containing information relating to the prevalence of disease and the public health." In 1927, Congress authorized a survey of the "salt-marsh areas of the South Atlantic and gulf States to determine the exact character of the breeding places of the salt-marsh mosquitoes."

***1927 - USDA Bureau of Chemistry name changed to Food, Drug and Insecticide Administration* - 44 Stat. 976, at p. 991 and 1002

In 1927, through a funding act, Congress transferred the Department of Agriculture Bureau of Chemistry's regulatory functions — including its duties to collect and examine specimens of manufactured drugs for compliance with the 1906 Pure Food and Drug Act — to a new USDA division called the Food, Drug, and Insecticide organization.

The Bureau of Chemistry's non-regulatory research program was renamed the Bureau of Chemistry and Soils, "for conducting the investigations contemplated by the Act of May 15, 1862 [Act to establish Department of Agriculture], relating to the application of chemistry to agriculture; for the biological investigation of food and drug products and substances used in the manufacture thereof, including investigations of the physiological effects of such products on the human organism; [and] to cooperate with associations and scientific societies in the development of methods of analysis."

Congress directed the new Food, Drug and Insecticide Administration "to cooperate with associations and scientific societies in the revision of the United States Pharmacopoeia and development of methods of analysis..." and established:

> "Hereafter the examinations of specimens of foods, drugs, insecticides, Paris greens, lead arsenates, and fungicides provided for by section 4 of the Food and Drugs Act of June 30, 1906, and by section 4 of the Insecticide Act of 1910, shall be made in the Food, Drug, and Insecticide Administration or in such other branches of the Department of Agriculture as the Secretary of Agriculture may direct."

In 1930, through another funding act, Congress shortened the name of the division to the Food and Drug Administration - 46 Stat 392, at p. 422

Key points:

Congress did not authorize the Food, Drug and Insecticide Administration, or the Food and Drug Administration, Bureau of Chemistry and Soils, or any other USDA division, to regulate viruses, toxins, vaccines or other biological products to identify adulterated or misbranded products under the 1902 Virus-Toxin law, which law did not define or prohibit adulteration or misbranding of viruses and toxins.

Congress also did not charge the USDA divisions with collecting, testing, analyzing or providing sworn testimony as to the physical or chemical properties of viruses, toxins, vaccines or other biological products.

**In 1928, Congress began authorizing traveling expenses for PHS officers to "attend meetings of associations for the promotion of public health" and for the transportation of personal effects for PHS officers, pharmacists and nurses "upon permanent change of station." In 1929, the list of diseases identified in Congressional funding acts as authorizing Presidents (in their discretion) to fund state and local health boards, included "threatened or actual epidemic of cholera, typhus fever, yellow fever, typhoid fever, smallpox, bubonic plague, Chinese plague or black death, trachoma, influenza, Rocky Mountain spotted fever, or infantile paralysis."

1929 - Act to establish narcotic farms, precursor to NIH Division of Mental Hygiene - PL 70-672

In 1929, Congress passed an Act "to establish two US narcotic farms for the confinement and treatment of persons addicted to the use of habit-forming narcotic drugs who have been convicted of offenses against the United States, and for other purposes" and placing the institutions under the control of the Treasury Secretary and under the medical supervision of the PHS Surgeon General, through a new Narcotics Division.

Summary:

Section 1 - Congress defined narcotic as "opium and coca leaves and the innumerable alkaloids derived therefrom, the best known...being morphia, heroin and codeine...cocaine...Indian hemp...and peyote..."

Congress defined "addict as "any person who habitually uses any habit-forming narcotic drug...so as to endanger the public morals, health, safety or welfare, or who is...so far addicted...as to have lost the power of self-control with reference to his addiction..."

Section 2 - Congress assigned the Attorney General, Treasury Secretary and Secretary of War to select sites for two institutions" to house convicted addicts and "addicts who voluntarily submit themselves for treatment." (The two facilities were later built in Lexington, Kentucky and Fort Worth, Texas.)...

At Section 5, Congress created a Narcotics Division within the PHS Office of the Surgeon General, to be directed by a physician in charge of the "management, discipline and methods of treatment" of addicts.

At Section 6, Congress authorized the Treasury Secretary to promulgate regulations, and directed the Surgeon General to provide State representatives "the benefit of his experience...through the publication and dissemination of information on methods of treatment and research in this field...to the end that each State" would provide similar facilities within their jurisdictions.

At Section 9, Congress authorized the Treasury Secretary to "establish industries, plants, factories or shops [within the narcotic farms] for the manufacture of articles, commodities and supplies" for the US Government.

At Section 10, Congress prohibited parole until the Surgeon General certified that the inmate is no longer a narcotic addict, and at Section 11, Congress directed Surgeon General examination of all inmates within one

month of the expiration of their sentences.

At Sections 15 and 16, Congress prohibited "escape or attempt to escape from a narcotic farm," punishable by up to 5 years imprisonment in addition to the original sentence, and prohibited assisting such escape attempts, punishable by up to three years imprisonment.

In June 1930, Congress changed the name of the PHS Narcotics Division to Division of Mental Hygiene (PL 71-357) and authorized and directed the Surgeon General to "make such studies and investigations...of the abusive use of narcotic drugs; of the quantities of crude opium, coca leaves, and their salts, derivative and preparations....as are necessary to supply the normal and emergency medicinal and scientific requirements of the United States; and of the causes, prevalence, and means for the prevention and treatment of mental and nervous diseases..."

This law is relevant to the history of federal quarantine and biological product law for several reasons. It created a pool of incarcerated subjects for drug research projects; it deepened federal-state financially-incentivized cooperation in alleged public health program operations; and it supported the attribution of mental and neurological disorders to factors other than injection of foreign biological material into humans and other mammals, creating an effective mechanism for suppressing public understanding of the connection between neurological disorders and vaccination.

The model — setting up and funding PHS and NIH divisions and institutes to allegedly look for causes of chronic diseases and thereby direct attention away from their induction by vaccination — has been replicated for many other disorders, including cancer, Sudden Infant Death Syndrome and autism.

**In 1930, the year the Hygienic Laboratory was renamed as the National Institute of Health (see below), Congress funded design and construction of the two narcotic farms and reduced the infectious disease list (diseases authorizing Presidents to supply funds to state and local health boards for prevention of epidemics) from the specific list (cholera, typhus, etc.) to the general form: "threatened or actual epidemic of infectious or contagious disease." In 1930 Congress also funded "educational exhibits...the preparation of public-health exhibits designed to demonstrate the cause, prevalence, methods of spread, and measures for preventing disease dangerous to the public health..." including "acquiring, transporting, and displaying exhibit material."

1930 - An Act to provide for coordination of public-health activities of the Government - PL 71-106

In April 1930, Congress passed "An Act to provide for the coordination of the public-health activities of the Government, and for other purposes."

Through this law, Congress gave the Treasury Secretary power to establish new divisions within the Public Health Service, and expanded, named (as the National Advisory Health Council) and added to the duties of the Hygienic Lab advisory board, a second function: to "advise" the PHS Surgeon-General "in respect to public-health activities."

Congress did not define *public health* and Congress did not assign the staff of the Hygienic Laboratory or the National Advisory Health Council any specific duties to draft or enforce regulations governing the propagation of viruses, toxins, vaccines and other biological products.

Summary:

Section 1 - Congress authorized the Treasury Secretary to detail PHS officers to any federal executive department or "independent establishment which is carrying on a public-health activity...to cooperate in such

work," and to pay PHS officers for such work.

Section 2 - Congress authorized the PHS Surgeon General to detail PHS employees to "educational and research institutions" to study and disseminate information on "scientific problems relating to public health;" and to make federal PHS facilities available to health officials and scientists. Congress authorized the Treasury Secretary to establish additional divisions in the Hygienic Lab in Washington DC, "as he deems necessary," and set up facilities to coordinate research and "demonstrations of sanitary methods and appliances."

Section 3 - Congress set up the structure of the Public Health Service to include administrative offices, and "field service" offices, the latter including "scientific offices and research laboratories."

Sections 4 and 5 - Congress authorized the President to set up regulations for the appointment of medical, dental, sanitary engineer and pharmacist officers.

Section 6 - Congress authorized the Treasury Secretary to order officers in the PHS reserve corps to active duty for training and assessment of "fitness" for the regular corps.

Section 7 - Congress authorized the President, upon notice by the Treasury Secretary, to appoint non-commissioned officers to positions requiring "highly specialized training and experience in scientific research" when commissioned officers were not available.

Sections 8 and 9 - Congress addressed pay for officers older than 45 disabled in the line of duty, examinations, promotions, length of service, pay and allowances.

Section 10 - Congress authorized the President to prescribe titles for commissioned officers, designated Assistant Surgeon Generals as "medical directors;" removed the prior limit on the number of active-duty senior surgeons and Assistant Surgeons General at large; and increased the pay of the PHS Surgeon General to match the Army Surgeon General.

Section 11 - Congress authorized the Treasury Secretary to appoint all officers and employees of the PHS other than commissioned officers, with a provision barring the Treasury Secretary from setting up qualification rules giving preference to candidates from any specific school of medicine.

Section 12 - Congress authorized PHS officers disabled "on account of sickness or injury incurred in line of duty" to receive medical, surgical and hospital services.

Section 13 - Congress named the 9-member advisory board to the Hygienic Laboratory (established in 1902 "for consultation relative to the investigations to be inaugurated, and the methods of conducting the same") the National Advisory Health Council; expanded its size to 14 members; authorized the PHS Surgeon General and Treasury Secretary to appoint the five additional board members, "from representatives of the public-health profession;" and tasked the board to "advise" the PHS Surgeon-General "in respect to public-health activities."

Key points:

Through this law, Congress gave the Treasury Secretary power to establish new divisions within the Public Health Service, and expanded, named and added to the duties of the Hygienic Lab advisory board.

Congress did not define the term *public health*.

Congress did not assign the National Advisory Health Council any specific duties to draft or enforce regulations governing the propagation of viruses, toxins and other biological products.

In 1944, through the Public Health Service Act of 1944, Congress assigned duties to the NAHC to provide "recommendation," along with the PHS Surgeon General, to the President for specifying (by Executive Order) communicable diseases, the prevention of which would authorize "apprehension, detention or conditional release of individuals" under quarantine regulations.

In 2002, Congress eliminated the "prerequisite for National Advisory Health Council recommendation before issuing quarantine rules" and downgraded the PHS Surgeon General's role from "recommendation" provider to the President, to provider of "consultation" to the HHS Secretary, who had taken over the Surgeon General's functions through another series of amendments, reorganizations, and authority transfers.

1930 - Hygienic Laboratory name changed to National Institute of Health; private research funding system established - PL 71-251

One month later, in May 1930, Congress changed the name of the Hygienic Laboratory to the National Institute of Health and created in it a system of fellowships and donation authorizations for "ascertaining the cause, prevention and cure of disease affecting human beings."

Summary:

Section 1 - Congress changed the name of the Hygienic Laboratory of the Public Health Service to the National Institute of Health, and transferred all "laws, authorizations and appropriations" to the new institute. Congress authorized the Secretary of the Treasury to use the existing Hygienic Lab site in Washington DC and to acquire more sites. Congress directed the Surgeon General to select, as administrators and employees, "persons who show unusual aptitude in science," and authorized appropriation of $750,000 for construction and equipment of additional buildings.

Section 2 - Congress authorized the Treasury Secretary to accept "gifts made unconditionally by will or otherwise for study, investigation, and research in the fundamental problems of the diseases of man" and for purchase of land and construction and equipment of buildings, with the proviso that "conditional gifts may be accepted if recommended by the Surgeon General and National Advisory Health Council," to be held in trusts, invested by the Treasury Secretary in US securities, and the principal or income spent for NIH purposes. Donations over $500,000 for research would be "acknowledged permanently" by the establishment of memorials, and the Surgeon General was authorized to establish NIH fellowships from donated funds.

Section 3 - Congress authorized the Surgeon General to appoint individual scientists (other than commissioned PHS officers) to NIH duties, and authorized the Treasury Secretary to promulgate regulations. Congress authorized the Surgeon General to designate fellowship scientists to conduct research in "other localities and institutions in this and other countries" during their fellowships.

Section 4 - Congress authorized the Treasury Secretary, with recommendations from the Surgeon General, under regulations approved by the President, to designate titles and fix compensation; to fix compensation for clerical and other assistants under civil service laws; and to spend funds for personal services, rents, reference books periodicals, exhibits, printing and binding.

Section 5 - Congress directed that NIH facilities be made available to "bona fide health authorities of States, counties, or municipalities for purposes of instruction and investigation."

Section 6 - Congress established that the NIH Director would have the rank, pay and allowance of a PHS medical director.

Key points:

Congress set up a mechanism for unconditional and conditional private financing of federal public health research, and the employment of non-governmental scientists.

Congress further linked the public health functions of State, county and municipal governments to federal scientific and medical research programs.

**In 1931, Congress renamed the Narcotics Division as the Division of Mental Hygiene. In 1934, Congress funded, under the Division of Mental Hygiene, Narcotic Farm, Lexington, Kentucky, "expenses incurred in pursuing and identifying escaped inmates and of interment or transporting remains of deceased inmates."

1935 - Federal Register Act - PL 74-251

Through the Federal Register Act, Congress elaborated on the process for executive legislation, further eroding the separation of powers doctrine and transferring legislative authority to the executive branch.

Summary:

Section 1 - Congress charged the US Archivist to create a new division in the National Archives Establishment, to print and distribute documents listed in Section 5, and authorized the President to appoint a director of the Division.

Section 2 - Congress required document sources (President, federal agencies, etc.) to provide an original and two copies of the documents listed in Section 5. The Division Director was required to log the documents by date and hour; make one copy immediately available for public inspection; store the original in the National Archives and send a copy to the Government Printing Office for printing.

Section 3 - Congress directed the Government Printing Office to publish all the documents listed in Section 5 "in a serial publication designated the 'Federal Register,' " to be published and distributed daily, and to contain the documents filed with the Division the previous day.

Section 4 - Congress defined *document* to mean "Any Presidential proclamation or Executive order and any order, regulation, rule, certificate, code of fair competition, license, notice, or similar instrument issued, prescribed, or promulgated by a Federal agency." Congress defined *Federal agency* to mean "the President...or any executive department, independent board, establishment, bureau, agency, institution, commission, or separate office of the administrative branch...but not the legislative or judicial branches..."

Section 5 - Congress listed the documents to be published in the Federal Register, including "all Presidential proclamations and Executive orders," with exceptions for those with "no general applicability...or effective only against Federal agencies or persons in their capacity as officers, agents, or employees;" documents the President determined "have general applicability and legal effect;" documents required to be published in the Federal Register by Act of the Congress; and other documents authorized by regulations prescribed with the President's approval, but not "comments or news items of any character."

Section 6 - Congress established a permanent Administrative Committee of three members: the Archivist, a Department of Justice officer appointed by the Attorney General, and the Public Printer. Congress charged the committee with prescribing regulations to carry out the Federal Register Act provisions, including how agencies should submit certified copies of regulations and other documents, which documents should be published, the number of copies, prices to be charged for copies, and other details.

Section 7 - Congress established that no documents published "shall be valid as against any person who has not had actual knowledge thereof" until the originals or certified copies had been filed and made available for public inspection, but availability of public inspection would "be sufficient to give notice...to any person subject thereto." Congress established that publication in the Federal Register created a "rebuttable presumption" that all the filing requirements had been fulfilled, and directed that the contents of the Federal Register "shall be judicially noticed" and cited by volume and page number.

Section 8 - Congress established that publication of notice in the Federal Register — for example, notices of public hearings — would be "deemed" as properly given to all persons residing within the continental United States if published within the Congressionally required time prescribed, or not less than 15 days if no time period prescribed by Congress.

Section 9 - Congress authorized the Treasury Department to take receipt of payments made for copies of the Federal Register, and charged the printing and distribution costs to the appropriations to the Government Printing Office. Congress authorized free use of the US mail for copies mailed by the US Government.

Section 10 - Congress made the provisions of Section 2 effective 60 days after approval (approval was July 26, 1935) and ordered publication to begin three days after that.

Section 11 - Congress required each agency, within six months after approval, to compile all the documents that had been issued before passage of the Federal Register Act and "still in force and effect and relied upon by the agency," and submit the compilations to the committee named in Section 6. Congress required the committee to report on the pre-Federal Register Act regulations and other documents to the President within two months after that, and required the President to determine "which of such documents have general applicability and legal effect" and authorize publication of a special edition of the Federal Register to publish those pre-Federal Register Act documents.

Section 12 - Congress exempted "treaties, conventions, protocols, and other international agreements, or proclamations thereof by the President."

Section 13 - Congress repealed all other acts to the extent they were in conflict with the Federal Register Act.

Key points.

Congress formally transferred legislative authority to President, Cabinet secretaries and agency officers, by setting up a system for executive branch legislation, further undermining the separation of powers between the legislative and executive branches.

1935 Social Security Act - PL 74-271

Congress passed the Social Security Act in August 1935, under the full title: "An Act to provide for the general welfare by establishing a system of Federal old-age benefits, and by enabling the several States to make adequate provision for aged persons, blind persons, dependent and crippled children, maternal and child welfare, public health, and the administration of their unemployment compensation laws; to establish a Social Security Board; to raise revenue; and for other purposes."

When first enacted, the Social Security Act had 11 titles, or sections, including: Title I, *Grants to States for Old-Age Assistance*; Title II, *Federal Old-Age Benefits*; Title III, *Grants to States for Unemployment Compensation Administration*; Title IV, *Grants to States for Aid to Dependent Children*; Title V, *Grants to States for Maternal and Child Welfare*, including Maternal and Child Health Services (Part 1), Services for Crippled Children (Part 2), Child-Welfare Services

(Part 3), and Vocational Rehabilitation (Part 4); Title VI, *Public Health Work*; Title VII, *Social Security Board*; Title VIII, *Taxes With Respect to Employment*; Title IX, *Tax on Employers of Eight or More*; Title X, *Grants to States for Aid to the Blind*; and Title XI, *General Provisions*.

There are now 21 titles, codified at 42 USC Chapter 7, Subchapters I through XXI.

Summarizing only Title VI, Public Health Work, of the original 1935 Social Security Act:

Section 601 - Congress authorized $8,000,000 "for the purpose of assisting States, counties, health districts, and other political subdivisions...in establishing and maintaining adequate public-health services, including...training of personnel..." starting with the fiscal year ending June 30, 1936.

Section 602 - Congress authorized the PHS Surgeon General, with Treasury Secretary approval, to allot the money to the States on the basis of three factors: population, "special health problems" and financial needs. Congress conditioned payments on State health authorities presenting plans to the Surgeon General, and obtaining Surgeon General approval for such plans.

Section 603 - Congress authorized $2,000,000 for the PHS to spend "for investigation of disease and problems of sanitation," including printing and binding of research findings, and travel expenses for PHS employees to travel to States, upon State request, to carry out investigations. Congress required the Treasury Secretary to provide reports to Congress on public health projects annually.

Key Points:

As noted above, the 1921 Sheppard-Towner Act for maternity and child welfare programs undermined federalist principles separating powers between the Federal and State governments by offering states Federal money — "Grants to States" — on condition that the States adopt and implement Federal policies.

The Sheppard-Towner Act also undermined family, community and religious support networks to transfer the dependency of distressed families from extended family, friends, neighbors and local civic and religious organizations to State and Federal officers distributing subsidies funded by payroll taxes on employers and employees.

The Sheppard-Towner Act expired in 1929, but most of its provisions were incorporated into the 1935 Social Security Act at Title V.

By linking federal payouts to population data, public health officers created incentives for State use of centralized registries and classification systems for disease diagnosis and cause of death determinations.

1936 - Act to extend PHS services to more seamen - PL 74-483

In 1936, Congress extended Public Health Service "medical relief" to seamen "not enlisted or commissioned in the Military or Naval Establishments" but "employed on US Government vessels (other than those of the Panama Canal) of more than five tons' burden and on State school ships," and to State school ships' cadets.

1937 - During NIH reorganization, Division of Pathology and Bacteriology renamed Division of Biologics Control - NIH accounts of NIH history.

As reported above, in a January 1910 JAMA paper, PHS Hygienic Laboratory Director Milton J. Rosenau referred to the 'division of pathology and bacteriology' as the division responsible for inspecting establishments

manufacturing viruses, toxins, serums and analogous products under the 1902 Virus-Toxin law and the 1902 "Act to increase the efficiency and change the name of the...Marine-Hospital Service."

Rosenau's claim is not supported by the text of the 1902 laws, which identified three divisions within the Hygienic Laboratory (chemistry, zoology and pharmacology); vested inspection authority with the Secretary of the Treasury, and vested rule-making authority with a three-member Surgeon-Generals board subject to Treasury Secretary approval.

In 1930, Congress renamed the PHS Hygienic Laboratory as the PHS National Institute of Health and authorized the Treasury Secretary to reorganize and establish new divisions in the Public Health Service.

The Division of Pathology and Bacteriology was renamed the Division of Biologics Control in 1937 during "a reorganization of NIH into eight divisions," according to NIH accounts of NIH history:

> "The Division of Biologics Control was established in 1937 at NIH from the laboratory that had responsibility for biologics. In 1944, the division became the Laboratory of Biologics Control. And in 1955, the Division of Biologics Standards (DBS) was formed as an independent entity at the NIH, but as the continuation of the previous division and laboratories."

Ostensible responsibility for regulation of viruses, toxins, serums and analogous products remained with the Division of Biologics Standards from 1955 until the DBS was administratively transferred to the Food and Drug Administration in 1972 and renamed the Bureau of Biologics.

**In 1936, Congress changed the name of the Narcotic Farm to The United States Public Health Service Hospital, Lexington, Kentucky; added a program called *Grants to States for public-health work*, for "assisting States, counties, health districts and other political subdivisions of the States in establishing and maintaining adequate public-health services, including the training of personnel," under provisions of the Social Security Act; and continued funding *Diseases and sanitation investigations*.

**In 1937, Congress funded a Public Health Service study of "investigations to determine the possibly harmful effects on human beings of spray insecticides on fruits and vegetables," under the *Diseases and sanitation investigations* program.

1937 - National Cancer Institute Act - PL 75-244

In August 1937, Congress passed the National Cancer Institute Act. The summary is included here because it relates to government and private institution interest in, and knowledge of, the cancer-causing effects of injecting foreign cells and cell-products (toxins) into humans and other mammals, also known as vaccination.

Congress did not define the term cancer in the 1937 law. Since 2009, FDA has defined cancer as "a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells," citing American Cancer Society, 2004. (*See* January 2009 FDA Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims at p. 8)

Summary of National Cancer Institute Act:

Section 1 - Congress established a PHS division called the National Cancer Institute, to "conduct researches, investigations, experiments, and studies relating to the cause, diagnosis and treatment of cancer," and to help other public and private organizations.

Section 2 - Congress authorized and directed the PHS Surgeon General to carry out the research programs, to promote coordination of research projects conducted by other "agencies, organizations and individuals, to "procure, use and lend radium;" to provide training; to provide fellowships; to obtain advice from cancer researchers in the US and abroad, and to cooperate with State health agencies "in the prevention, control, and eradication of cancer."

Section 3 - Congress created the National Advisory Cancer Council to have six members appointed by the Surgeon General, with Treasury Secretary approval, "from leading medical or scientific authorities who are outstanding in the study, diagnosis, or treatment of cancer," to serve three-year terms.

Section 4 - Congress authorized the National Advisory Cancer Council to review research projects and approve projects that "show promise;" to collect information about studies being carried out in the US or any other country, and publish such information; to review applications from public and private universities, hospitals and laboratories requesting grants for cancer research; to recommend "conditional gifts" for approval by Secretary of the Treasury; and to make recommendations to Surgeon General for carrying out the National Cancer Institute Act.

Section 5 - Congress authorized the Surgeon General to purchase radium; make it available for research projects; and to lend it to institutions studying "the cause, prevention, or methods of diagnosis or treatment of cancer;" to provide training facilities for diagnosis and treatment of cancer; to establish and maintain research fellowships "to procure the assistance of the most brilliant and promising research fellows;" to secure help and advice from experts from the US and abroad; to make grants for research projects; and to adopt additional means to carry out the research projects.

Section 6 - Congress authorized the Treasury Secretary to accept unconditional gifts for research and acquisition of land and construction and maintenance of buildings, and to accept conditional gifts if recommended by the Surgeon General and National Advisory Cancer Council. Congress directed the gifts to be held in trusts and invested in securities of the US, with principal or income expended for cancer research. Congress authorized donations of $500,000 or more to be acknowledged with permanent memorials.

Section 7 - Congress authorized $750,000 for construction and equipment of a building for cancer research and $700,000 per year to support research, traveling expenses, medical books, passenger-vehicles, and printing and binding of publications.

Section 8 - Congress authorized the appointment of commissioned PHS officers to carry out the research programs, and authorized the Surgeon General, with Treasury Secretary approval, to "make such rules and regulations as may be necessary."

Provisions of the 1937 National Cancer Institute Act were incorporated into the Public Health Service Act of 1944 and subsequently expanded.

1938 - Federal Food Drug and Cosmetics Act - PL 75-717

In 1938, Congress passed the Federal Food, Drug and Cosmetic Act. The new law consolidated and expanded on the 1906 Pure Food and Drug Act, incorporating most provisions of the 1906 law — including its definitions for adulterated and misbranded drugs, labeling provisions, and procedures for specimen collection, testing and criminal prosecution — into Chapter 2, *Definitions*; Chapter 3, *Prohibited acts and penalties;* Chapter 4, *Food*; Chapter 5, *Drugs and Devices;* Chapter 6, *Cosmetics;* Chapter 7*, General Administrative Provisions;* Chapter 8*, Imports and Exports.*

The 1938 law added a section (FDCA Section 505, codified at 21 USC 355) governing "new drugs" and setting up application and review procedures to be carried out by the Secretary of Agriculture.

At Chapter 8, Miscellaneous, Congress explicitly stated:

> "Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the virus, serum and toxin Act of July 1, 1902."

Congress cited to a reprint of the 1902 Virus-Toxin law published in the 1934 edition of the US Code as a chapter titled Viruses, Serums, Toxins, Anti-Toxins, Etc.

Key point:

The application, inspection, testing, review and compliance enforcement provisions of the 1938 Federal Food, Drug and Cosmetic Act pertaining to product definition, identification, labeling, purity, adulteration and misbranding were inapplicable to manufacturing, licensing, and interstate and international trafficking of viruses, toxins, vaccines and other biological products.

**In 1938, Congress funded the new National Cancer Institute within the PHS, under the National Cancer Institute Act.

1939 Reorganization Act - PL 76-19,

In early April 1939, Congress passed the Reorganization Act of 1939, ostensibly motivated "by reason of continued national deficits beginning in 1931," [following the stock market crash of October 1929 and subsequent economic depression and New Deal programs] making it "desirable to reduce substantially Government expenditures."

The law, not summarized in detail here but available for reader review (PL 76-19), transferred a form of legislative authority from Congress to the President, by authorizing unilateral "transfer, consolidation, or abolition" of federal executive agencies and functions, "more speedily...than by the enactment of specific legislation."

The second part of the act set up complex Congressional rules to make it politically difficult for Congress to debate or reject any reorganization plan prepared by a President, such that transmitted plans were virtually guaranteed to go into effect.

Congress authorized the President to determine the changes needed "to increase...efficiency;...to group, coordinate and consolidate agencies;...to abolish...agencies as may not be necessary; and...to eliminate overlapping and duplication of effort..." and required the President to transmit plans to Congress before Jan. 21, 1941.

In late April 1939, President Roosevelt transmitted Reorganization Plan No. 1 to Congress, followed by Reorganization Plan No. 2, transmitted to Congress in May 1939.

By Joint Resolution adopted June 7, 1939, (Pub Res. 76-138), Congress accepted the two reorganization plans, which went into effect July 1, 1939 and were published in the Federal Register the same day (4 FR 2727 and 2731).

Through Reorganization Plan No. 1 of 1939 and Executive Order 8248 (4 FR 3864, Sept. 8, 1939), Roosevelt

created the Executive Office of the President and the Federal Security Agency (FSA), and transferred the Public Health Service and its divisions and functions, from the Treasury Department to the new executive agency. Other agencies transferred to the new Federal Security Agency included the US Employment Service (from Department of Labor); Office of Education (from the Department of the Interior); National Youth Administration (from the Works Progress Administration), and the Civilian Conservation Corps. The FSA was simultaneously consolidated with the Social Security Administration.

Through additional reorganization acts and reorganization plans, the Federal Security Agency was abolished in 1953 and its functions were transferred to the Department of Health, Education and Welfare (HEW). The functions of the Public Health Service and the PHS Surgeon General were transferred to the HEW Secretary in 1966. In 1979, Congress and President Carter passed an act to create the Department of Education, and changed the name of the HEW Department to the Department of Health and Human Services.

Key Points:

The Reorganization Act represents one example of acts through which Congress abdicated its lawmaking authority and its oversight (checks and balances) duties, gutting the separation of powers between the legislative and executive branches.

It's one of the key acts through which Congress created the so-called "Deep State" of permanent civil administrators.

1940-1943 - Biological Warfare Laboratories set up within Federal Security Agency

Although not covered in detail here, readers may be interested in learning more about the establishment, between 1940-1943, within the Federal Security Agency established in 1939 (later renamed Health, Education and Welfare Department, now Health and Human Services Department) of the National Defense Research Committee, Office of Scientific Research and Development, War Bureau of Consultants, War Research Service (biological warfare), and US Army Biological Warfare Laboratories (Camp Detrick), and how the federal government officers and agencies involved in those war programs were related to federal vaccination programs as developed from the late 1940s through the present.

1940 - FDA transferred from Department of Agriculture to Federal Security Agency. (54 Stat. 1234 at 1237)

Under Roosevelt's Reorganization Plan No. 4 of 1940, promulgated under the 1939 Reorganization Act passed by Congress, President Roosevelt transferred the Food and Drug Administration and all of its functions, except its functions under the Insecticide Act of 1910 and the Naval Stores Act, to the Federal Security Agency, under the direction and supervision of the Federal Security Administrator, and renamed the Chief of the Food and Drug Administration as the Commissioner of Food and Drugs.

Key Points:

Reorganization Plan No. 4 was silent as to whether any laboratory would take on the functions formerly carried out by the USDA Bureau of Chemistry, including collection and testing of drug specimens, which again, did not include collection and testing of virus and toxin specimens, which were not subject to regulation under the 1938 Food Drug and Cosmetics Act or the 1906 Pure Food and Drug Act.

** In 1941, Congress funded a new PHS program called *Emergency health and sanitation activities (national defense)*, "to assist State and local health authorities in health and sanitation activities (1) in areas adjoining military and naval reservations, (2) in areas where there are concentrations of military and naval forces, (3), in areas adjoining

Government and private industrial plants engaged in defense work and (4) in private industrial plants engaged in defense work..." and another one called *Training for nurses (national defense).*

**In 1943, Congress funded a new States Relations Division within the PHS, under the Social Security Act of 1935, consolidating federally-funded state-level programs including *Grants to States for public-health work* (established 1936); *Interstate quarantine service* (1890, 1913) and *Prevention of epidemics* (1904).

1943 - Public Health Service Act of 1943 (PL 78-184)

On Nov. 11, 1943, Congress and President Roosevelt passed an act "relating to the organization and functions of the Public Health Service, and for other purposes."

The November 1943 law (which was followed by the July 1944 adoption of the Public Health Service Act of 1944, to be covered in Part 5 of this series) laid out the new organizational structure, "powers and duties," and programs.

Summary of Public Health Service Act of 1943:

Section 1 - Public Health Service in the Federal Security Agency will include Office of the Surgeon General, National Institute of Health (the Hygienic Laboratory established in 1887), and two bureaus: The Bureau of Medical Services and Bureau of State Services.

Congress authorized the PHS Surgeon General, under the supervision and direction of the Federal Security Administrator, to assign all the previously authorized functions of the PHS to the four offices and to establish new "divisions, sections and other units," to "abolish existing divisions, sections and other units," and, from that point on, to "establish, transfer and consolidate divisions, sections, and other units, and reassign their functions for the efficiency of the Service."

Section 2 - Congress directed that the NIH Director would detail, from the regular corps, the "chiefs" of the two new bureaus (medical services and state services) and the Chief Medical Officer of the US Coast Guard, and that while serving in those positions, they would be classified as Assistant Surgeon General with corresponding pay and allowances.

Section 3 - Congress laid out terms for temporary details for officers to serve as division chiefs, and authorized -- -- in the Office of Surgeon General -- a Dental Division and a Sanitary Engineering Division.

Section 4 - Congress authorized -- "in time of war or national emergency determined by the President" -- temporary promotions with increased pay and allowances, and exempted promoted officers from having to renew their oath of office or take a new oath.

Section 5 - Congress set up a system for review of the records of commissioned officers above the level of Assistant Surgeon every three years, and for separation from the Public Health Service for officers found to be unqualified.

Section 6 - Congress set up a continuity plan "in case of the absence or disability of the Surgeon General and the Assistant to the Surgeon General."

Section 7 - Congress amended Sec. 9 of the April 9, 1930 reorganization act to add a paragraph authorizing appointments to a junior grade corresponding to second lieutenant in the Medical Department of the Army, eligible for promotion to Assistant Surgeon grade after one to two years and an examination.

Section 8 - Congress defined the terms "full military benefits," and "limited military benefits," and authorized commissioned officers of the Public Health Service, regular and reserve, to receive full or limited benefits, depending on whether they served "in time of war," while detailed to the Army, Navy or Coast Guard and other factors. Congress further authorized the President, "in time of war...by Executive order" to declare the commissioned corps of the PHS "a part of the military forces of the United States"

Section 9 - Congress authorized PHS commissioned officers to receive benefits for injury or death as civil officers and employees of the United States.

Section 10 - Congress authorized surviving beneficiaries of dead commissioned PHS officers to receive six months' pay and benefits under Sec. 9.

Section 11 - Congress authorized the Federal Security Administrator to transfer funds between appropriations to carry out PHS reorganization, with the approval of the Director of the Bureau of the Budget.

Key points:

Congress transferred all authority to reorganize the Public Health Service to the Surgeon General and Federal Security Administrator, including establishing, transferring and abolishing divisions, and "reassigning functions."

Congress reinforced the status of the Public Health Service as a federal military program.

Congress reinforced that one core function of the federal Public Health Service was "State Services."

BRIEF ANALYSIS:

For this report, the authors are not offering analysis of the parallel developments in speed of telecommunications (enabling disease-outbreak allegations to reach ports before ships); centralization of general and scientific publishing, data collection and statistical disease and cause-of-death classification systems; scientific research into methods of inducing cancer, autoimmune disease, neurological disorders, gastrointestinal disorders and other chronic, life-limiting conditions; transfer of lawmaking authority from legislative to executive branches, weakening of judicial authority by legislative enactment, and federal preemption and bribery to weaken state and local authority.

We plan to publish additional analysis after the series is published in full.

We'd like to focus reader attention on careful review of the Congressional authorization acts and Presidential reorganization acts demonstrating the consistent non-presence of provisions directing federal agencies to establish biological product definitions; to establish measurable, enforceable standards for product identification, labeling, purity, potency, safety, efficacy; or to establish procedures for specimen collection, analysis, recall, seizure, and destruction.

As a result of this non-presence, no federal agency has ever published or enforced rules governing biological product identity, labeling, purity, potency, safety, efficacy or specimen collection, analysis, recall, seizure, and destruction procedures.

Update Oct. 10, 2024 - Following leads from a 2016 paper by Terry S. Coleman: *Early Developments in the Regulation of Biologics* (Food and Drug Law Journal, Vol 71, No . 4, pp. 544-607), on Oct. 10, 2024, we located six regulatory publications published before the Federal Register Act:

- 1903.02.21 PHS Treasury Regulations for the Sale of Viruses, Serums, Toxins and Analogous Products

- 1909.05.11 PHS Treasury Regulations for the Sale of Viruses, Serums, Toxins and Analogous Products
- 1919.02.12 PHS Treasury Regulations for the Sale of Virues, Serums, Toxins and Analogous Products
- 1923.08.01 PHS Treasury Regulations for the Sale of Viruses, Serums, Toxins and Analogous Products
- 1934.03.13 PHS Treasury Regulations for the Sale of Viruses, Serums, Toxins and Analogous Products
- 1935.02.25 PHS Treasury Regulations for the Sale of Viruses, Serums, Toxins and Analogous Products

The earliest version of regulations pertaining to biological products for human use, published in the Federal Register, under executive branch authority as transferred by Congressional statutes, addressing manufacture of viruses, toxins, serums and analogous products, that the authors had located as of October 9, 2024 is a 1940 version, published in the Federal Register on Oct. 17, 1940 (5 FR 4107) and codified at 42 CFR 22.1 to 22.115, Viruses, Serums, Toxins, and Analogous Products.

Careful review of the 1940 human-use biological product regulations codified at 42 CFR 22, and all successor regulations, including

- 42 CFR 73, Biologic products (1947),
- 21 CFR 273, Biological products (1972-1973),
- 21 CFR 600-680, Biological products (1973 to present), and
- 42 CFR 73, Select agents and toxins (2002 to present)

demonstrates the consistent non-presence of mandatory provisions (mandatory meaning provisions that are not discretionary, waived, exempted, preempted, suspended, or otherwise rendered inapplicable to biological products including all vaccines) that are essential for the regulation of any product intended for consumption by or injection into human beings, such as

- product definitions enabling product identification by physical or chemical attributes;
- physical or chemical product identification standards and identification testing protocols;
- safety standards apart from short-term survival tests for animals including rabbits, mice, and guinea pigs;
- any safety standards for human product recipients;
- any efficacy standards for human product recipients;
- specimen collection and testing procedures;
- assignment of specimen collection and testing duties;
- product recall, seizure, analysis, and destruction procedures;
- assignment of recall, seizure, analysis and destruction duties;
- criminal prosecution procedures; and
- assignment of criminal prosecution duties.

In other words, virus and toxin manufacturers and regulators have not done the biological product regulatory standard-setting, regulatory compliance and regulatory compliance enforcement that no law has ever required them to do.

Manufacturers have pretended to comply with standards that do not exist, and regulators have pretended to enforce compliance with standards that do not exist.

Why have they jointly engaged in such massive, coordinated, legalized deceit?

To jointly conduct legalized, deniable, interstate and international traffic in heterogeneous, unstable mixtures of poisons — vaccines — for the purpose of intentionally sickening, mutilating and killing people.

Part 5 - 1944-1972: Law and public policy imbued with scientific misconduct to better induce irrational fear of disease and irrational trust in vaccination.

Published Feb. 28, 2025

By Lydia Hazel and Katherine Watt

Outline

I. Introduction

So far in our pilgrimage to understand how perverted legal instruments (statutes, regulations, executive orders, treaties, trade agreements and contracts) have made possible the legalized, ongoing, vaccine- and pesticide-driven mass poisoning of the world's people, we have presented timelines of laws enacted between 1798 and 1943 and between 1972 and the present.

Our goal is to give readers a scaffolding on which to attach more knowledge. The volume of available information, and the complexity and moving target character of the deception programs make it difficult to do anything more than provide a scaffold.

We are confident that our basic conclusions are supported by the evidence from the wording of legal instruments themselves, and from the written record surrounding the application of the laws, including government and academic reports, published scientific and medical literature, litigation records (stipulations and judicial decisions), and historical accounts written by researchers whose work was not funded by governments, private institutions or universities.

These conclusions follow.

1) Regulation or licensing of biological product and vaccine manufacturing in the United States, by the Food and Drug Administration and its precursors, establishes and applies alternative, surrogate, proxy, indirect,

uncontrolled, correlative, probability-based standards to manufacturing methods and product quality assurance methods.

2) Because the standards are correlative, and therefore not standards at all, the procedures presented to the public as regulation have instead been a simulation of regulation, a suggestion-to-the-mind of observers, without substance or materiality.

3) Regulatory simulation of biological product manufacturing has been going on continuously since the initial construction of the legal frameworks for biological products in 1902 with Congressional passage of the Virus-Toxin law through the present.

4) The basic reason for the simulation is that the simulators have wanted the public to believe — contrary to the truth — that vaccines are a class of products that can be stabilized and standardized and, in stable, standardized, identifiable and identified forms, can be demonstrated to have stable properties or attributes such as purity, therapeutic effectiveness and strength.

5) These properties are denoted using many different terms within legal instruments. Some of the other terms are sterility, safety, efficacy, specific results, potency, dosage, contaminated, adulterated, adventitious agents, bioburden, and extraneous proteins.

6) Because the contents of vaccine bottles are propagated by living organisms, vaccines are processes, and not products. And because they are non-self organic matter injected into the blood of a recipient organism, they can also be understood as injectable pesticides. They offer a much more concentrated, effective delivery mechanism than aerial and surface spraying.

7) As living organisms or dynamic processes encased in steel or glass, vaccines cannot be fully identified, defined, characterized, stabilized or standardized, and thus cannot be demonstrated to have stable properties or attributes such as purity, effectiveness and strength.

8) Given all of the above, regulation and standardization in a substantive, material form is practically and theoretically impossible.

Over the past eight decades, those who use vaccines to poison babies, children and adults under the guise of therapeutic benevolence have made changes to the wording of biological product and communicable disease control law. In most cases, these wording changes have been made to obscure or delay emergence of evidence from advancements in analytical techniques and equipment, which would expose the intentional harmfulness of vaccination to public view, and to compensate for growth in public scientific literacy.

Why have legislators, financial officers, military officers, public health officers, scientists, vaccine manufacturers, doctors and lawyers wanted people to believe the lies that a non-standardizable process is a standardized product and that harmful products are beneficial products?

We believe the evidence supports the conclusion that these government officials and professionals seek to induce false trust by suggesting feasible and rigorous quality control oversight where none occurs, and to ensure product safety and therapeutic benefit, where neither are possible, to induce compliance with vaccination campaigns.

They want people to take vaccines voluntarily, repeatedly and without resistance, and to vaccinate their children, so that more people will get sick, be sicker, and die earlier, without the poisoning crimes being traceable to the killers, and within a legal system incapable of stopping, prosecuting and punishing the criminal acts.

We believe the evidence supports the conclusion that biological product regulation is a web of interwoven simulations, and that the evidence demonstrates how and by whom these simulations are performed.

Some of the performers -- vaccinating doctors, nurses and pharmacists who have trusted the information provided to them during training and the teachers who provided that information -- have believed they are performing good acts with true therapeutic, disease-prevention effects. They believed error to be truth, but they believed it sincerely and with good will, out of ignorance and not malice.

For some of the performers who know the truth about epidemiology, pathology, virology and vaccines, the motivation is greed and the goal is money: patient visits, drug sales, campaign contributions, bribes, getting people on the public dole as disabled, and then off the public dole as dead.

For others who know the truth, and who organize the work of doctors, nurses, pharmacists, manufacturers, legislators, judges and civil administrators, it's about dominance, control, and exploitation.

It's war, disguised.

It's about destruction of life and productive capacity.

It's about orchestration of scarcity.

It's about keeping people sick, weak, disordered, indebted, confused, depressed, anxious, dependent, infertile, and incapable of producing and distributing goods and services to support themselves, their families and their neighbors.

Abbreviations

- BoB - Bureau of Biologics
- CFR - Code of Federal Regulation
- DBS - Division of Biologics Standards
- EO - Executive Order
- FDA - Food and Drug Administration
- FDCA - Food Drug and Cosmetic Act of 1938
- FR - Federal Register
- FSA - Federal Security Agency
- HEW - Department of Health, Education and Welfare
- LBC - NIH Laboratory of Biologics Control
- LVR - NIH Laboratory of Virology and Rickettsiology
- NSDM - National Security Decision Memorandum
- NIH - National Institutes of Health
- PHS - Public Health Service
- PHSA - Public Health Service Act of 1944

II. Historical Context; Overview of Four Layers of Scientific-Legal Misconduct

Part 5 is the final installment in the series, to fill in the information for the immediate post-World War II period from 1944 to 1972, which encompasses:

- Congressional enactment of the Public Health Service Act of 1944, including Section 351, *Biological products* and Section 361, *Control of communicable diseases*;
- aerial (by planes) and surface spraying of human, animal, insect and plant populations using organophosphate and other organic pesticides and herbicides (organic: carbon-based, derived from living organisms or synthesized to mimic products of living organisms);
- centralized funding of scientific and medical research;
- centralized control of scientific and medical publishing;
- centralized production and distribution of merged news, drama, and advertising content, through radio, film, television, magazines and newspapers as well as text, black-and-white and color photographs, audio soundtracks and moving pictures (video);
- electrification and development of refrigerated storage and transportation systems for food and drugs;
- US-licensed *Japanese encephalitis* vaccine, 1945;
- first US-licensed combination vaccine (*diphtheria*, *tetanus* and *pertussis, DTP*), 1948;
- *polio epidemic* promotional advertising campaign which included centralized diagnostic criteria (for individual cases) and morbidity and mortality classification data reporting and data distribution (population-scale or epidemiological) for a collection of symptoms of systemic poisoning known as *poliomyelitis, infantile paralysis*, *flaccid paralysis, polioencephalitis* and other terms, which symptom constellations appeared in medical practice and scientific and medical literature coincident with the development of industrialized manufacture and use of organic pesticides in the mid-1800s;
- *polio* vaccines introduced by "field trials" (1952-1954) followed by nationwide mass vaccination campaigns starting in 1955;
- *Asian influenza epidemic* promotional advertising campaign, 1957;
- US-licensed *measles* vaccine, 1963;
- US-licensed *mumps* vaccine, 1967;
- US-licensed *rubella* vaccine, 1969;
- *Hong Kong influenza epidemic* promotional advertising campaign, 1968; and
- *swine influenza epidemic* promotional advertising campaign and mass vaccination campaign, 1976, including first comprehensive liability indemnification scheme for vaccine manufacturers by Congressional statute.

Layers of deception

Broken down into broad categories, there are four layers to the legal deception program that made a legal hole through which injectable organic pesticides (vaccines) have been propagated at industrial scale, bottled, refrigerated, transported through interstate commerce, and used on people and animals since 1902.

Layer 1

Mutual general exclusions exist between the 1938 Food Drug and Cosmetics Act (descendant of the 1906 Pure Food and Drug Act), and the 1944 Public Health Service Act (descendant of the 1902 Virus-Toxin law, as follow:

1938 FDCA, Section 902(c): "Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the virus, serum, and toxin Act of July 1, 1902"; and

1944 PHSA, Section 351(g): "Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug and Cosmetic Act."

Layer 2

Congress enacted, by statute, different lists of terms or phrases for product standards, laying out which properties or attributes of production facilities, processing methods, packaging and products were subject to enforcement under the FDCA, for non-biological products, and under the PHSA, for biological products.

1938 FDCA, Section 505(d) authorized the Secretary of Agriculture (later Federal Security Agency Administrator, later Health, Education and Welfare Secretary) to issue orders refusing to permit new non-biological drugs to enter interstate commerce on several grounds.

The manufacturing-related grounds to deny permission for distribution were:

> "upon finding...that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality and purity."

1944 PHSA, Section 351(d) authorized the Federal Security Agency Administrator (formerly Treasury Secretary, later HEW Secretary) to issue "licenses for the maintenance of establishments" to "propagate or manufacture" any biological product designated as a "virus, therapeutic serum, toxin, antitoxin or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound)."

The manufacturing-related standards for issuing licenses were:

> "upon a showing that the establishment and the products for which a license is desired meet standards designed to insure the continued safety, purity, and potency of such products..."

The most important word in the FDCA section is identity, and that's the most crucial omission from the PHSA section.

Biological products are not legally required to be identifiable or identified.

Without an identified, identifiable, stable product, it is not practically or theoretically possible to insure qualities, properties, characteristics or attributes of propagation materials and methods, or to insure attributes that could

inhere in a product itself, such as safety, purity or potency, in initial or in continued form.

Layer 3

Administrative agency regulations implemented Congressional intent to maintain two separate government oversight or product endorsement pathways (permits, authorizations, approvals, licenses) for two distinct categories of products: FDCA-governed non-biological products and PHSA-governed biological products, more properly understood as bottled biological processes.

Post-1944 agency regulations exempted all new biological products from regulation as "new drugs" under the 1938 FDCA. This enabled their legal introduction and delivery through interstate commerce without proof that manufacturing methods preserved "identity, strength, quality and purity."

The categorical exemption of biologics (vaccines) from FDCA 505 new drug application provisions entered into the Code of Federal Regulations (CFR) renumbered from 21 CFR 2.109 in the 1947 printing of the CFR to 21 CFR 1.109 for the 1949 printing of the CFR, as follows:

> "21 CFR 1.109. New drugs, exemption from section 505 of the [FDCA] act. A new drug shall not be deemed to be subject to section 505 of the [FDCA] act if it is a drug which is licensed under the Public Health Service Act of July 1, 1944 [...], or under the animal virus-serum-toxin law of March 4, 1913..."

By 1956, the provision was numbered 21 CFR 1.109a. (21 FR 9890). By 1963, the provision was numbered 21 CFR 130.2 (28 FR 6377). By 1974, the provision was numbered 21 CFR 310.4 (39 FR 11680), where it stands today.

A related series of regulations also exempted all "drugs intended solely for investigational use" from section 505(a) of the FDCA act, which prohibited introduction or delivery into interstate commerce of new drugs that had not filed new drug applications under FDCA 505.

The phrase "Caution: New Drug - Limited by Federal (or United States) law to investigational use" appeared on labels of polio vaccine used during field trials between 1952 and 1955, indicating that campaign organizers sought a double-layer of shielding from FDCA 505 new drug application standards.

The "investigational use" exemption is not covered in detail in this report, but it runs from 21 CFR 2.114 (1947) through 21 CFR 1.114 (1949), 21 CFR 130.3 (1963) to 21 CFR 312.1 (1974).

A version of these exemptions, authorizing interstate delivery of "investigational new drugs," now stands at 21 CFR 312.2.

Layer 4

To give the appearance of substance to vaccine manufacturing regulation, Federal Security Agency administrators (later HEW secretaries) drafted and published simulations of specific "standards" and enforcement mechanisms for biological product establishments licensed under the PHSA, for processing, storage, packaging, labeling and distribution methods or procedures, and for product characteristics.

These regulations for licensing of biological product establishments mimicked the substantive, material standards applied to non-biological drugs under the FDCA, enforced by the Food and Drug Administration in cooperation with the US-Pharmacopeia-National Formulary, but were not substantive, applicable, applied, enforceable, or enforced.

This is the most complex layer to understand and describe, it is the subject of the rest of this report, and it has the highest concentration of terms, definitions, exclusions, waivers, exemptions, suspensions and omissions. Words and phrases are often undefined, ill-defined or only defined in relative or contingent terms. Words and phrases used at one time are replaced with different words and phrases a few years later.

When reading through our broad descriptions of how the regulatory simulation system developed and has been used, please keep in mind the difference between performative simulation -- the projection of fictional but highly realistic illusions of scientific, medical, legal and publishing integrity -- and real, observable acts and omissions.

III. Scientific, Medical and Mathematical Misconduct

We've chosen to begin this timeline of misconduct in 1913, noting that 20th century deceptions and omissions of material facts were built atop foundations laid in the 18th and 19th centuries by Edward Jenner, Robert Koch, Paul Ehrlich, Emil von Behring, Louis Pasteur, Rudolph Virchow, Ernst Heinrich Weber and Gustav Fechner.

We hope our work laying out the history of legal misconduct founded upon scientific misconduct, supports the work of authors documenting the history of scientific misconduct and suppression of dissenters' work, and also supports a new period of scientific discovery based on the observations and research materials and methods of Ignaz Semmelweis (1818-1865); Antoine Bechamp (1816 to 1908) and Gunther Enderlein (1872 to 1968).

Supporting documents are linked in Footnote 3.

1913 - Anaphylaxis, Charles Richet

In 1913, Charles Richet published a book called *Anaphylaxis*, describing research investigating induction of anaphylaxis -- systemic detoxification or allergic responses -- by parenteral (outside the digestive system) injection of complex non-self biological materials such as bacteria, plant and animal proteins and lipids into living mammalian animals.

Richet received a Nobel Prize for his work, also in 1913.

Organisms whose cells and tissues Richet extracted, injected, and to which he observed anaphylactic responses ranging from mild itching to convulsions and death, included Man-o'-War jellyfish, mice, guinea pigs, rabbits and dogs, which extracts also contained any bacteria or other microscopic organisms living in or on them.

Richet demonstrated that injecting blood taken from an animal that had been rendered sensitive during a first round of injections of non-self biological material, into a healthy, untreated animal, would cause the healthy, untreated animal to also experience anaphylactic reactions. He called this process of inducing anaphylaxis in an untreated animal, through injection of the blood of a previously anaphylactized animal, passive anaphylaxis.

Animals injected with materials that induced such responses were described as "anaphylactized" and the material in the blood was described as "anaphylactogen."

> "An anaphylactic state is produced by taking the blood of an anaphylactized animal and injecting it into a normal animal subject. The anaphylactogen poison is therefore a chemical substance contained in the blood."

Richet observed that white mice and some breeds of rats did not experience anaphylaxis.

Other researchers in the same field cited by Richet included: Milton J. Rosenau and John F. Anderson of the US-PHS Hygienic Laboratory, Clemens von Pirquet, Charles Mantoux, Bela Schick, Emil von Behring and Maurice Arthus.

At the individual level, the harm caused by anaphylaxis has been called serum sickness, allergy and hypersensitivity syndrome.

It manifests as rashes, itching, and sneezing at the mild end of the spectrum to chronic autoimmune disorders, organ failure and death at the severe end.

19th and early 20th century studies of anaphylaxis and serum sickness were developed further through subdisciplines of biology including pathology, virology, immunology, toxicology and immunotoxicology. Researchers studied how living organisms respond across time intervals to exposure, invasion or overload of foreign biological organisms, including both the organic (carbon-based) particles which living organisms produce naturally, and those which humans began producing at industrial scale through synthetic chemistry techniques.

The anaphylaxis studies by Rosenau, Richet and their colleagues also formed the basis for government-directed vaccination and immunization policies and programs as components of disease diagnosis and disease classification systems (epidemiology) and communicable, transmissible or infectious disease control.

1934 - Probability units or probits, Charles Ittner Bliss

Immunity unit and *antitoxin unit* were the earliest terms applied by scientists and physicians to give the impression that specific results or potency for viruses, serums, toxins and antitoxins could be observed, measured, defined, described and predicted for recipients of a packaged product. Milton J. Rosenau, director of the US-PHS Hygienic Laboratory from 1899 to 1909, for example, used the term immunity unit in a 1905 Hygienic Laboratory Bulletin: *The immunity unit for standardizing diphtheria antitoxin.*

These "units" were derived by dilution and arbitrary assumptions, from the median minimum lethal dose of toxic, heterogeneous, unstable mixtures of foreign biological substances, when injected into a group of living test subjects such as guinea pigs, mice, rabbits and dogs, suggesting a prediction as to the probability of harm to members of a population or group considered in the aggregate or collective.

In 1934, Charles Ittner Bliss, trained in biology but with an interest in statistics, introduced another probability-derived term to describe the functional capacity (strength, potency, effectiveness, toxicity) of a material substance to cause organ damage, organ failure and death when dispersed or administered to living creatures within time and space using different methods of dispersal or administration.

Bliss published a report — 'The method of probits' (Science, 1934) — on how to mathematically convert data such as the percentage of a pest killed by a pesticide into a "probability unit" or "probit."

Probit joined biological product potency nomenclature such as *immunity unit* (in use by 1905); *antitoxin unit* (by 1909); *international unit* (by 1931); and *international antitoxic unit* (by 1946).

Probability-based pseudo-measurement units are measures of probability that a substance will have a defined effect on a predictable proportion of a population of living creatures in the aggregate. They can be re-formatted to suggest the probability that an exposure or dose will have a defined effect on an individual, but there is no way to predict the specific effect of a specific dose on a specific living cell, insect, animal or person at a specific time and place, because the infinite complexity and variety of the starting condition and dynamic biological processes comprising the specific cell, insect, animal or person and their relationships to other organisms and experimental conditions cannot be known.

Other probability-derived measurement terms include median lethal dose or LD_{50} , that is, dose of a substance that will kill 50% of the subjects receiving it expressed as mass of substance administered per unit mass of test subject; median infective dose or ID_{50} , that is, dose that has a 50% probability of producing a specified response to infection considered as symptoms or signs of disease or death; tissue culture median infective dose or $TCID_{50}$, that is, dilution of a [presumed-present, stable, isolatable] virus required to infect 50% of a given cell culture; and Ct_{50} , that is, measure of intensity of exposure as a function of concentration and time.

Other probability units are derived from formulas based on the proportion of particles in a sample capable of

causing a presumed effect and the probability that any one such particle will have that capacity or function, such as infectious unit (IFU), plaque forming unit (PFU), colony forming unit (CFU) and transduction or transducing unit (TU).

Probability units are proxy measures from observing a population of living cells, insects, animals or people during and after exposing them to poisons, counting the ones that have observable symptoms of detoxification processes (also called disease or infection) as well as the dead ones, and then expressing those numbers as a proportion of the starting population.

All of these units depend, for their own validity, on the validity of the method that proponents (of the measurement unit) claim or presume has established the real presence of a named toxic particle or organism (i.e., sarin nerve gas, or a specific virus such as rabiesvirus or poliovirus) and on a real causal relationship between the presence of the named particle and observed effects.

To the extent the cited scientific methods do not, in truth, establish a real causal relationship between the presence of named particles and observed effects, such as cell death in a dish or paralysis or death in a living animal, the units used to measure the amount of matter and the potency or capacity of the matter to induce predictable effects are false units of measure.

1939-1954 studies in inducing tissue damage, brain and spinal cord damage, and death in rats, white mice, monkeys and dogs through serial passage of bacteria, mouse, rat, horse, cow, dog, monkey and human tissue mixtures by injection

In July 1939, the *Journal of Experimental Medicine* published a paper by Rockefeller Institute investigator Leslie T. Webster titled 'A mouse test for measuring the immunizing potency of antirabies vaccines.'

Webster assumed that a material substance he called "rabiesvirus" passaged through dogs was the active component, within an aliquot of brain tissue and "horse serum," that caused rabies disease symptoms. He purported to demonstrate the "immunizing potency" of antirabies vaccine by injecting serial dilutions into inbred W-Swiss white mice (not subject to anaphylaxis, per research by Richet and others), followed by observation of the proportion of dead mice in each test group and measurement of "neutralizing antibodies in the serum" as a surrogate endpoint or proxy .

1939 - Inducing brain and spinal cord damage, paralysis and death in rats and white mice through serial passage of brain and tissue culture mixtures by injection.

In September and December 1939, Charles Armstrong published two papers in the US Public Health Service journal *Public Health Reports*.

In the September 1939 paper, 'The experimental transmission of poliomyelitis to the Eastern cotton rat,' Armstrong described receiving a sample of brain and spinal cord tissue taken from an 18-year old-boy who had died with cause of death attributed to polio in August 1937. Armstrong stated: "a strain of virus was recovered from the material which has now been through 15 monkey passages and which clinically, and pathologically as reported by Surgeon R. D. Lillie, is apparently a strain of poliomyelitis."

Armstrong assumed that poliovirus was a stable, transmissible particle of matter, assumed that it was present in the boy who had died, assumed it had transmitted person-to-person to infect the boy, and assumed that it had caused the boys' death.

He then claimed to demonstrate that it was solely and specifically the presumed poliovirus particles within mixtures of human, monkey, and rat brain and spinal cord tissue and bacteria, which he injected into fresh cell

and tissue cultures, that caused the cell death observed in the plates (cytopathic effect or cytopathogenic effect).

And he claimed to demonstrate that it was solely and specifically the presumed poliovirus material within the mixtures, which he injected into healthy rats and monkeys intranasally (up the nose), subcutaneously (under the skin), intramuscularly, and intracerebrally (into the brain), that caused tremors, paralysis and death observed in the animals.

In the December 1939 paper, 'Successful transfer of the Lansing strain of poliomyelitis virus from the cotton rat to the white mouse,' Armstrong described additional passages and inoculations, resulting in organ damage, tremors, paralysis and death in healthy white Swiss mice. (See Richet's work, above, on inbred Swiss mouse lack of susceptibility to anaphylaxis.).

Armstrong also described "neutralization" tests involving rats injected with mixtures of "virus" strains and "poliomyelitis antisera" derived from blood drawn from monkeys that had recovered from "virus"-induced paralysis attacks. Almost all of the rats subjected to the virus-antisera injections died.

Jamie Andrews summarized Armstrong's work in 2021: "No purified/isolated “virus” is ever presented in either paper nor is pathogenicity proven."

In January 1949, John F. Enders, Thomas H. Weller and Frederick C. Robbins published a paper in *Science*, 'Cultivation of the Lansing Strain of Poliomyelitis Virus in Cultures of Various Human Embryonic Tissues.'

Enders subsequently published at least two more papers on similar work on poliomyelitis virus and measles virus: 'Cultivation of Poliomyelitis Virus in Cultures of Human Foreskin and Embryonic Tissues' (August 1949, *Proceedings of the Society for Experimental Biology and Medicine*) and 'Propagation in Tissue Cultures of Cytopathogenic Agents from Patients with Measles (June 1954, *Proceedings of the Society for Experimental Biology and Medicine*).

Enders and his colleagues used the same basic materials and methods as Armstrong, and the mathematical probability methods for quantification used by Rosenau and Bliss.

They injected slurries of cells and tissues of bacteria, mice, rats, monkeys, and human beings into cell and tissue cultures, and into healthy mice, rats and monkeys; observed organ failure, tremors, paralysis and death of the animals; extracted tissues from the diseased and dead animals; and repeated the cycle.

The novelty they introduced, which they then reported in the scientific literature, was laboratory methods for using tissues and cells taken from the arm muscles, leg muscles, intestines, skin and brains of human embryos and the foreskins of male human children as components of the biological slurries and cell and tissue cultures.

Enders received the Lasker Prize and Nobel Prize in 1954 for his work.

In 2002, Merck vaccine developer Maurice Hilleman would describe Enders' January 1949 paper as marking the "beginning of the modern era of vaccines" as a "breakthrough technology for cell culture propagation of viruses."

Discussion

The 1939 papers by Webster and Armstrong, and the Enders papers published between 1949 and 1954, set the frame for the next 85 years of scientific, medical and legal misconduct and deception of the public to believe false premises.

In cell biology, observed cell stress, fragmentation and death is known as the cytopathic effect or cytopathogenic

effect.

Some of the terms used in scientific literature to denote cells undergoing stress and death processes, and fragments of such cells, include viruses, antibodies, spores, toxins, antitoxins, endotoxins, exotoxins, enzymes, proteins, exosomes, endosomes, lipids, peptides, polypeptides, nucleic acids, amino acids, alkaloids, rickettsia, antigens, toxigens, pathogens, immunogens, viroids, virions, prions, cytokines, phages, phagocytes, lymphocytes, macrophages and bacteriophages.

Dying and dead cells and cell fragments, detected by microscopic observation, suggest that a living organism was enduring an invasion or attack at the time the samples were drawn and observed.

Virologists, immunologists and toxicologists measure the cytopathic or cytopathogenic effect using probability-based units of measure.

And they attribute mechanistic meaning to the observed existence of dead cells and cell fragments: that the host organism was losing to the foreign invaders or overload of commensal organisms (infection, disease, death) or that the organism was overcoming the challenge (healing or becoming tolerant or immune).

This is the basis for "antibody titres" as a surrogate marker, biomarker, proxy, or probability-based measure of current infection status, capacity to transmit or spread infection, and capacity to respond more quickly, with fewer symptoms, to future destabilizing processes.

Stefan Lanka, Jamie Andrews, Sasha Latypova, the late Tracey Northern and others are demonstrating the invalidity of foundational scientific methods underlying contagion theory and genetic theory, because of the inherent time-dependent, uncontrollable changes in form for products of biological processes in living organisms.

We believe that the same materials and methods (emulsified bacterial and animal cells and tissues injected into brains and blood of other animals, followed by observation of organ failure and death) are used as evidence to support many different claims in scientific disciplines other than pathology, epidemiology, virology and vaccine manufacturing, which claims themselves require separate investigations to isolate each variable and demonstrate causal relationships.

The materials and methods used by Bliss, Armstrong, Enders and their colleagues and followers, are used to support the following premises, none of which are true:

- that a stable, unique, identifiable, isolatable particle of matter (*virus*) exists outside of a living organism and is present in a specific place and time in any cell culture undergoing cell death and in any organism undergoing disease, healing/recovery of equilibrium or death;
- that the same particle specifically and uniquely causes the observed disease and death;
- that the same particle undergoes reproduction or propagation (cell division and growth) in a cell or tissue culture or in a living organism;
- that the same particle can be inserted, in isolated or purified form, into a new organism without being inextricably bound up with the other complex molecules, nutrients and organisms in the living culture media; or
- that an organism, into which the particle of matter has been inserted, that does not exhibit cell death, organ failure, or death, has been protected from these events by the prior insertion of a modified form of the same particle (*vaccination*), and that this is evidenced by the detectable presence of another stable, unique, identifiable particle of matter (*antibody*).

In other words, the cycle of forcible extraction of biological matter, for forcible insertion into another organism for whom it is foreign, is interpreted — in the corrupted, disintegrated, perverse scientific disciplines of pathology, epidemiology, virology and biology and in the corrupted, disintegrated medical practice of vaccination — as simultaneously evidence of disease and as a correlate of protection against disease.

IV. Infusion of Scientific and Medical Misconduct into Legal Misconduct

Supporting documents are linked in Footnote 4.

A. 1944 - Public Health Service Act

In July 1944, Congress enacted the Public Health Service Act of 1944. It was a companion act to the Public Health Service Act of 1943, which had set forth a new organizational structure for the US Public Health Service.

The 1944 PHSA consolidated and revised federal laws governing Public Health Service administration; research programs, including selection of projects eligible for federal funding and publication of reports; federal-state cooperation programs, including funding tied to preparation of state public health plans and submission of state "vital statistics" records; operation of public hospitals; care of lepers; care of narcotics addicts; regulation of biological products; designation (by executive order) of communicable diseases and operation of communicable disease control programs (quarantine and inspection); cancer research programs; and receipt of gifts.

This series is focused on just two of those subjects: regulation of biological products (PHSA 351-352) and control of communicable diseases (PHSA 361-366).

B. Quarantinable communicable disease designation by executive order

The 1944 PHSA section on communicable disease control carried forward and revised authorities that Congress had previously granted the President and the PHS Surgeon General under the headings "Prevention of Epidemics" and "Quarantine Service."

This sequence of laws set up a system under which Presidents designate communicable diseases by executive order.

Any collection of non-specific symptoms of illness exhibited by human beings can be classified as a "communicable disease" without any supporting evidence or evidentiary review process that a specific material substance caused the symptoms, can be transmitted from person to person, or that those exhibiting symptoms will not, in most cases, recover without complications after brief illness.

Communicable disease control law connects to biological product laws by way of 1) false classification of diseases as organism-caused and communicable; 2) false classification of organism-caused communicable diseases as causes of morbidity and mortality entered into centralized statistical registries (epidemiological surveillance); and 3) the bottling and labeling of vaccines -- toxic, heterogenous, unstable mixtures of allegedly transmissible, allegedly disease-causing organisms -- as preventatives for what are now often described under the non-specific heading "vaccine-preventable diseases."

On March 26, 1946, President Harry S. Truman issued the first presidential executive order under Section 361 of the 1944 Public Health Service Act, "specifying communicable diseases for the purpose of regulations

providing for the apprehension, detention, or conditional release of individuals to prevent the introduction, transmission or spread of communicable diseases."

The list of "communicable diseases" was:

> Anthrax, Chancroid, Cholera, Dengue, Diphtheria, Favus, Gonorrhea, Granuloma Inguinale, Infectious Encephalitis, Leprosy, Lymphogranuloma Venereum, Meningococcus Meningitis, Plague, Poliomyelitis, Psittacosis, Ringworm of the Scalp, Scarlet Fever, Smallpox, Streptococcic Sore Throat, Syphilis, Trachoma, Tuberculosis, Typhoid Fever, Typhus, Yellow Fever.

Many of the "specified" diseases, were not, in fact, communicable or transmissible diseases.

Three of these terms — encephalitis, meningitis and poliomyelitis — were terms developed by centralized medical and scientific data collection and publishing institutions in the early to mid-20th century to denote symptoms of inflammation and breakdown of brain and spinal cord tissue, primarily caused by poisoning carried out through spraying of chemical herbicides, insecticides and rodenticides (pesticides, biocides) and through vaccines bearing labels alleging their contents were derived from organisms that allegedly caused diseases denoted as smallpox, diphtheria, tetanus, pertussis and influenza.

The symptom constellations had previously been described in medical and scientific literature under names including Heine-Medin disease, Strumpell's disease II, infantile paralysis, flaccid paralysis, polioencephalitis, encephalitis lethargica, and Theiler's encephalomyelitis.

C. 1944 PHSA, textual analysis

Congress enacted three apparent changes to biological product regulation through the 1944 PHSA, specifically at section 351(d):

> PHSA 351(d). Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in sub-section (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations made jointly by the Surgeon General, the Surgeon General of the Army, and the Surgeon General of the Navy, and approved by the Administrator, and licenses for new products may be issued only upon a showing that they meet such standards.

There is a lot packed into that paragraph.

Congress added what looked like a condition that biological product makers show compliance with product standards, in order to obtain licenses for specific products, not just for the general activity of propagating products.

And Congress added a list of attributes apparently (but not substantively) applicable to products, compliance with which was an apparent (but not substantive) condition for product license issuance.

Prior to the 1944 Congress, manufacturers were required to submit applications only for "licenses for the maintenance of establishments." There was no mention of licenses for individual products. The Treasury Secretary (later Federal Security Agency Administrator) issued each establishment a license number, and that number was the number that appeared on labels of all products the company bottled, labeled and distributed.

This is still the case today: there are no license numbers issued for specific products. The license number printed on each vaccine bottle label, since 1902, has been the license number assigned to the manufacturing company when it first applied for an establishment license. The license number also stays with the company over time, as the company is bought, sold and renamed. Pfizer, for example, holds US License No. 0001, the number originally assigned to Parke, Davis & Co., which became Warner-Lambert in 1970, and was bought by Pfizer in 2000.

The wording of 351(d) is what makes it possible for regulators and manufacturers to suggest to the public that a license number corresponds to a specific, identifiable product, not to the establishment in which it was bottled, but not be required to "insure" any specific attributes of any product produced by the company.

"The establishment and the products" are a single legal unit.

Both the establishment and all of its products receive the same (single) license, not several (plural) licenses corresponding to products in the plural.

As such, the "standards" described in the paragraph also apply to the establishment and its products existing together, not to individual products distinct from their manufacturer.

In practice, this boils down to the main principle of biological product regulation, which is that if inspectors find the rooms in a factory to be well-lit, with proper ventilation and plumbing, with available hot water and working equipment, with written records purporting to document the propagation history and proper storage and handling of cell and tissue cultures and other materials, and written records documenting the processing methods purportedly used to make the finished products, then the "continued safety, purity and potency" of the package contents has been "insured."

There are no physical standards applicable to the products as things in themselves.

By 1924, an alert reporter had already identified this as a giant problem. Norman Hapgood, testifying at a Congressional committee, described the system succinctly:

> "The law regulating the sale of these serums and toxins for human beings makes but one requirement, and that is that this stuff, whether dirt or dung, or whatever it is, shall be put up in a laboratory which is hygienically conducted. An inspector can go in and say that the methods are clean, and on that basis alone they are regulated…"

In 1944, Congress added the text of section 351(d) but did not change the way that licensing and inspection procedures serve as a legal hole through which anything — "dirt, dung, or whatever it is" — may be bottled and distributed and used with the appearance, but not the substance, of having been subjected to regulatory enforcement.

Prior to 1944, the list of biological products apparently (but not substantively) regulated by the Public Health Service included "virus, therapeutic serum, toxin, antitoxin or analogous product."

In the 1944 PHSA, Congress added the phrase "arsphenamine or its derivatives (or any other trivalent organic arsenic compound)."

Congress did not add the term "vaccine" to the list of biological products in 1944; Congress added the term in 1970, but did not require the HEW Secretary to define the term vaccine in regulations, and as of 2025, the term is still not defined in regulations.

In 1944, Congress also left untouched the very short list of required package markings (label requirements), limited to:

> "the proper name of the article contained therein; the name, address and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results."

D. 1947 - First post-PHSA regulations published

i. Original structure of biological product regulations, 1902-1944

For the first four decades of the biological product regulatory simulation scheme (1903-1944), when most vaccines were propagated and used at the city or state level, there were five broad sections of agency regulations ostensibly implementing the licensing scheme Congress enacted through the 1902 Virus-Toxin law.

These basic provisions were written to suggest to the public that quality control system equivalent to the 1906 Pure Food and Drug Act and USP-NF production recipes and quality control tests for finished products for plant-derived and synthetic chemical drugs was in place and operational.

The five broad sections addressed

1. licenses and definitions;
2. procedures for inspection of establishment premises, equipment and methods;
3. standards for establishments (lighting, ventilation, plumbing, storage), equipment and animal care;
4. standards for labeling; and
5. procedures for examination of products.

From 1903 to 1944 the license sections of biological product regulations contained no product definitions with objective, observable, measurable physical or chemical characteristics, no defined scientific methods for identifying products, and no references to any non-governmental organization (like the USP-NF) as sources for production recipes or quality control testing methods.

The 1903 regulations contained no definitions for products at all.

In 1909, the Treasury Secretary and Surgeon Generals' board adopted a list of about 15 products defined as biological products simply by being listed by name, including "anti-diphtheric serum or diphtheria antitoxin, antitetanic serum or tetanus antitoxin...bacterial vaccines...and vaccine virus."

The 1919 regulations set forth an early version of the circular, non-material, non-measurable, indirect or intent-based definitions still in use today.

As of 1919, a virus was defined as " a product containing the minute living cause of an infectious disease."

A toxin was defined as "a product containing a soluble substance poisonous to laboratory animals or to man in doses of one milliliter or less of the product, and having the property, following the injection of nonfatal doses into an animal, of producing therein another soluble substance which specifically neutralizes the poisonous substance and which is demonstrable in the serum of the animal thus immunized."

An analogous product was defined as "(a) prepared from a virus, including microorganisms actually or potentially virulent, or (b) prepared from some constituent of the blood, or (c) intended for specific

immunization or therapy..."

Those definitions have remained in basically the same relative and contingent (non-objective) form ever since; current definitions are listed under 21 CFR 600.3(h).

From 1903 to 1944, licenses were issued for establishments, "to engage in the manufacture, barter and sale" of viruses, serums and toxins. There were no objective rules or licensing procedures addressing products as pre-existing or as new.

From 1903 to 1944, biological product regulations set forth procedures for inspection of facilities, equipment and methods. The regulations listed things site inspectors could look at, and authorized inspectors to obtain samples of finished products to send to the Hygienic Laboratory for examination but did not require inspectors to obtain samples or the Hygienic Laboratory to test them or publish test methods or results, and did not authorize on-site inspectors to directly assess manufacturing methods or the quality of finished products. The subjects of inspection were limited to "location, construction or administration of establishments which would tend to endanger the potency or purity of the products."

These limited inspector duties and authorities were set forth in 1903 and entirely eliminated in 2019. In eliminating inspector duties and authorities in 2019, FDA gave as the reason: " to remove outdated requirements, accommodate new [risk-based] approaches, and provide flexibility without diminishing public health protections." (83 FR 3631)

From 1903 to 1944, biological product regulations set forth standards for facilities. These covered subjects such as construction of bleeding rooms and stables for vaccine animals "to permit thorough hosing down;" stables to be "well lighted and well ventilated;" "hot water supplies to bleeding rooms and stables; "sterilization and subsequent handling of containers;" "efficient screening" of laboratories during "fly season;" and animal care and record-keeping.

From 1903 to 1944, biological product regulations set forth standards for contents of product labels. Labels were required to contain the name of the manufacturer; address of the manufacturer; license number (assigned to the establishment, not to any specific product prepared within the establishment); proper name of product; minimum potency of product if any; "No U.S. standard of potency" if no potency standard established; lot number; and date of manufacture or issue with period of potency, or expiration date.

Labels were not required to contain any information about the identity of any substances, quantity, mass, volume, concentration, purity, sterility, or predicted effects. The absence of these information items on labels rendered it impossible for any product to be deemed adulterated, contaminated or misbranded through any assessment method analogous to the requirements of the FDCA for non-biological drugs and rendered it impossible for any recipient to obtain information necessary to provide informed consent to treatment.

From 1903 to 1944, biological product regulations set forth procedures for examination of products by PHS NIH laboratory staff, but (as stated above), it was optional for an inspector to collect samples and forward them to the PHS laboratory. If NIH officers tested the samples at all, they tested the samples using unpublished, unvalidated test methods, comparing unstable mixtures of biological material bottled at the commercial facility to unstable mixtures of biological material bottled at NIH laboratories.

From 1903 to 1944, the only product qualities addressed in the regulations were purity and potency, and these were not mentioned or defined in the 1902 Congressional act.

PHS required no specific methods to be used to demonstrate purity. For some products, makers were expected to

demonstrate potency similar to reference products provided by Public Health Service officers. The reference products, if they existed at all, were subject to the same intrinsic heterogeneity and instability of the commercially-prepared products, and potency standards were expressed in probability-based, non-objective "immunity units." Further, testing responsibility was assigned to the commercial manufacturer, with options for on-site inspectors representing the PHS to collect samples and submit them to the PHS Hygienic Laboratory for testing, but no requirement that the PHS Hygienic Lab test the products or publicly report the results. For other products, makers were simply directed to print on the label: "No U.S. standard of potency."

ii. How biological product regulation changed after Congress passed the 1944 PHSA

As the Federal Security Agency Administrator and three-member Surgeon Generals' board began to implement the provisions of the 1944 Public Health Service Act into regulations published in the Federal Register, they provided more detailed descriptions of licensing, labeling and inspection rules and procedures and general standards for establishments.

They published the first post-PHSA version of the regulations in 1947.

The same broad section headings were carried forward, into the post-1944 period, including:

1. definitions;
2. licensing procedure;
3. establishment inspection;
4. establishment standards (ventilation, record-keeping, etc.);
5. standards for product labels; and
6. general standards for products.

These basic provisions were still unintelligible, inapplicable and unenforceable, while continuing to falsely present to the public a quality control system for biological products equivalent to the 1938 FDCA 505 and USP-NF system for non-biological drugs.

For the first time in 1947, biological product regulations included definitions for the standards, qualities or attributes -- "continued safety, purity and potency" -- that Congress had introduced in the 1944 PHSA when requiring, for license issuance, compliance with regulations "designed to insure" those standards.

The 1947 regulations also incorporated, for the first time, a suggestion of new product license forms and procedures, but without substance; provisions setting forth general standards for safety, purity and potency; and a section called "Additional Standards" setting forth additional standards for specific products, starting with Trivalent Organic Arsenicals, to be tested for stability, solubility, arsenic content, moisture and relative non-toxicity.

Definitions

The 1947 regulations defined dating period as "the period beyond which the product cannot be expected beyond reasonable doubt to yield its specific results."

Expiration date was defined as "the date of termination of the dating period."

Standards was defined as "specifications and procedures applicable to an establishment or to the production, content, testing, labeling, or release of products prepared therein."

For the adjectives, however, instead of simply defining the words, they were defined with specificity-evading phrases: "the word...," "as applied," "is interpreted to apply" and "is interpreted to mean."

Quoting from the definitions section of the 1947 regulations:

> "The word "continued" as applied to the safety, purity and potency of products, is interpreted to apply to the dating period.
>
> The word "safety" is interpreted to apply to the relative freedom from harmful effect to the recipient when a product is prudently administered taking into consideration the character of the product in relation to the condition of the patient at the time.
>
> The word "purity" is interpreted to mean the degree of freedom from extraneous matter, whether harmful to the recipient, deleterious to the product or otherwise, in the finished product.
>
> The word "potency" is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result."

Given the intrinsic, insurmountable living nature of biological products, the actual meaning of these terms is very different from what the above suggests, as follows.

"Continued" actually means "decaying" and "unstable." Therefore a product's assigned "dating period," "expiration date," and "the period beyond which [it] cannot be expected beyond reasonable doubt to yield its specific results" are completely arbitrary. The specific outcomes will vary immeasurably from person to person, contingent upon the original composition of biological material and non-biological additives, the degree of transformation and decay that has occurred during the bottling, refrigeration and thawing of the bottled mixture, and the biology of each recipient.

"Safety" actually means "toxicity" or "specific results" such that the product causes harm by eliciting a rejection response to a purported "nonfatal dose" of foreign organic matter in the recipient organism.

"Purity" means "heterogeneity," as an indicator of how many different living organisms and organic particles of matter produced by organisms may be found in any given container. It is related to identity, sterility, adulteration, contamination and labeling

"Potency," means the degree, strength or intensity of toxicity or toxic specific result.

When Congress, through the PHSA of 1944, directed the Public Health Service to promulgate "standards designed to insure the continued safety, purity, and potency of such products," it directed the Public Health Service to publish simulations of standards that would insure that unstable, decaying, toxic mixtures of biological material could be legally bottled, distributed and used.

Product license

The 1947 biological product regulations, at 42 CFR 73.5, introduced a simulation of a product-specific licensing procedure complying with, and also masking the unitary nature of, each single license number encompassing each numbered establishment and all of the products distributed from its premises, without identifying, defining, or assessing any products in themselves.

Unlike the preceding provision (42 CFR 73.4), which carried forward the "Form of license" text laying out how

Establishment License numbers would be issued, to whom and by whom, the "product license" provision did not provide a form for the license, an author, or a recipient.

The "product license" was not required to contain any more substantive information about product identity, ingredients or therapeutic effects than the "establishment license" alone.

42 CFR 73.5 simply stated, "Each product license shall designate: (a) The manufacturer; (b) the establishment; (c) the license number of the establishment; (d) the proper name of the product, with additional specifications, if any, which may be approved or required for additional labeling purposes."

We have never located any document in the historical record purporting to be a "product license." In available lists of "US-licensed vaccines," such as the list provided in Appendix D of the 2002 NIH-NIAID Jordan Report, all vaccines produced by any one drug company hold the same license number. For example, Merck vaccines bearing measles, mumps, rubella, hepatitis, and pneumococcal names are all designated by License No. 0002-001.

Standards for Products: General

The 1947 biological product regulations, at sections 42 CFR 73.70 to 73.79, introduced the early form of what would later become known as "lot release."

These provisions suggested enforcement mechanisms to insure relative (not objective) qualities for products that mimicked the standards under the FDCA that authorized removal of drugs from interstate commerce if "the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality and purity." Recall: these qualities of non-biological drugs were defined by the USP-NF compendia (now known as Critical Quality Attributes or CQAs), and USP-NF was responsible for designating quality control testing materials and methods.

The lot release system set up for biological products was riddled with get-around clauses.

Examples include:

"[n]o lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with the standards applicable to such product" in a context in which there are no applicable standards;

"[t]ests for potency shall be made on each lot only after completion of those processes of manufacture which may affect the potency of the final product" in a context in which none of the processes of manufacture can be defined with specificity, and potency is an unmeasurable, infinitely variable factor of the interaction of the biological organisms in the starting materials with each other and with the animal or human recipient; and

"[t]he contents of a final container of each filling of each lot shall be tested for identity, if such a test is available, and for safety either after the labels have been affixed to the final container or affixed, both outside and inside, to the multiple container storage receptacle just prior to its sealing for storage purposes, except that exceptions to this procedure may be authorized by the Institute to apply when the volume of the final container is very large and when more than one lot is processed each day," in a context in which there are no available identity tests, and in a context in which general safety tests (added in 1960 at 42 CFR 73.72, eliminated in 2015, 80 FR 37971) are comprised of injecting "maximum volume tolerated" into two mice and two guinea pigs, and assessing whether or not they sicken or die in the next seven days, and "variations of this test, either in the volume injected or in the species of test animal used" are authorized.

Lot release testing was to be conducted by manufacturers themselves, with an option, but no requirement, for manufacturers to send samples to NIH for testing.

"Tests for safety, purity and potency applicable to the product shall be completed for each lot of any licensed product prior to its release by the manufacturer, and samples of any lot of any licensed product may at any time be required to be sent to the Institute for examination," again, in a context in which there are no valid, applicable tests for safety, purity or potency.

"Standard units or samples for comparison made available by the Institute shall be applied in testing for potency all forms of diphtheria antitoxin, tetanus antitoxin... and other products for which such units are available," in a context in which reference products are not held by NIH for products, and if they are held, their potency is expressed in probability-based, non-objective "immunity units."

Labeling

The 1947 biological product regulations, at sections 42 CFR 73.50 to 73.55, expanded upon the earlier forms of non-identifying label contents.

As reported above, container labels between 1902 and 1944 were required to provide label readers with the proper name of the product; name, address and license number of manufacturer; lot number and expiration date.

As of 1947, the outside carton was required to contain:

> (a) the preservative used and its concentration;
> (b) the volume of the contents, if a liquid, or the weight, if a solid, and the potency or dosage if more than one strength is dispensed;
> (c) the recommended storage temperature;
> (d) the words "Shake Well," or equivalent, when indicated by the character of the product,
> (e) the dose and route of administration recommended or reference to such directions in an enclosed circular;
> (f) the source of the product when a factor in safe administration; and
> (g) minimum potency of product expressed in terms of official standard of potency or, if potency is a factor and no standard of potency has been prescribed, the words "No U. S. standard of potency,"

all in a context in which there is no stable potency, strength or dose because the biological material is unstable and mixed and effects vary immeasurably and unpredictably over time and across recipients, and in which the source of the product is an unidentifiable collection of many biological organisms.

Additional Standards

The 1947 biological product regulations, at sections 42 CFR 73.90 to 73.96, added the first "Additional Standards" section, purported to require that Trivalent Organic Arsenicals be tested, by manufacturers and regulators, for "stability, solubility, arsenic content, moisture and relative non-toxicity."

In 1956, additional standards for poliomyelitis vaccine were added, and in 1957, additional standards for adenovirus vaccine were added.

The additional standards were inapplicable and ineffective from the day they appeared in the regulations

because they were based on the fictional scientific methods laid out by Leslie Webster (1939), Charles Armstrong (1939), and Enders et al (1949-1954), by way of Jonas Salk, Joseph Smadel and William Workman (more information below).

Mixtures of bacterial, animal and human cells and tissues were to be cultured in nutrient media (chicken embryos; cow, pig, horse serums; salts, sugars, amino acids), fixed with formalin or other toxic preservatives, and injected into mouse and monkey brains and muscles. Mouse and monkey blood was to be tested for non-specific antibodies, which would be reported as specific to alleged disease-causing agents. Mice and monkeys were to be killed and necropsied. Brain tissue was to be tested for cytopathic effect/lesions. The sick and dead proportions of mouse and monkey groups were to be counted. And "equivalent methods" and "alternative demonstrations" would be permitted as needed.

The conduct of even these pretenses of NIH testing was suspended by internal policy by 1962 (Smadel memo) and the "Additional Standards" sections were eliminated in their entirety in 1996. (61 FR 40153)

E. 1945-1959 - DDT pesticide campaigns; DTP combination vaccines; polio vaccination campaign

In October 1945, the US government authorized general use of aerial and surface spraying of DDT and other organic pesticides, allegedly to eradicate mosquito and fly populations allegedly carrying diseases such as typhus and polio. DDT had been authorized for use on US Army soldiers since 1943.

In 1948, the DTP combination vaccine (diphtheria, tetanus and pertussis) entered into use.

Between 1945 and 1953, US production and use of DDT increased, and reported polio cases increased.

In March 1955, Johannes Ipsen and Harry E. Bowen published a paper titled 'Effects of Routine Immunization of Children with Triple Vaccine (Diphtheria-Tetanus- Pertussis)' in *American Journal of Public Health*.

Ipsen and Bowen worked with the Massachusetts Department of Public Health Biologic Laboratories and Harvard School of Public Health. In the paper, they described the application of scientific and mathematical methods (the Bliss-Webster-Armstrong-Enders methods) of vaccine development, immunity units, and potency testing through blood antibody titers, to a statewide population, using the term "serologic epidemiology."

These simulations of scientific integrity had already been used for decades in mouse, rat, dog and monkey populations in government and commercial drug manufacturing laboratories, and on small human communities such as island populations (1905-1920, Philippines, smallpox products), soldiers at military bases (bacterial meningitis and other products, 1918, Fort Riley, Kansas), and schoolchildren (diphtheria products, 1921, New York City).

In 1955, Ipsen and Bowen interpreted the results of serologic epidemiology studies conducted in a state-sized pool of human subjects: adult and child populations in Massachusetts injected with the products since 1949.

They mentioned the "current poliomyelitis vaccine trials," referring to the nationwide vaccination of 1st through 3rd-graders by the National Foundation for Infantile Paralysis using vaccines developed by Jonas Salk and manufactured by commercial drug manufacturers.

> "Evaluation of the effect of an immunizing agent occurs by way of a number of test stages each with a particular purpose and all contributing to the total evaluation: (1) animal tests, (2) tests on human volunteers, (3) the field assay and (4) use in public health.

> The first two are usually conducted solely by the laboratory that produces the prophylactic. Antigenicity in animals is evaluated by the measurement of antibody and protection against the disease produced in animals. Tests on human volunteers (perhaps starting with enthusiastic staff members) elucidate antibody response in man and evaluate the harmful side effects of the agent.
>
> The field trial is a novelty created by modern statistical thought. It is the effort of a team of specialists, involving a circumscribed population. The measurement of effect is the incidence of naturally occurring disease in two matched groups, vaccinated and non-vaccinated.
>
> The fourth stage, general use in public health, lacks the criteria for strict scientific inference and yet it is the final and severest test for the product.
>
> Diphtheria and tetanus toxoids came into general use without field trials; first, because the concept had not yet been formed, and second, because antitoxin measurements and Schick tests were considered unique measurements of immunity to infection..." (March 1955, 'Effects of Routine Immunization of Children with Triple Vaccine (Diphtheria-Tetanus- Pertussis)' in *American Journal of Public Health*.

With the 1949-1955 DTP campaign, American public health officers further developed the performative system: manipulating and reporting data to promote vaccination by bolstering the plausibility of fictional narratives about disease causality and disease agent transmissibility; the existence of "reservoirs of disease" and agents in human, animal and bacterial hosts, including asymptomatic carriers; testing and diagnostic criteria based on non-specific antibodies classified as disease-specific; antibody titer dilutions and arbitrary delineations to interpret results as indicators of infection or indicators of natural or artificial immunity; and classification of biological responses to pesticide exposure and vaccine injury as natural infection.

As polio diagnoses rose, Jonas Salk and the National Foundation for Infantile Paralysis began laboratory production and animal testing of polio vaccines in 1952.

In early 1953, Congress and President Dwight Eisenhower abolished the Federal Security Agency and transferred the functions of the FSA Administrator to the Secretary of the new Department of Health, Education and Welfare (HEW). Eisenhower appointed Oveta Culp Hobby as FSA Administrator in January 1953, and then appointed Hobby as the first HEW Secretary effective April 11, 1953.

In December 1953, Joseph Smadel (Army Medical Services Graduate School) and William G. Workman (chief of PHS Laboratory of Biologics Control) prepared "provisional standards" for manufacture of polio vaccine, derived from Jonas Salk's laboratory methods, which were derived from Enders' methods, derived from Armstrong's, derived from Bliss's "probability unit" quantification of toxic exposure and Webster's false mouse antibody basis for demonstrating immunizing potency.

Those production protocols were distributed, with cell lines, tissue cultures and other starter materials from government and university laboratories to six selected drug, pesticide and chemical companies including Parke Davis, Eli Lilly, Cutter, Wyeth, Pitman-Moore, and Sharp and Dohme to make and supply product for the field trials organized by the National Foundation for Infantile Paralysis (now called March of Dimes) and Salk.

The manufacturers assembled and bottled the materials, labeled the contents as "Poliomyelitis Vaccine," and shipped them to Salk and the field trial locations.

On April 12, 1955, Thomas Francis Jr. of the University of Michigan announced that the Salk-NFIP field trials had been successful, starting his Ann Arbor press conference by stating: "The vaccine works. It is safe, effective, and potent."

The same day, HEW Secretary Oveta Culp Hobby licensed the six companies to manufacture millions of doses and distribute the doses through interstate commerce, while US-PHS NIH Laboratory of Biologics Control (LBC) officials provided updated production protocols to the manufacturers.

The updated protocols, still based on the Bliss-Webster-Armstrong-Enders-Salk scientific and mathematical methods for demonstrating disease causality, virus isolation, virus propagation and vaccine potency, would form the basis for production method and potency reports submitted back to LBC to reinforce the illusion of manufacturing standards and quality assurance for the general public.

In late April and May 1955, public health officials claimed to detect harmful lots of vaccine produced by Cutter Laboratories in California, attributing polio diagnoses among children and adults to "infectious virus" in the Cutter vaccines. The investigators had available to them the same unvalidated scientific methods for diagnosing disease and classifying cases by cause to facilitate statistical fraud, pin vaccine harms on one manufacturer, and generate momentum for the construction of a more elaborate, more centrally-controlled false-front federal quality control and product testing system. Cutter recalled doses remaining on shelves, took a financial hit, but quickly recovered the lost income, expanded its facilities and moved on.

In June 1955, the NIH National Microbiological Institute Laboratory of Biologics Control was elevated to become the Division of Biologics Standards, firmly positioning DBS as a federal quality control institution analogous to the USP-NF for non-biological drugs to provide government endorsement of vaccine products and control of national vaccine supply chains.

In August 1955, Congress passed the Polio Vaccination Act (PL 84-377) providing federal funding for state vaccination campaigns targeting children and pregnant women: "any individual who has not attained the age of twenty years and any expectant mother."

In August, the US Public Health Service published an account of PHS polio epidemic surveillance and polio vaccine development programs in PHS *Public Health Reports*.

In February 1956, Congress passed an act to extend the duration of the Polio Vaccination Act, through June 30, 1957. (PL 84-411)

In September 1958, Congress relieved the Army and Navy Surgeon Generals of their duties to serve on the three-member Surgeon Generals' board assigned through the 1902 Virus-Toxin law to draft and promulgate biological product regulations. The move left regulation drafting authority with the PHS Surgeon General alone and approval authority with the HEW Secretary. (PL 85-881)

By the 1958 print edition of the Code of Federal Regulations, HEW Secretary Marion B. Folsom had added to biological product regulations "additional standards" at 21 CFR 73.100 to 105, based on the Webster-Armstrong-Enders-Salk methods, for Poliomyelitis Vaccine (21 FR 9890, Dec. 12, 1956) and Adenovirus Vaccine (22 FR 7560, Sept. 24, 1957).

F. 1955-1972 NIH-DBS regulatory simulation acts and omissions; J. Anthony Morris

Roderick Murray earned a medical degree from Harvard Medical School in 1941. He served for five years as an infectious disease control specialist in an Army medical laboratory in the South Pacific. Murray joined NIH in 1947 as a commissioned PHS officer in the Laboratory of Biologics Control (LBC). He then served as Director of the NIH Division of Biologics Standards (DBS) after the LBC was elevated to division status in June 1955 until the biological product regulation program transferred to the FDA and was renamed Bureau of Biologics in 1972.

Harry M. Meyer earned a degree from the University of Arkansas School of Medicine and took a research position with the Army Medical Corps. He was recruited in 1959 to direct the NIH-DBS Laboratory of Virology and Rickettsiology, and served as the first director of the FDA Bureau of Biologics when the biological product regulation program transferred in 1972.

When Meyer took over the FDA Bureau of Biologics in 1972, Murray was appointed as special assistant to the director of the National Institute of Allergy and Infectious Diseases and then retired in 1973.

Joseph Smadel earned a medical degree from the Washington University School of Medicine in St. Louis in 1931 and in 1933 was a part of the team that claimed to recognize an outbreak of St. Louis encephalitis virus. Smadel then worked in virology at the Rockefeller Institute under Homer Swift and Thomas M. Rivers.

In 1940, he joined the U.S. Naval Reserve, and in August 1942, joined the U.S. Army Medical Department Professional Service School (MDPSS), known by 1953 as the Walter Reed Army Institute of Research (WRAIR). Smadel served as Chief Virologist with the First Medical General Laboratory in the European Theater assigned to control typhus outbreaks in the Mediterranean in May 1943, and then became director of the WRAIR Department of Virus and Rickettsial Diseases. In 1956, Smadel transferred from WRAIR to serve as NIH Associate Director. In 1962, he received the Lasker Clinical Medical Research Award, and in 1963 became Chief of the NIH-DBS Laboratory of Virology and Rickettsiology, dying later that year.

In 1959, J. Anthony Morris was recruited to NIH by Smadel to conduct vaccine research and serve as the "influenza control officer" under Smadel, DBS Director Roderick Murray and HEW Secretary Abraham Ribicoff. Ribicoff served as HEW Secretary from 1961 to 1962, was later elected to the Senate and oversaw Congressional handling of Morris's 1971 employment complaints.

In 1971, Morris filed an employment grievance against NIH leaders. Reporting on the grievance proceedings in 1972, Nicholas Wade wrote that Morris alleged "that he had been harassed and pressured to leave the DBS because of his doubts about the potency and efficacy of commercial influenza vaccine." Morris transferred to the FDA Bureau of Biologics when it was established in 1972, and was fired in 1976. His firing was attributed, by the officials who fired him, to insubordination.

Morris's complaints led to NIH internal investigations, a GAO investigation commissioned by Senator Ribicoff, and a series of reports in *Science* magazine written by Nicholas Wade.

Morris' duties as influenza control officer included receipt of manufacturer reports about the production and potency of vaccines, and testing of submitted product samples against NIH reference products to confirm or refute manufacturer claims as to potency as part of the lot release process.

Manufacturer claims were based on the "additional standards" protocols inserted into federal biological product regulations by NIH officers, first published in the Federal Register in December 1956. The NIH-DBS protocols were based on Smadel's protocols developed between 1952 and 1955 during the Salk/NFIP polio vaccine field trials and mass vaccination campaigns. Smadel's protocols were based on the scientific and mathematical papers published by Bliss in 1934, Webster and Armstrong in 1939, and Enders in 1949 and 1954.

During the 1971-1972 investigations, as reported by Wade, Morris testified that after taking over duties of influenza control in 1960, he had frequently opposed the release of subpotent vaccines but was overruled by his supervisor, Joseph Smadel. For a time, Morris refused to sign the documents to authorize lot release, and Smadel signed them instead.

Morris testified that, on Sept. 18, 1962, Smadel drafted an internal memo ordering Morris to pass vaccines on the basis of the manufacturers' tests alone. The memo stated: "The manufacturer will provide full data on the potency assay of his lots which are submitted for release. Furthermore, release by the DBS will be on the basis of data submitted by the manufacturer and not on the basis of results obtained in this institution."

Morris testified that, three days later, Smadel gave Morris a written order instructing Morris not to test specific vaccine lots that were going to be released, and ordering Morris to destroy the test animals (about 2,000 mice) that had been vaccinated with two lots of the influenza vaccine.

Morris testified that he continued to protest the release of subpotent vaccines.

Roderick Murray testified that the internal Smadel policy ordering regulators to sign lot release documents based solely on manufacturer claims about potency continued in force after Smadel's death in 1963.

Wade reported: "Under the terms of Smadel's directive...Morris's job...was simply to check that the vaccine lots were potent according to test results provided by the manufacturers."

G. October 1962 - Vaccination Assistance Act and Drug Amendments Act

In October 1962, Congress passed two relevant acts.

One was the "Vaccination Assistance Act" (PL 87-868), which provided $36 million to the Surgeon General to make grants to states, targeting all children under the age of 5 for "intensive vaccination programs" using vaccines that manufacturers and federal public health officers claimed offered protection against polio, diphtheria, whooping cough (pertussis) and tetanus.

The other was the "Drug Amendments of 1962" (PL 87-781), also called the Kefauver-Harris Act, after its sponsors, Senator Estes Kefauver and Representative Oren Harris.

Passage was ostensibly driven by the thalidomide scandal: thousands of miscarriages and birth defects among women who took thalidomide during pregnancy, mostly in the UK, Spain, Australia, New Zealand, Germany and Canada.

The Drug Amendments act amended FDCA 505, pertaining to premarket efficacy and safety demonstrations for new drugs that manufacturers sought to deliver through interstate commerce.

To repeat: its provisions were not applicable to vaccines because of the blanket exemptions between PHSA-governed biological products and FDCA-governed non-biological drug products and other exemptions for "investigational drugs" subject to the PHSA.

In the original 1938 FDCA, the term *new drugs* was defined as "any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use..." (1938 FDCA 201)

In 1962, Congress added effectiveness terms so that new drug was defined as "any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use..."

The 1962 amendments also added in "effective" language in several parts of FDCA 505 addressing conditions under which a regulator could withdraw or suspend approval for a non-biological new drug. Without such suspension or withdrawal action, the application is deemed approved and the drug can be marketed.

In 1962, through the Drug Amendments act, Congress added a third condition under which approval could be suspended: "on the basis of new information...that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have...in the labeling..." (FDCA 505(e)(3))

The 1962 amendments defined substantial evidence as "consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

Prior to 1962, even if a manufacturer presented no substantial evidence of effectiveness for a new drug, the FDA could not, on that basis, prevent the new drug from entering interstate commerce.

To repeat: the provisions of the 1962 Drug Amendments Act were not applicable to vaccines because of the blanket exemptions between PHSA-governed biological products and FDCA-governed non-biological drug products and other exemptions for "investigational drugs" subject to the PHSA.

By the 1967 print edition of the CFR, HEW secretaries had added "additional standards" for live, oral polio vaccine and live and inactivated measles vaccines. "Additional standards" were later added for live mumps vaccine (1969); pertussis vaccine (1969); diphtheria toxin for Schick test (1969); live rubella vaccine (1970); typhoid vaccine (1970); tuberculin (1970); smallpox vaccine (1972); and combination vaccines.

All of them were based on the Bliss-Webster-Armstrong-Enders-Salk-Smadel protocols: unworkable and invalid simulations of standards for production and quality control testing of bottled heterogeneous, dynamic biological processes, falsely presented as purified, stabilized, immune-stimulating preventatives for diseases that are not caused by transmissible infectious agents. All of them were removed from the regulations in 1996, replaced by non-binding Guidance for Industry documents prepared by the FDA, and manufacturer-generated reports about Chemistry, Manufacturing and Controls, potency testing, and cGMP compliance submitted with Biologics License Application packages.

In November 1969, Congress and President Nixon passed the Defense Authorization Act, funding and setting up a reporting system for "research, development, test and evaluation and procurement of all lethal and nonlethal chemical and biological agents."

A week later, on Nov. 25, 1969, Nixon gave a speech announcing US renunciation of first use of lethal chemical weapons, incapacitating chemicals, and lethal biological agents and weapons together with a plan to "confine its biological research to defensive measures such as immunization and safety measures."

The same day Henry Kissinger, Chair, Joint Chiefs of Staff, issued National Security Decision Memorandum 35, exempting from the renunciation of chemical weapons "the use of riot control agents or herbicides," and exempting from the renunciation of bacteriological weapons, "research into those offensive aspects of bacteriological/biological agents necessary to determine what defensive measures are required." On Feb. 20, 1970, Kissinger issued NSDM 44, renouncing "the production for operational purposes, stockpiling and use in retaliation of toxins produced either by bacteriological or biological processes or by chemical synthesis," with the provision: "The United States military program for toxins will be confined to research and development for defensive purposes only."

In 1970, Congress and President Nixon passed an act to establish a Commission on Population Growth (PL 91-213) and the Heart Disease, Cancer, Stroke, and Kidney Disease Amendments to the 1944 PHSA (PL 91-515) adding the word 'vaccine' to the list of regulated biological products but not defining the term.

In 1971, US Army biological weapon production and testing facilities at Pine Bluff Arsenal, Arkansas were transferred to the FDA and renamed the National Center for Toxicological Research.

By Federal Register notice published Feb. 25, 1972, Assistant HEW Secretary for Health and Scientific Affairs Merlin K. DuVal "concurrently re-delegated" the non-regulation of biological products from the NIH Division of Biologics Standards to the FDA Bureau of Biologics and published a memorandum of understanding signed by NIH Director Robert Q. Marston and FDA Commissioner Charles Edward. (38 FR 4004) The HEW Secretary at the time was Elliot Richardson, former Secretary of Defense, Attorney General, Secretary of Commerce and Undersecretary of State.

By Federal Register notice published June 29, 1972, Acting Deputy Assistant Secretary for Management (HEW) Wayne M. Wilson transferred the Division of Biologics Standards from the National Institutes of Health to the Food and Drug Administration and renamed it the Bureau of Biologics. (38 FR 12865)

V. DISCUSSION

Public confidence in, and use of, vaccines and biological products is promoted through a shell game in which there is no actual pea (regulatory functions or enforceable product standards) under any of the shells, and the names of the fake-regulatory divisions are changed as the divisions move across government departments along with their fake-regulatory or regulatory-simulation functions.

In Section IV we described in more detail how imaginary or fictional peas are presented as real peas, and how the shells are moved around to maintain the illusion that fictional peas are real.

As readers begin to absorb the information presented so far, and interpret the history of vaccination campaigns and federal vaccine regulation acts and omissions, in light of the fundamental infirmity of biological product regulation, there are two mechanisms we want to highlight.

Labeling acts and omissions are important because they occur at the point at which manufacturer claims about a product, regulator endorsement of those claims, and consumer knowledge meet.

Lot release acts and omissions, under "Additional Standards" provisions, are important because they occur at the point at which product manufacturer claims and regulator assessments and endorsements meet.

The basic principle of product manufacturing regulation is that if starting materials and equipment, human workers, processing methods and quality control testing of finished products are sound, then finished products will also be sound, and those who buy and use the finished products can trust that the products will work properly.

The drug manufacturing quality control system set up for non-biological drugs, in 1906, under the Pure Food and Drug Act, is now operated under systems referred to as current Good Manufacturing Practice rules (cGMP) drafted by national and international regulatory bodies; Chemistry, Manufacturing and Controls (CMC) reports submitted by drug makers to regulators; and Critical Quality Attributes (CQAs) established by the US Pharmacopeia-National Formulary and similar organizations in other countries.

Again, the basic premise is that if a product maker starts with high quality raw materials and uses a sound method for refining and shaping the materials into finished products, then the finished products will also be of good quality, and that if the makers and regulators have developed valid tests to check whether the finished product contains what it's supposed to contain, doesn't have flaws or impurities, and does what it was designed to do, and those tests are properly conducted, then the finished products will be of good quality and fit for

human use.

This system works well for making good quality inanimate objects such as doorknobs, automobiles and planes.

This system also works well for synthetic chemical drugs and drugs extracted from plants, especially drugs consumed through the digestive tract and lungs. The identity and purity of the starting materials for synthetic chemical drugs and plant extracts are known and stable. The process steps are knowable, controllable, and predictably reproducible. It is possible to make tests to check the identity and purity of the finished product, and it's possible to measure the metabolism of the drug as it passes through a living creature by measuring distinct, stable chemical metabolites isolated from samples of saliva, exhaled breath, urine, feces and blood.

But for a biologic propagated by higher biological organisms — bacteria, mammals and human beings which only exist in living, communal, relational, dynamic and teleological forms — the identity and purity of starting materials (living cells, tissues and organisms) is not known and is not stable.

Process steps for biological product production include propagation of living organisms in nutrient media followed by steps purported to "inactivate" or "kill" the organisms while retaining active biological function, followed by refrigeration to slow the biological processes still underway, followed by thawing to speed up the biological processes, and followed by injection of the material into a living body to interact with ongoing biological processes inside the animal or human.

The precise character of these steps is not known, controllable or reproducible.

There exist no valid tests to assess or ensure the quality of finished products, or measure effects through identifiable metabolites, for the same reason there exist no pure, stable starting materials and no sound processing methods: higher biological organisms don't exist in isolation but in community, and they don't exist in stable and determinate form but in living, indeterminate, dynamic and teleological form.

The men and women who wanted people to trust biological products and vaccines, as if vaccines had been made and regulated like doorknobs, bicycles and non-biological drugs, needed to set up what looked like a standardized manufacturing and a quality control system without actually being substantive. They needed something that looked like the USP-NF drug recipes and quality control system.

The "as-if" system they developed works through a handful of ways.

Regulations include the word "standards." But because starting materials don't have stable identity or purity and the methods don't yield the products manufacturers and regulators claim they do, biological products have no predictable, measurable effects. And because there exist no physical measurement methods but only probability-based pretend "units" there can be no standards.

They're imaginary standards, or fictions.

Regulations then include words and phrases to render the fake standards inapplicable to products and other words or phrases to waive the applicability of the fake standards.

For example, by the 1958 printing of the Code of Federal Regulations, NIH Division of Biologics Standards had added a section called "Additional Standards: Poliomyelitis Vaccine." Subsections addressed methods of production, cultivation of virus, filtration, virus titer methods, inactivation methods, tests for safety and potency, tests involving inoculation and subsequent blood tests of monkeys, interpretation of the titer test results, extraneous protein tests, as well as dosing, labeling, dating, and samples and reports to be sent to DBS.

The last section, "equivalent methods," stated that "modification of any particular manufacturing method or process or the conditions under which it is conducted as set forth in the additional standards...shall be permitted whenever the manufacturer presents evidence to demonstrate that such modification will provide equal or greater assurances of the safety, purity and potency of the vaccine as the assurances provided by such standards, and the Surgeon General so finds and makes such finding a matter of official record."

The "equivalent methods" were to be permitted in a context in which the baseline methods for assurance of "safety, purity and potency" were, themselves, insubstantial and false. The regulations authorized the substitution of new methods of performing the illusion of precise product manufacturing and testing for the original methods of performing the illusion of precise manufacturing and testing.

Between 1947 and 1996, biological product regulations included "Additional Standards" sections for trivalent organic arsenicals, and for vaccines purported to prevent polio, diphtheria, tetanus, pertussis, measles, mumps, rubella, typhoid, smallpox and several other named, allegedly communicable and allegedly vaccine-preventable diseases.

Then in 1996, FDA removed the "Additional Standards" sections from the biological product regulations entirely, for both bacterial products (21 CFR 620 at the time) and for viral vaccines (21 CFR 630 at the time). In their place, the FDA substituted dozens of its own Guidance for Industry documents for drug manufacturers containing explicitly "non-binding recommendations," and the Chemistry, Manufacturing and Controls (CMC) sections of Biologics License Application forms submitted by manufacturers to FDA, thus authorizing manufacturers to set their own product standards and set forth the quality control tests they (the drug companies) claimed they (the drug companies) would use to assess final products for compliance with the product standards they'd set for themselves.

What reasons did FDA give for the removal of "additional standards?"

“Regulations in this part are more appropriately specified in the product license.

As currently written, these regulations can be too restrictive for certain products because they specify particular methodologies or standards when alternatives may be available that provide the same level of assurance of safety, purity and potency.

Allowing the product standards to be specified in the product license will give manufacturers the flexibility to improve their products and make appropriate changes to their methods of manufacture.

Therefore, these regulations may be unduly restrictive and are duplicative and unnecessary.” (60 FR 53480)

As of 2025, regulations authorizing drug makers to make post-approval changes to manufacturing and quality control methods are located at 21 CFR 601.12.

VI. SUMMARY

The research disciplines of virology and communicable disease epidemiology and the medical practice of vaccination are fictions. Viruses, presented as unique, stable, transmissible organisms, are fictional. Potency expressed as probability of inducing observable symptoms in exposed, living organisms is fictional. Reference standard products, presented as suspensions containing unique, stable, transmissible organisms, in whole or in part, as viable, inactivated or killed, are fictional. Antibody titres as measures of infection status and immunity status are fictional.

For the first four decades of the biological product regulation scheme (1902-1944), most vaccines were prepared and used at the city or state level.

By the end of World War II, cell and tissue culture methods, electrification and refrigerated storage and transportation systems, synthetic chemical manufacturing methods, aerial and surface chemical dispersion methods, mass-market magazine, film and television media, and data centralization had been developed, mostly by American and German military and public health officers, far enough to make possible national and international communicable-disease outbreak simulations and vaccination campaigns.

Starting in 1947, fictional American product quality and quality control standards for biological product manufacturing were published in the Code of Federal Regulations and reflected in license applications submitted by manufacturers to federal regulators and in letters of approval and lot-release documents issued by federal regulators to manufacturers.

Public Health Service and NIH officials in the early years, and FDA officials since 1972, have played the role of performance directors: leading the cast and crew; supervising costumes, props, advertising and promotional events; rewriting scripts and stage directions (changing terms and definitions, adding, revising and deleting provisions), and shielding backstage areas from public view.

VII. Connections to US military chemical and biological warfare programs, and corroborating reports published after 1972

Although not addressed in this series, records of American chemical and biological weapons research and development programs, especially since the putative end of World War II, are also relevant.

Diseases classified as communicable by executive declaration have, historically and at present, been characterized as national security, public health and biological threats, whereby vaccine development, manufacturing and deployment become "biodefense" programs conducted by and within federal public health agencies, and by and within federal military institutions. Individuals have moved between, and sometimes served simultaneously in, military and public health offices.

Biodefense programs have been directed and conducted by individuals such as George W. Merck, Henry L. Stimson, Ira Baldwin, Sidney Gottlieb, Paul Vories McNutt, Allen Dulles, Abram S. Benenson, Robert McNamara, Abraham Ribicoff, Elliot Richardson, William D. Tiggert, Frank Olson and Joseph Smadel.

Institutions involved include the Walter Reed Army Institute of Research, Department of Biologics Research (now called Pilot Bioproduction Facility); National Defense Research Committee; Office of Scientific Research and Development; War Bureau of Consultants; War Research Service (embedded in the Federal Security Agency); Chemical Warfare Service; U.S. Army Biological Warfare Laboratories at Camp (later Fort) Detrick (Maryland), including Special Operations Division (SOD), founded in 1949 to conduct research on covert ways to use chemical weapons; US Army Chemical Corps; Army Medical Department; Army Medical Unit; US Army Medical Research Institute of Infectious Diseases (US-AMRIID); US Army Medical Research and Development Command Unit (US-AMRDU); Pine Bluff (Arkansas) Arsenal; National Center for Toxicological Research at Pine Bluff Arsenal; Vigo (Indiana) Ordnance Plant; Dugway (Utah) Proving Ground; Plum Island (New York) Animal Disease Center; National Bio and Agro-Defense Facility (Manhattan, Kansas).

Some corroborating reports published after 1972 include:

- 1980, Answers to Questions on Selected FDA Bureau of Biologics' Regulation Activities (US General Accounting Office/GAO, Comptroller General);

- 1985 to present, FDA Points to Consider and Guidance for Industry documents, which are non-binding suggestions to manufacturers regarding materials and methods substituted for inapplicable, unenforced non-standards of 21 CFR 620 and 630 and their precursors ("additional standards" for bacterial products and viral vaccines were removed by Federal Register Notice, Revocation of Certain Regulations, Biological Products, 60 FR 53480; 61 FR 40153, effective Aug. 12, 1996);
- 2002, Jordan Report 20th Anniversary Accelerated Development of Vaccine 1982 to 2002 (NIH-NIAID, named for William S. Jordan);
- 2008, The dangerous impurities of vaccines, from the 2008 book *Fear of the Invisible* by Janine Roberts, wherein she writes — "...It was thus a shock to discover from this top-level scientific workshop that the viruses in our current vaccines are not in a sterile fluid as I had presumed, but in a soup of unknown bits and pieces, a veritable witches' brew of DNA fragments, added chemicals, proteins and, even possibly prions and oncogenes, all of which would easily pass through the filters used, to be injected into our children. Our vaccines, I thus learnt, are not filtered clean but are suspensions from the manufacturers' "incubation tanks" in which the viruses are produced from "substrates" of mashed bird embryo, minced monkey kidneys or cloned human cells. These suspensions are filtered before use but only to remove particles larger than viruses. The point of the vaccine is that it contains viruses, thus these must not be filtered out. This means there remains in the vaccine everything of the same size or smaller, including what the manufacturers call "degradation products"— parts of decayed viruses or cells. I also learnt that the only official checks made for contaminants in vaccines are for a few known pathogens, thus ignoring a vast host of unknown, unstudied, small particles and chemicals. These eminent doctors reported at these vaccine safety meetings that it is simply impossible to remove these from our common vaccines — and this would of course also apply to vaccines for pets, farm animals and birds...;"
- 2011, WHO manual for the establishment of national and other secondary standards for vaccines, wherein it is written --"*Biologicals* are substances which cannot be fully characterized by physico-chemical means alone, and which therefore require the use of some form of bioassay...a laboratory procedure for the estimation of the nature or potency of a material by means of the reaction that follows its application to some elements of a living system (examples include animals, tissues, cells, receptors and enzymes). The potency of the material being measured is often defined in International Units or, in some circumstances, may be defined in terms of International System of Units (SI), by comparison with the reaction of the system to a biological reference preparation..."
- 2011, US Supreme Court decision: Bruesewitz v. Wyeth, 562 U.S. 223 , wherein it is written — "...the FDA has never even spelled out in regulations the criteria it uses to decide whether a vaccine is safe and effective for its intended use...";
- 2016, Early Developments in the Regulation of Biologics (*Food and Drug Law Journal*, Terry S. Coleman);
- 2017, New quality-control investigations on vaccines: micro- and nanocontamination, (*International Journal of Vaccines and Vaccination*, Antonietta Gatti and Stefano Montanari); and
- 2018, Informed Consent Action Network (ICAN) v. US-HHS, stipulation, USDC, Southern District New York, 18-cv-03215, wherein it is written "The [Department]'s searches for records did not locate any records responsive to your request" for records of safety monitoring for the national childhood vaccination program, under the 1986 NCVIA law, between 1986 and 2018."

FN - 1972 to present: FDA non-regulation of biological products and vaccines (Watt series)

- Dec. 19, 2023 - Legalized FDA non-regulation of biological products effective May 2, 2019, by Federal Register Final Rule, signed by then-FDA Commissioner Scott Gottlieb.
- March 8, 2024 - Part 1: Mutual Recognition Agreements. First in series on legal links connecting domestic and international non-regulation of non-medicines
- March 12, 2024 - Part 2: Statutory and regulatory definitions for drugs, biological products, and biosimilars

- March 15, 2024 - Part 3: Deregulation of biological product manufacturing, mid-1990s to present
- March 20, 2024 - Part 4: Vaccines have always been heterogeneous mixtures of toxins used to intentionally sicken people and animals
- March 21, 2024 - Part 5: Vaccine and related biological product manufacturing as US government-licensed poison manufacturing Evidence from November 1986 'mandate for safer childhood vaccines' codified at 42 USC 300aa-27, and July 2018 stipulation by HHS.
- April 3, 2024 - Part 6: On why FDA revised written non-rules for non-regulation of biological products to make them more unintelligible, inapplicable and unenforceable since the 1990s.
- April 25, 2024 - Part 7: Terms, phrases and organizations involved in worldwide regulatory and manufacturing deception surrounding vaccines and other biological products.
- May 21, 2024 - Part 8: There is no legal limit to the amount of so-called contamination that can legally be included in vaccines or any other biological products.
- May 25, 2024 - Part 9: On FDA buildings as virtual mailboxes to project the public illusion of biological product manufacturing regulation.
- June 4, 2024 - Part 10: Sen. Rand Paul, FDA Modernization Act 2.0, and animal testing of new drugs.
- June 17, 2024 - Part 11: Pretense of biological product manufacturing de-regulation layered on pretense of biological product manufacturing regulation.
- July 5, 2024 - Part 12: 120+ years of legalized, US-government-led pharmaceutical fraud.

FN - Section III - Scientific, Mathematical, Medical Misconduct

- 1913 - Anaphylaxis (Charles Richet)
- January 1934 - The method of probits, (*Science*, Charles Ittner Bliss)
- July 1939 - A mouse test for measuring the immunizing potency of antirabies vaccines (*Rockefeller Institute*, Leslie T. Webster)
- September 1939 - The experimental transmission of poliomyelitis to the Eastern cotton rat (US-PHS Public Health Report, Charles Armstrong)
- December 1939 - Successful transfer of the Lansing strain of poliomyelitis virus from the cotton rat to the white mouse (US-PHS Public Health Reports, Charles Armstrong)
- 1970 - Health Aspects of Chemical and Biological Weapons (World Health Organization)
- January 1949 - Cultivation of the Lansing Strain of Poliomyelitis Virus in Cultures of Various Human Embryonic Tissue (*Science*, John F. Enders, Thomas H. Weller and Frederick C. Robbins, paywalled by AAAS)
- August 1949 - Cultivation of Poliomyelitis Virus in Cultures of Human Foreskin and Embryonic Tissues (*Proceedings of Society for Experimental Biology and Medicine,* Thomas H. Weller, Frederick C. Robbins and John F. Enders, paywalled by SagePub)
- Nov. 1953 - Public Health Aspects of the New Insecticides, *American Journal of Digestive Diseases*, Morton Biskind. References include DDT Poisoning and X Disease in Cattle, *J. Am. Vet. Med. Assoc.* (Biskind, 1949) and DDT Poisoning and the Elusive "Virus X," *American Journal of Digestive Diseases* (Biskind, 1949)
- 1954.06.01 – Propagation in Tissue Cultures of Cytopathogenic Agents from Patients with Measles (*Nature*, John F. Enders and Thomas C. Peebles, paywalled by SagePub)
- March 1955 - Effects of Routine Immunization of Children and Triple Vaccine (Diphtheria-Tetanus-Pertussis), *American Journal of Public Health*, Johannes Ipsen and Harry E. Bowen
- Aug. 1955 - Technical Report on Poliomyelitis Vaccine (US-PHS *Public Health Reports*)
- 1957 - The Poisoned Needle (Eleanor McBean)
- June 2015 - Dismantling the Virus Theory (Stefan Lanka)
- Jan. 2020 - The Misconception Called Virus Part 1 (Stefan Lanka)
- Feb. 2020 - The Virus Misconception Part 2 (Stefan Lanka)
- March 2020 - The Virus Misconception Part 3 (Stefan Lanka)

- April 2020 - Initiators of Corona Crisis: Virologists Who Claim the Existence of Disease-Causing Viruses are Committing Scientific Fraud and Must Be Prosecuted (Stefan Lanka)
- Nov. 2020 - The Misinterpretation of Antibodies (Tracey Northern translation of July 2020 German report)
- May 2021 - The Germ Theory, an Idiots Guide; PDF (Tracey Northern)
- May 2021 - Contagion, Fact Checked; PDF (Tracey Northern)
- May 2021 - Going Viral, A Recipe for Disaster; PDF (Tracey Northern)
- June 2021 - The Amino Age and The New abNormal Doctors; PDF (Tracey Northern)
- Oct. 2021 - The Lansing Strain of Polio Jamie Andrews ViroLIEgy; PDF (Jamie Andrews)
- Sept. 2024 - The second shot, or what do vaccinators and sewer rats have in common? Reviewing Charles Richet's work on anaphylaxis, awarded the Nobel Prize in 1913. (Sasha Latypova)
- Sept. 2024 - On vaccination as intentional induction of chronic and acute anaphylaxis. (Katherine Watt, condensed transcript of Latypova-Ruby discussion).
- Sept. 2024 - Vaccine-induced food allergies: turning [even organic and healthy] food into poison (Sasha Latypova)
- Sept. 2024 - Antibodies and surrogate endpoints: more pieces of the scientific and regulatory fraud puzzle. Translation of July 12, 2020 German report: Misinterpretation of Antibodies, republished November 2020 by Northern Tracey. (Katherine Watt)
- Oct. 2024 - Anaphylaxis, Alpha-gal, Pasteur, Richet, Voltaire... and the Queen of England. (Sasha Latypova)
- Nov. 2024 - The Spanish Flu Hoax & The Rosenau Contagion Study (Jamie Andrews)
- Nov. 2024 - Methods of deceit underlying pathology, virology and genetics Jamie Andrews of the Virology Control Studies Project, interviewed by Sasha Latypova, condensed transcript; PDF (Katherine Watt)
- Jan. 2025 - Probit, probability unit as related to public deception campaigns, vaccines and other biological and chemical weapons. (Katherine Watt)
- Feb. 2025 - The Polio Hoax (Aldhissla)
- Feb. 2025 - Rabies Recipes: How sane doctors were defeated by the insane scientists 140 years ago. (Sasha Latypova)

FN - Section IV - Legal Misconduct

- July 1944 - Public Health Service Act of 1944 (PL 78-410)
- Smallpox Vaccination in the Philippines 1905-1920
- Dec. 2020 - The Spanish Flu, a blueprint for 2020; Fort Riley, KS (Tracey Northern)
- July 2022 - Toxicology vs Virology: The Rockefeller Institute and the Criminal Polio Fraud (William Engdahl)
- Aug. 2018 - Human Experimentation in Public Schools: How Schools Served as Sites of Vaccine Trials in the 20th Century (Will D. Schupmann)
- March 1946 - Executive Order 9708 (Harry S. Truman)
- 1947 version, federal Biologic Products regulations (Code of Federal Regulation)
- 1949 version, federal Biologic Product regulations (Code of Federal Regulations)
- Oct. 1998 - A calculated risk: the Salk polio vaccine field trials of 1954 (Marcia Meldrum)
- Aug. 1955 - Polio Vaccination Assistance Act - PL 84-377
- Aug. 1955 - Technical Report on Poliomyelitis Vaccine (US-PHS *Public Health Reports*)
- Feb. 1956 - Act to extend the Polio Vaccination Assistance Act - PL 84-411
- 1958 version Biologic Products regulations (Code of Federal Regulations)
- 1960 version Biologic Products regulations
- Oct. 1962 - Kefauver-Harris Drug Amendments of 1962 (PL 87-781)

- Oct. 1962 - Vaccination Assistance Act (PL 87-868)
- 1967 version Biological Products regulations
- 1968 version Biological Products regulations
- 1969 version Biological Products regulations
- Nov. 1969 - US Policy on Chemical Warfare and Bacteriological/Biological Research Programs (National Security Decision Memorandum 35, Henry Kissinger)
- Feb. 1970 - US Policy on Toxins (National Security Decision Memorandum 44, Henry Kissinger)
- 1970 version Biological Products regulations
- 1971 version Biological Products regulations
- 1972 version Biological Products regulations
- Feb. 25, 1972 - Division of Biologics Standards: In the Matter of J. Anthony Morris (Nicholas Wade, *Science*, paywalled by JSTOR)
- March 3, 1972 - Division of Biologics Standards: Scientific Management Questioned (Nicholas Wade, *Science*, paywalled by JSTOR)
- March 10, 1972 - DBS: Officials Confused over Powers (Nicholas Wade, *Science*, paywalled by JSTOR)
- March 17, 1972 - Division of Biologics Standards: The Boat That Never Rocked (Nicholas Wade, *Science*, paywalled by JSTOR)
- March 28, 1972 - GAO report: Problems Involving the Effectiveness of Vaccines
- April 7, 1972 - DBS: Agency Contravenes Its Own Regulations (Nicholas Wade, *Science*, paywalled by JSTOR)
- June 30, 1972 - DBS Scientist to Head New [FDA] Vaccine Bureau (Nicholas Wade, *Science*, paywalled by JSTOR)
- Feb. 25, 1972 - 1972.02.25 37 FR 4004 HEW Notice redelegation biologics NIH 42 CFR 73 adding FDA concurrent redelegation
- June 29, 1972 - 1972.06.29 37 FR 12865 HEW Notice transfer NIH-DBS to FDA and upgrade to Bureau biologic regulation effective 1972.07.01
- July 13, 1972 - 1972.07.13 37 FR 13724 HEW FDA Statement of Organization, Functions, Delegation, Bureau of Biologics
- Aug. 9, 1972 - 1972.08.09 37 FR 15993 HEW Notice transfer regulation biologic from NIH 42 CFR 73 (later select agent toxin program) to FDA as 21 CFR 273 (later 21 CFR 600-680)

Chapter 2

Science and Mathematics: Virus models, antibody models, probability units, immunogenicity, anaphylaxis

Supplemental Material: Interview transcripts, short notes, original Bailiwick posts, and cross-posts.

NOTE: These reports provide overviews only. For details, please see written work by Stefan Lanka, Jamie Andrews, Sasha Latypova, Tracey Northern, Mike Yeadon, Mark Gober and others who are methodically exposing the absence of scientific integrity in the fields of medicine, virology, microbiology, immunology and toxicology.

Latypova and Watt discuss DOD-controlled, BigPharma-manufactured, FDA-authorized bioweapons[4]

November 2022 video discussion; transcript[5] by Dave Ratcliffe, Ratical.org

Sasha Latypova:

> …Yes. The contract that Warner [Mendenhall] was mentioning, that's the contract between CDC and the vaccination centers. It's actually—people can read it that specifies this whole language about federal property until it's injected. Oh—and this whole diversion language [pp. 4-5, June 2021 provision, Sept. 2022 download[6]]. Which I found ridiculous. I think ostensibly they wrote it because, "Oh my God, these are in such short supply, we need to vaccinate," as you said, they needed this blitz as fast as possible. Inject everyone, because people will realize sooner or later they're being lied to. And so they were, "Okay, they're in such a short supply, you cannot divert them because every little vial counts."
>
> But here we are, couple years later, there are hundreds of millions of unused vials, hundreds of millions. So there's no shortage of them.
>
> And by the way, anything approved for market, formally approved by the FDA for market, and they come in fully approved, is — I worked in clinical trials. You can order it through licensed provider and do experiments with it, do studies with it as a third party independent researcher. It's totally valid and okay.
>
> And everybody does it for competitive reasons and other things. So that was always positive. When I told my colleagues about it, they were like, "What? No, we do this all the time, but with approved products, we do research." And I said, "No, you can't. This is a federal property."

Katherine Watt:

> And also the internat— two things about that. One is, you also have written about, and I have written about the international contracts,[7] which specifically put in there that no third party independent testing of the contents can be done.
>
> But the bigger picture of the combination of the adverse effects from the fraudulent trial, that are helping people understand somewhat of what's in them and the analysis of the smuggled vials before injection, which is also helping people figure out, gets to your bigger point that you make all the time: that nothing in the vials corresponds to what's on the label.
>
> So we actually have literally no idea what is in any of these things. The only way we can get back to and reverse engineer and find out is by looking at how does it damage people and what does it, what are the properties of it when you look at it under a microscope or whatever...
>
> That's such a big aspect of the thing that people think that they know what they've taken and they

[4]https://bailiwicknews.substack.com/p/a-latypova-and-a-watt-talk-about

[5]https://ratical.org/PandemicParallaxView/ALwKW-DomesticBioteroProg-110422.html

[6]https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2023/02/2021.06.11-hhs-cdc-re-us-gov-crime-diversion-of-vaccines-prohibited-dl-09.2022.pdf

[7]https://bailiwicknews.substack.com/p/biotech-idolatry-dod-pfizer-contracts

actually don't even know what they've taken.

Sasha Latypova:

No. Nobody knows what they've taken. Also, I try to caution my colleagues who are taking, as you know, face value, what's written in, let's say scientific journal about mRNA injections. They assume that it's produced as it's described in scientific literature. It couldn't be farther from the truth. Then they make all kinds of assumptions. Oftentimes they're very, very well-written papers and very thoroughly researched if you assume that this is the product. Right. But what we're finding in reality —

Katherine Watt:

—You can't make that assumption.

Sasha Latypova:

It's a huge problem because I also work with networks of physicians who are trying to understand how to treat patients and without understanding what they got injured by, we can't really figure out how to treat them properly. I mean, we know certain things. We know that for the most part, it's poisoning of the blood and there's particular characteristics that are exhibited in the blood. But that's also the more convenient way to test people without huge equipment and expensive labs and so on, versus a blood draw, right. That's all we can do so far and try to manage symptoms with various trial and error of simple programs and generic products. But that's nowhere near where this needs to be. We need full disclosure. We need full understanding of what's in those vials, who got injured by what, so that we can properly treat the vaccine injured.

Katherine Watt:

Which is made even more complicated by the fact that it probably wasn't the same stuff in each of the vials. And it goes back to the part where I think, I don't know if it was CDC or FDA or who, but somewhere in the U.S. government shortly after the rollout said you should not do antibody testing of people who have taken the shots, because that's not going to show you anything that would be useful to know. And maybe they even put a financial thing, like we will not cover tests.

But that, I think that helps reinforce the point that they didn't want people to be able to do pre- and post-injections of their own blood work to see what was in their blood before and what was in their blood after…

Intentional elusivity of definitions for virus and vaccine.

Published Aug. 21, 2024

KW email to SL

Followed one of the links provided by a commenter at your latest, picked up name of Charles Richet, awarded Nobel in 1913 for his work on anaphylaxis. Skimmed his lecture, attached, just fyi. Eugenics addressed in last page or two. Anaphylaxis and death from it, Richet says, is sad for the individual, but an important method for purifying the human race over time.

He mentions Milton Rosenau, who was the director of the Hygienic Lab between 1899 and 1909, key period for biologics manufacturing/mass poisoning system set-up, and also did a lot of research in dogs, guinea pigs, humans, others, on poisoning, toxins, vaccines, serums, anaphylaxis. He's a key figure in the early history.

Richet and Rosenau and their work also mentioned in 1967 book by Graham Wilson, *Hazards of Immunization.*

SL to KW:

…Richet:

> "We are so constituted that we can never receive other proteins into the blood than those that have been modified by digestive juices. Every time alien protein penetrates by effraction [forcible entry; injection], the organism suffers and becomes resistant.
>
> This resistance lies in increased sensitivity, a sort of revolt against the second parenteral injection [outside the intestines; intravenous, intramuscular, or subcutaneous] which would be fatal.
>
> At the first injection, the organism was taken by surprise and did not resist. At the second injection, the organism mans its defences and answers by the anaphylactic shock. Seen in these terms, anaphylaxis is an universal defence mechanism against the penetration of heterogenous substances in the blood, whence they cannot be eliminated."

I did not know that anaphylaxis is all allergy to foreign proteins. I thought it was only very an extremely severe reaction. Richet basically explains how any protein, if injected is detrimental to the body (and I believe to the microbiome).

I would agree with this - no "biologics" should ever be used based on his research and based on what he said in this speech.

KW

The protein info was interesting to me too, as a piece of evidence about how long the vaccinators have known that what they were doing was always harming the recipients, to a greater or lesser degree based on unpredictable aspects of the mix of stuff in the vial and the unique biology of the specific living organism.

I connected it with some early 1990s FDA guidance (that I had to buy from Mary Ann Liebert Inc. because I couldn't find it at FDA archives) called "Points to Consider in Human Somatic Cell Therapy and Gene Therapy," with references to "autologous, allogeneic or xenogeneic living cells" and Mike Yeadon and others'

points about the powerful biological drive to distinguish self from non-self and reject non-self, and how the mRNA/DNA proteins, encased in the LNPs, get past so many of the defense mechanisms.

And I was interested in Richet's account of the etymology of the word anaphylaxis, as the opposite (*ana*) of protection (*phylaxis*) = deliberately rendering an organism hypersensitive.

Weaponized proteins.

SL

In general, I think this self-non-self differentiation is a fundamental law of nature. Every living thing is unique and irreplaceable and is a whole unit from beginning to end. There are no interchangeable parts. Sheldrake introduce the idea of "holons" to describe this.

By the way, in Richet's 1913 book, *Anaphylaxis*, he calls the poison that he prepared by dissolving tentacles of Actinaria (I think it's the sea anemone) in glycerin "virus of Actinaria."

Bingo. It's always been a poison. It's on p.23 of the pdf file.

KW

Yes, that's why the original biologics regulation law in 1902 was called the Virus-Toxin Law.

Early on, virus, toxin, antitoxin, serum and vaccine were used interchangeably…

I've been struggling to grasp and express the definitional overlaps and duplications/substitutions/elisions under 42 USC 262, *Regulation of biological products*, etc. for many months.

- March 13, 2024 - Regulatory simulations at home and abroad: statutory and regulatory definitions for drugs, biological products, and biosimilars.

By 1973, under the statutory authority of 42 USC 262, FDA had published some biological product definitions in a list that didn't include *vaccine.* [Congress didn't add the term *vaccine* to the statute list of biological products until 1970, and HHS-FDA has never defined *vaccine* in drug product manufacturing regulations.]

FDA defined several terms at 21 CFR 600.3, but did not define the term vaccine.

> "21 CFR 600.3 (h) - Biological product means any virus, therapeutic serum, toxin, anti-toxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man.
>
> 21 CFR 600.3(h)(1) - A virus is interpreted to be a product containing a minute living cause of an infectious disease and includes but is not limited to filterable viruses, bacteria, rickettsia, fungi, and protozos.
>
> 21 CFR 600.3(h)(2) - A therapeutic serum is a product obtained from blood by removing the clot or clot components and the blood cells.
>
> 21 CFR 600.3(h)(3) - A toxin is a product containing a soluble substance poisonous to laboratory animals or to man in doses of 1 milliliter or less...and having the property, following the injection of non-fatal

doses into an animal, of causing to be produced therein another soluble substance which specifically neutralizes the poisonous substances and which is demonstrable in the serum of the animal thus immunized.

21 CFR 600.3(h)(4) - An antitoxin is a product containing the soluble substance in serum or other body fluid of an immunized animal which specifically neutralizes the toxin against which the animal is immune.

I later thought that maybe *vaccine* fell under that "analogous product" category. (March 15, 2024 - Deregulation of biological product manufacturing, mid-1990s to present. Don't-ask-don't-tell as applied to vaccines and other difficult-to-characterize, highly-susceptible-to-contamination medical-military poisons.)

21 CFR 600.3(h)(5) A product is *analogous*:

(i) *To a virus* if prepared from or with a virus or agent actually or potentially infectious, without regard to the degree of virulence or toxicogenicity of the specific strain used.

(ii) *To a therapeutic serum*, if composed of whole blood or plasma or containing some organic constituent or product other than a
hormone or an amino acid, derived from whole blood, plasma, or serum.

(iii) *To a toxin or antitoxin*, if intended, irrespective of its source of origin, to be applicable to the prevention, treatment, or cure of disease or injuries of man through a specific immune process…

But *vaccine* also falls under the *protein* category added in Feb. 2020 (85 FR 10057), just as the fake clinical trials for Covid-19 vaxxes were starting.

21 CFR 600.3(h)(6) -

A *protein* is any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. When two or more amino acid chains in an amino acid polymer are associated with each other in a manner that occurs in nature, the size of the amino acid polymer for purposes of this paragraph (h)(6) will be based on the total number of amino acids in those chains, and will not be limited to the number of amino acids in a contiguous sequence.

Which is what you're getting at with the spike protein, shark-tooth analogy.

The earliest published regulatory definitions I've found so far are the 1947 definitions in 42 CFR 73, which was the biological products section at that time, and is now the "select agents and toxins" section.

The biological products section was moved to FDA and renumbered 21 CFR 600 et seq in 1973, with the definitions basically the same as the 1947 version, and they remained basically the same (maybe some minor changes) up until Feb. 2020 when the *protein* definition was added.

The "select agents and toxins" section was added under the statutory authority of 42 USC 262a, by HHS at 42 CFR 73, through the same 2002 law (Public Health Security and Bioterrorism Preparedness and Response Act, PL 107-188) that the "qualifying stage," "precommunicable" language was added to the quarantine sections at 42 USC 264, 42 CFR 70 and 42 CFR 71.

Just bought two 1910 JAMA articles by Milton Rosenau, second director of the Hygienics Laboratory. (Jan. 22, 1910 - Vaccine Virus, and Jan. 22, 1910 - The Federal Control of Vaccines, Serums, etc.*)*

Haven't read them yet - I found the abstracts a month or so ago and filed them away because of his definition of *vaccine virus*, using the term "specific principle" to refer to the non-specific contents of a disease pustule erupting from calves that have been injected with disease-causing material.

Rosenau, 1910:

> "*Vaccine virus* is the specific principle in the material obtained from the skin eruption of calves [1] having a disease known as vaccinia.…
> This material scraped from the skin eruption is called vaccine "pulp." The fluid which exudes after the pulp is taken is called vaccine "lymph."
> Both the pulp and the lymph are mixtures containing epithelial cells, serum, blood, leucocytes, products of inflammation, debris, bacteria, etc., in varying proportions…
>
> The specific principle of vaccinia is unknown. The organism, whatever it is, exists chiefly in the epidermal lesions, and the pulp, therefore, contains more potent and concentrated virus than the lymph…"

Sasha Latypova on "the second shot," anaphylaxis, vaccination and scientific paradigm shifts.

Published Sept. 4, 2024

With her permission, I'm cross-publishing a report Sasha Latypova published yesterday: Sept. 3, 2024 - The second shot, or what do vaccinators and sewer rats have in common? Reviewing Charles Richet's work on anaphylaxis, awarded the Nobel Prize in 1913.[8]

I think Sasha is making major contributions to a paradigm shift in the sciences of disease causality (both short-term, self-limiting, "communicable" or "infectious" disease and chronic disease) and immunology, as such shifts were articulated by Thomas Kuhns in his 1962 book *The Structure of Scientific Revolutions*.[9]

And she's doing it without institutional support; with limited, if any, collaborator support; and without academic scientific credentials.

The knowledge gained by Charles Richet, Nicolas Arthus, Milton Rosenau, John Anderson, Bela Schick and their colleagues in the last decades of the 19th century and first decades of the 20th century could have been used to promote human health, fertility and longevity.

Instead, the knowledge was manipulated, mischaracterized, suppressed and weaponized in the form of vaccination programs — intentional, methodical "anaphylactising" or sensitizing of humans and animals against a wide range of substances — to weaken and degrade human health, fertility and longevity.

The knowledge was used to cause those harms with plausible deniability.

I hope many people will grasp what Sasha is painstakingly uncovering and help her develop the new paradigm.

I think more people understanding this material will help bring worldwide vaccination programs to a close sooner, so that new generations of babies and children can be born and grow up without being intentionally poisoned; so that those already poisoned can at least stop getting more poisons put into their bodies; and to maybe help support healing for the vaccine-injured.

*

The second shot, or what do vaccinators and sewer rats have in common? Reviewing Charles Richet's work on anaphylaxis, awarded the Nobel Prize in 1913.

By Sasha Latypova

Remember this quote? April 6, 2023 "The second shot almost did me in. As in I almost died."[10] (Sage Hana, quoting Robert Malone, Jan. 13, 2022, How bad is my batch?[11])

The second shot, 21 days apart. Why the second shot and why 21 days, exactly? Let's take a look.

[8]https://sashalatypova.substack.com/p/the-second-shot-or-what-do-vaccinators
[9]https://en.wikipedia.org/wiki/The_Structure_of_Scientific_Revolutions
[10]https://sagehana.substack.com/p/the-second-shot-almost-did-me-in
[11]https://www.malone.news/p/how-bad-is-my-batch

The anaphylaxis research history.

Charles Richet[12] (Wikipedia entry)

> Charles Robert Richet (25 August 1850 – 4 December 1935) was a French physiologist at the Collège de France and immunology pioneer. In 1913, he won the Nobel Prize in Physiology or Medicine "in recognition of his work on anaphylaxis". Richet devoted many years to the study of paranormal and spiritualist phenomena, coining the term "ectoplasm". He believed in the inferiority of black people, was a proponent of eugenics, and presided over the French Eugenics Society towards the end of his life.

I would like to acknowledge that I knew not much about anaphylaxis other than it is a dangerous, life-threatening allergic reaction. I witnessed it in a local grocery store pharmacy that administered covid vaccines. A young apparently healthy man (in his 30s) dropped on the floor immediately after the injection and was lying there when I walked in. Everyone was behaving like it wasn't a big deal. I wanted to be let off this planet.

While working on this article, I ran a quick CDC VAERS query. All vaccines for all time in VAERS (about 30 years) produced 12,200+ anaphylactic reactions and 2200+ shocks. Covid-19 vaccines produced 9,000+ anaphylactic reactions and 1000+ anaphylactic shocks.

mRNA injections are responsible for 11k of the total 12k reported anaphylactic reactions. However, that's not the entire story of anaphylaxis.

Katherine Watt pointed me to Charles Richet's Nobel Prize acceptance speech and to a couple of articles by this author (Northern Tracey).[13]

I suggest you read them. The author was way ahead of all of us on this topic.

Katherine published on our email exchange at the time: Aug. 26, 2024 - Intentional elusivity of definitions for virus and vaccine (Katherine Watt)

As I mentioned in my email exchange with Katherine, Richet's own work clearly referred to the poison he made from tentacles of Actinaria (sea anemone) as the "virus of Actinaria."

This confirmed one more time what we already knew: viruses are not some sort of natural "seeds" of disease, randomly flying around and jumping strangers.

They are poisons - either natural toxins excreted by plants, bacteria and animals, or poisons made by people like Richet and now CDC/pharma. They do not transmit by air or casual contact.

What becomes apparent from reviewing Richet's 100+ year old research: the only thing you really need to worry about with respect to "viruses/poisons" is an injection of biologics (proteins) for the second time within the anaphylaxis window that starts typically after 20 days and lasting anywhere from months to years to the lifetime.

This can happen in nature from the second bite of an animal/insect carrying same biological toxin (a very low probability event nowadays), or from what is now forced by the government policy — from the needle wielded

[12]https://en.wikipedia.org/wiki/Charles_Richet

[13]https://northerntracey213875959.wordpress.com/2022/01/16/russian-roulette/

by a brainless money whore masquerading as a healthcare provider who is doing it for the 90th time in your or your child's life "because science."

The original biologics regulation law in 1902[14] was called the virus-toxin act. Early on, virus, toxin, antitoxin, serum and vaccine were used interchangeably, because the vaccinators knew what they were propagating in the labs and licensed establishments."

Biological poisons.

This led me to become intensely interested in Richet's work. I found his book describing the work on anaphylaxis published in 1913. I am including several quotes [screenshots in original[15]] from it, so you can read for yourself.

Richet alluded to vaccination being a failure from the first attempts, because, instead of producing expected immunity, it produced violent reactions or even death from minute (not considered dangerous) amounts of the toxin at the second exposure.

This happened in a random % of the population.

One example quoted anaphylaxis rates from injecting cattle with anthrax serum: approximately 10% became violently ill and many died.

The population who would react anaphylactically is *a priori* not distinguishable from others, because it is not known who is already sensitized to which biological substances.

1913, *Anaphylaxis* (Charles Richet):

> "Thus, before my experiments with the virus of Actinaria were made, the only precise scientific idea relative to the sensitivity of animals to second injections was that *sometimes* some animals, instead of being immunised by first injections, were sensitised, and that *sometimes* animals whose blood contained large quantities of antitoxin succumbed to weak doses of toxin."

This is still the case. There is no way to determine upfront who will be anaphylactically sensitized by an injection of a biologic (a protein).

The establishment healthcare denies this, proclaiming all vaccines "very safe."

This is categorically not true, as becomes very apparent once you read Richet's work related to injecting biological substances, even benign ones like milk or albumins (derived from wheat and other cereals).

Digesting a protein and injecting it directly into the blood stream are two entirely different things!

For example, it is safe to ingest snake venom for most people (provided no sores or abrasions in the mouth). I am not advising you try this, but sucking the venom out immediately post bite has been used as a bush medicine method. However, a snake bite delivering the same venom directly into the blood stream is an entirely different story.

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[14]https://en.wikipedia.org/wiki/Biologics_Control_Act

[15]https://sashalatypova.substack.com/p/the-second-shot-or-what-do-vaccinators

You notice that Richet talks about the "second injection."

This refers to the nature of anaphylaxis: the first interaction with an injected toxin may be not even noticed, be well tolerated or may be at worst mildly irritating. After a period of 2-3 weeks, the second exposure, however, may become very dangerous or fatal.

The second exposure in most of Richet's experiments was by injection. However, with high enough sensitization by the first injection, the anaphylaxis could also result from environmental exposure or ingestion, depending on the degree of sensitization to the "allergen," or "toxigen" as he termed it.
Do you understand peanut allergy, gluten allergy, soy allergy, etc. now? The things that didn't exist before peanut oil, wheat albumins and other common food proteins became widely used in vaccines (and were proclaimed "generally safe" because it's just food).

Importantly, Richet has demonstrated that anaphylaxis, anaphylactic shock and the variety of allergic reactions are all the same phenomenon, stemming from the same thing — a sensitizing exposure by proteins reaching the blood stream and bypassing normal digestion.

Richet provided principles of anaphylaxis in his book.

1913, *Anaphylaxis*, Richet:

> Before dealing with the actual study of anaphylaxis I will mention the leading principles laid down in my papers of 1902.
>
> 1. A definite incubation period is necessary before anaphylaxis can be induced.
> 2. The anaphylactic state lasts many weeks.
> 3. There may be some similarity between anaphylaxis and immunity.
> 4. Anaphylaxis is to a certain extent specific; that is to say, the second injection should be of the same nature as the first.
> 5. The symptoms of anaphylaxis are immediate and intense, while the symptoms of primary intoxication are mild.
> 6. The anaphylactising substance is thermostable.
> 7. The anaphylactising toxin affects the central nervous system, and the essential phenomenon is a disorganisation of this system, with a considerable fall in the arterial blood pressure.

He also summarized findings from other researchers working on anaphylaxis at the time [1903-1910].

Notice especially points 8 and 10 — this describes anaphylaxis from "vaccination" and subsequent allergic reactions, even to non-proteins (crystalloids):

Richet, *Anaphylaxis*, 1913:

1. Several primary injections of normal serum into an animal develop an anaphylactic state. A toxin is not required, therefore, to create anaphylaxis. Anaphylaxis follows the injection of non-toxic and harmless substances; it is alone necessary that they be of an albuminoid nature (Arthus, 1903).
2. Accidents observed in man, following injections of serum, are anaphylactic phenomena (Pirquet and Schick, 1903).
3. A single injection of antitoxic serum leads to anaphylaxis on a second injection of normal serum,

even if the second dose is extremely small (Theobald Smith, 1906), even as much as 0.00001 cc. (Rosenau and Anderson, 1906). Normal serum has exactly the same effects in first injections as antitoxic serum (Otto, 1906).

4. It is possible by intercurrent injections to prevent the appearance of the anaphylactic state (Otto, 1906). This is anti-anaphylaxis (Besredka and Steinhardt, 1906).
5. Animals inoculated with a known micro-organism are, in a definite and specific manner, anaphylactised to the toxin of this micro-organism.
6. The specificity of anaphylaxis is so precise that it is possible for the purposes of forensic medicine to determine, by the presence or absence of an anaphylactic reaction, the type of animal whose blood has been injected, although an extremely weak dose was administered (Rosenau and Anderson, 1907; Besredka, Uhlenhuth, 1909).
7. There is a form of anaphylaxis termed *passive*; that is to say, the blood of anaphylactised animals injected into normal animals produces anaphylaxis in them after a large number of injections (Nicolle, 1906), occasionally *after a single primary injection* (Ch. Richet, 1907).
8. Anaphylaxis may be produced by mixing *in vitro* the serum of anaphylactised animals with antigen, and injecting the mixture into normal animals (Ch. Richet, 1907).
9. There is a definite relationship between the production of the anaphylactising toxigen, the formation of precipitate, and the deviation of the complement (Friedberger, 1909).
10. Animals sensitised by anaphylactising substances are, to a certain extent, sensitised to all poisons, even crystalloids (Ch. Richet, 1910).

These are the main points established between 1902 and 1910. In the course of this work the actual experiments on which the definite theory of anaphylaxis is established will be pointed out. Although this is intended to be a summary of the work on anaphylaxis to date, I may be allowed to include a number of facts observed by myself and as yet unpublished."

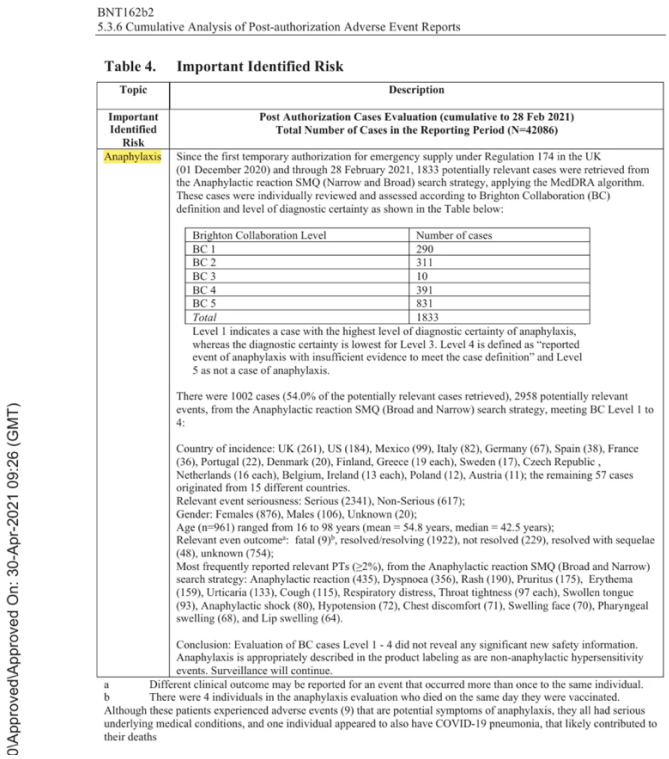
*

Richet found that the state of anaphylaxis sets in after a period of 2-3 weeks (it can vary), and depending on the initial toxin/protein, the sensitization state may last from weeks to years, and possibly be permanent.

At the time that he wrote the book, he mentioned that in people anaphylactic/allergenic state was observed up to 6 years, but it may be permanent.

Do you see now, why most vaccines are delivered in at least 2 doses, and they are separated by at least 21 days? They want to see if they induce severe anaphylaxis (i.e. life-threatening kind).

Here's Pfizer's "postmarketing experience" document, compiling adverse events as of Feb 2021 (first 2 months of vaccine rollout):



BNT162b2
5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

Table 4. Important Identified Risk

Topic	Description
Important Identified Risk	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Anaphylaxis	Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 1833 potentially relevant cases were retrieved from the Anaphylactic reaction SMQ (Narrow and Broad) search strategy, applying the MedDRA algorithm. These cases were individually reviewed and assessed according to Brighton Collaboration (BC) definition and level of diagnostic certainty as shown in the Table below:

Brighton Collaboration Level	Number of cases
BC 1	290
BC 2	311
BC 3	10
BC 4	391
BC 5	831
Total	1833

Level 1 indicates a case with the highest level of diagnostic certainty of anaphylaxis, whereas the diagnostic certainty is lowest for Level 3. Level 4 is defined as "reported event of anaphylaxis with insufficient evidence to meet the case definition" and Level 5 as not a case of anaphylaxis.

There were 1002 cases (54.0% of the potentially relevant cases retrieved), 2958 potentially relevant events, from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy, meeting BC Level 1 to 4:

Country of incidence: UK (261), US (184), Mexico (99), Italy (82), Germany (67), Spain (38), France (36), Portugal (22), Denmark (20), Finland, Greece (19 each), Sweden (17), Czech Republic , Netherlands (16 each), Belgium, Ireland (13 each), Poland (12), Austria (11); the remaining 57 cases originated from 15 different countries.
Relevant event seriousness: Serious (2341), Non-Serious (617);
Gender: Females (876), Males (106), Unknown (20);
Age (n=961) ranged from 16 to 98 years (mean = 54.8 years, median = 42.5 years);
Relevant even outcome[a]: fatal (9)[b], resolved/resolving (1922), not resolved (229), resolved with sequelae (48), unknown (754);
Most frequently reported relevant PTs (≥2%), from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy: Anaphylactic reaction (435), Dyspnoea (356), Rash (190), Pruritus (175), Erythema (159), Urticaria (133), Cough (115), Respiratory distress, Throat tightness (97 each), Swollen tongue (93), Anaphylactic shock (80), Hypotension (72), Chest discomfort (71), Swelling face (70), Pharyngeal swelling (68), and Lip swelling (64).

Conclusion: Evaluation of BC cases Level 1 - 4 did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.

a Different clinical outcome may be reported for an event that occurred more than once to the same individual.
b There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their deaths

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This table is not all cases of anaphylaxis, of course, but only the most severe form — the shock.

Anaphylaxis is all allergic reactions and autoimmune disease, but these things are very easy to deny as they take a while to manifest and are not immediately deadly. The industry has developed perfect gaslighting strategies: "genetic mutations," "toxic food," "stress," "novel syndromes," and even better — glorification of chronic illness via movies, advertising, non-profits and other economic activity feeding off vaccine-induced destruction of natural health.

In case of mRNA vaccines, they absolutely knew that they are killing people with anaphylaxis, but since that was the goal of the military weapon, the shots have not been removed and continue being pushed on the public.

Another interesting observation made by Richet is that white mice and some of the breeds of rats do not experience anaphylaxis. No wonder these animals are now the staple of pharmaceutical research!

While Richet himself seemed to be very much pro-vaccination, his main conclusions about anaphylaxis speak soundly against it.

It is impossible to design a safe vaccine, because it is impossible to predict anaphylactic reactions. Each individual is unique, a product of heredity and interactions with environment. Introduction of foreign, non-self proteins is an assault on this natural equilibrium and can only result in a disaster.

Richet, *Anaphylaxis*, 1913:

> "Partly as the result of the food that has been taken, and partly as the result of multiple microbic infections which have attacked him and most often pass unnoticed, each individual is profoundly different from his neighbour, each has been prophylactised or anaphylactised to different degrees against different substances.
>
> Each is himself, and not another. Each has his idiosyncrasies, or, to put it better, his humoral individuality, as well as his psychological individuality, to differentiate him.
>
> Previous impressions, so variable in different persons, render each person's intelligence peculiar and personal. In the same way humoral impressions, if such an expression is permissible, induce in each individual a humoral personality just as characteristic of him as his intellectual personality."

*

That vaccination in people induces anaphylaxis was known early on.

Richet, *Anaphylaxis*, 1913:

> "Since the earliest use of sero-therapeutic injections definite phenomena have been observed to follow them, and naturally, as I was the first to use them, I was the first to describe them (*Bull. de la Soc. de Biologie*, 1891, 17th January): they included erythema, pruritus, more or less generalised urticaria, with slight fever and malaise. Later other observers saw and described them.
>
> But until Pirquet and Schick in 1903 drew attention to it no relation had been observed between these sero-therapeutic manifestations and the fact that they were not primary. It had not been recognised that they only occurred after second or third injections; that is to say, that they were anaphylactic phenomena.
>
> Pirquet and Schick called these symptoms serum disease, and they have given a detailed description of it."

And was given the name "allergy," possibly to hide the fact that it's vaccine-induced anaphylaxis:

Richet, *Anaphylaxis*, 1913:

> "The delayed reaction observed in predisposed individuals, who are exceptional from the eighth to the twelfth day, usually the tenth, appears sooner in reinjected individuals, that is to say, about the fifth or sixth day. The reaction is then always hastened, although never immediate.
>
> The following table, dealing with ninety-one cases of anaphylaxis, is given by Pirquet and Schick.
>
> Pirquet and Schick have called this phenomenon of reaction of an organism to a foreign substance allergy, but it seems to me unnecessary to introduce this word along with anaphylaxis."

Interval between the First and Second Injection.	Reaction only Immediate.	Reaction Delayed.	Reaction both Immediate and Delayed.
From 10 days to 1 month	21 (87%)	0	3 (13%)
From 1 month to 6 months	21 (63%)	5 (15%)	7 (22%)
Over 6 months . .	2 (6%)	30 (88%)	2 (6%)

These psychos would even kill themselves, and still not get the message:

Richet, *Anaphylaxis,* 1913:

> "Although the symptoms may be intense and sometimes even alarming, most frequently they end by recovery. Nevertheless there have been fatal cases. A well-known physician who had given himself an injection of antiplague serum, repeated it a year later, and died in a few hours of fainting fits, coma, and asphyxia. Doerr states that there are nearly twenty published fatal cases, but he added that in some instances death was probably as much due to the diphtheria as to the serum."

*

Substances that induce anaphylaxis — colloids.

Richet, 1913:

> "Crystalloids do not induce anaphylaxis, but colloids, almost without exception, are capable of inducing it."

Colloids vs crystalloids

Colloids and crystalloids are two types of fluid solutions used for intravenous (IV) infusion in medicine. The primary distinction between them lies in their particle size, composition, and behavior in the body.

Colloids

- Consist of large particles (0.5-100 nm) that do not pass through semi-permeable membranes, such as capillary walls
- Examples: gelatin, albumin, hetastarch, dextran
- Act as plasma volume expanders, maintaining blood volume and pressure
- Have a high oncotic pressure, which helps to draw fluid into the vascular compartment
- May cause anaphylaxis in some patients
- More expensive than crystalloids
- Suitable for patients with severe fluid loss, trauma, burns, or sepsis

Crystalloids

- Consist of small particles (less than 0.5 nm) that can pass through semi-permeable membranes
- Examples: normal saline (0.9% NaCl), lactated Ringer's solution, 5% dextrose in water
- Act as isotonic or hypertonic solutions, expanding extracellular fluid volume
- Have a lower oncotic pressure, which can lead to fluid accumulation in tissues
- Less likely to cause anaphylaxis
- Generally less expensive than colloids
- Suitable for patients with mild to moderate fluid loss, dehydration, or electrolyte imbalance

In general, small molecule drugs do not cause anaphylaxis.

Vaccines are, of course, colloids as they contain a mixture of proteins and lipids in suspension.

Properly matched blood transfusions do not generally produce anaphylaxis. However, since all blood banks are now contaminated with mRNA-injected blood, it is not possible to say that they are safe. I personally would not accept blood, except from a known donor.

Richet proposed that a "toxigen" which developed after the initial sensitizing injection in the blood was responsible for subsequent state of anaphylaxis.

Richet, *Anaphylaxis*, 1913:

> "...the word toxigen, besides having been given to this substance first, has this further advantage, that it indicates the essential fact of passive anaphylaxis —that is to say, that toxigen without being toxic itself can give rise to an exceedingly powerful poison on coming into contact with antigen."

*

<u>"Infectious disease" explained by anaphylaxis</u>

The phenomenon of anaphylaxis may help explain both the natural outbreaks of what appears as "contagious illness" in human history and the skyrocketing chronic illness in the modern western populations.

It is known that the bacteria implicated in diseases like cholera or the plague are commonly present in the intestinal tracts of many people and do not seem to cause any issues. Then, how does an epidemic of the plague or cholera occur?

Imagine living in a crowded, rapidly growing European city around 15th - 17th century...with raw sewage flowing in the middle, domestic animals sharing lower floors of the buildings, no plumbing, sanitation or refrigeration of food. The rats are very common. They bite and the bites carry common proteins found in that area's sewage.

Once enough people in the same area have been bitten for the first time, some weeks go by, anaphylactic state develops, and then the rats bite some of the same people again. If enough of these events occur, an "epidemic" of the plague/smallpox/cholera starts in this community.

Hygiene, plumbing, water sanitation, refrigeration and air conditioning were the most significant technological

innovations that defeated epidemics by removing the chances of injection of anaphylactizing toxigens by common pests.

So, instead, we now have the establishment "healthcare" assaulting the society like the medieval sewer rats with poisoned needles.

All vaccines contain two main sources of injury — the proteins that are used to formulate them, including the toxins ("viruses") and the vehicle which frequently contains other common proteins like albumins (gluten allergy), egg proteins, soy, corn, casein (milk intolerance), etc.

There are also "contaminants" and "adjuvants" such as toxic metals, and more recently with introduction recombinant vaccines — DNA plasmids that transfect cells.

The mRNA shots are even worse as they contain numerous toxic vectors.

Now imagine a baby getting 70+ different shots, most in several doses. It is guaranteed that the baby will get anaphylactized to many commonly encountered proteins, and that a chronic inflammation/allergy will result. Anaphylaxis, being an intestinal reaction, is also tied to destruction of microbiome, which I will address in later articles. Practically all chronic conditions, especially in children, can be tied back to vaccine-induced anaphylaxis.

Many people state that food that we eat and the environment are full of toxins. While this may be true, especially for some locations and some socioeconomic groups, the food and environmental toxicity pales in comparison to what happens when the toxins, especially proteins are injected directly into the bloodstream.

I am in full support of improving the quality of food and cleaning up the environmental pollution, but if we need a policy to combat the chronic disease epidemic, there is one straightforward answer that all politicians and most experts today soundly ignore — the catastrophic damage to health induced by vaccines.

I would like to end with the quote from Richet, 1913 Nobel Prize Lecture:

> "We are so constituted that we can never receive other proteins into the blood than those that have been modified by digestive juices. Every time alien protein penetrates by effraction [forcible entry;[16] injection], the organism suffers and becomes resistant.
>
> This resistance lies in increased sensitivity, a sort of revolt against the second parenteral injection [outside the intestines;[17] intravenous, intramuscular, or subcutaneous] which would be fatal.
>
> At the first injection, the organism was taken by surprise and did not resist. At the second injection, the organism mans its defences and answers by the anaphylactic shock.
>
> Seen in these terms, anaphylaxis is an universal defence mechanism against the penetration of heterogenous substances in the blood, whence they cannot be eliminated."

[16]https://www.merriam-webster.com/dictionary/effraction

[17]https://www.merriam-webster.com/dictionary/parenteral#:~:text=of%202%20adjective-,par%C2%B7%E2%80%8Ben%C2%B7%E2%80%8Bter%C2%B7%E2%80%8Bal%20p%C9%99%2D,by%20way%20of%20the%20intestines

On vaccination as intentional induction of chronic and acute anaphylaxis.

Published Sept. 12, 2024

Sept. 6, 2024 discussion by Jane Ruby and Sasha Latypova, condensed transcript. Video links on Rumble[18]; BitChute[19]; Substack.[20] Full transcript[21] (PDF)

Jane Ruby, Introduction

What if all the so-called epidemics like plague, cholera, and smallpox are the body's natural reaction and resistance to foreign proteins that are only ever in play because they're introduced by injection vaccines and their additives? That would mean that the entire spectrum of human illness: autoimmunity, obesity, diabetes, and other chronic illnesses, could all be traced and tied to a specific reaction in the body, intentionally induced by the real mechanism of action of vaccines...

It may be important to take a new look at the term *anaphylaxis*, a term normally reserved for a serious allergic reaction that has a rapid onset and is life-threatening and requires immediate medical attention...

In reviewing the work of 1913 Nobel Prize winner Charles Richet, biotech expert and analyst Sasha Latypova, and legal expert Katherine Watt have a broader take on this condition because they believe it may be at the center of what is injuring people and killing them in this mass genocide operation...

Sasha, let me start out by first asking you how you and Katherine Watt became interested in even digging into this topic and why you think it's important right now.

Sasha Latypova

Right. So as you know, maybe, Katherine has been working on a very large project, going back through vaccine-related laws in the United States all the way back to the 1700s. So she and another collaborator are writing, she calls it "the beast," a report on how all these laws and all this framework has been put in place and specifically looking at definitions.

As you know, definitions are very important of — what is *vaccine*, what is what, what is *virus*…because definitions in law are basically everything. And so that work is ongoing.

And as part of this work, she came across Charles Richet's Nobel Prize. And she sent me originally his 1913 Nobel Prize acceptance speech[22], a lecture, which I read, and I was shocked by it.

And then I decided to research it further and I actually went into archives and I found his book...[*Anaphylaxis*[23]]...I read his book and I kind of understand what he did and the conclusions that he made. He also cites other authors working in the same area at the same time.

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[18]https://rumble.com/v5dx2yd-all-vaccines-prime-illness-by-injection-of-food-proteins.html
[19]https://www.bitchute.com/video/vcqVWfc3NENd
[20]https://sashalatypova.substack.com/p/anaphylaxis-by-vaccines-discussion
[21]https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/09/2024.09.06-anaphylaxis-by-vaccine-jane-ruby-and-sasha-latypova-transcript.pdf
[22]https://www.nobelprize.org/prizes/medicine/1913/richet/lecture/
[23]https://annas-archive.org/md5/cbf8666b6f20327802abe4e4d5787adc

...At the turn of the 20th century...there were a lot of these gentlemen scientists...people who had independent financial means and they were interested in different topics of science...The original story says that the Prince of Monaco invited him on his yacht, which is a huge ship that was traveling in the Mediterranean, and they went to research the jellyfish, the Man-o'-War, the very dangerous jellyfish. And so from then on, when they returned, he started working with different poisons that he made from similar things.

Getting Man-o'-War was kind of difficult. So he created what he himself called virus of Actinaria. It turns out the virus of Actinaria is basically tentacles of sea anemone that are dissolved in glycerin.

At that time, viruses were — the definition of viruses was poison. So he made poison and he described how he made it. And he called it *virus*, which was the scientific nomenclature at the time.

This whole mythology about *virus* being this particle that infects and flies around and you get it from casual contact. That wasn't there.

It was already well understood that that doesn't happen. And viruses are something you inject to poison.

That's what he was doing in his laboratory experiments. He mostly worked on dogs. He poisoned a lot of dogs. And other people that he collaborated with or knew about worked with rodents. Well, actually rabbits and guinea pigs and sometimes other animals. Turns out white mice and some breeds of rats do not experience anaphylaxis. So isn't it surprising how they're the staple of pharmaceutical research?...

In addition to his interest in anaphylaxis and vaccination or early attempts at vaccination, he was a eugenicist...He thought that black people were inferior. And he was actually a president of eugenics society in Europe and I think in France... It's a little bit of a digression, but it's important to understand. So this stems from Darwinism, by the way, and there was a lot of scientific debate at the time. The main concern of these rich people who were also doing science, because there wasn't a centrally-funded science at the time, was..."How do we prevent these poor classes that are dirty and inferior from overbreeding?" And actually Darwin was against that, but not because he was for some humanitarian goals. His position was, "If we prevent them from overbreeding then we don't have the competitive evolutionary selection."

These ideas come from...the richer classes, more well-to-do classes who themselves called themselves "well-bred," from trying to limit and prevent overbreeding of poor classes, which they associated with infectious diseases, epidemics, general dirty stuff, crime...That was their attempt to limit it. And that's why they devised all these methods.

Richet was working on it, although he didn't, in the book at least, he doesn't say explicitly his goals. He just kind of lays out the scientific stuff. I think they were working on figuring out how can we both prevent epidemics and limit the reproduction of the dirty classes. Obviously, now this is all expended on all of us.

Now it seems that the globalists kind of view us in the same way that at the time they were viewing poor working classes. So they view all the world as overpopulated. "We're getting, you know, resources are constrained," which is not true. "And we need to limit the population." And this is the mechanism by which they have been limiting population systematically.

Jane Ruby

...I think a lot of people understand now that this whole vaccine program for the last couple of centuries has been to injure, create medical conditions and to take down over time, keep culling off the population.

But what I think you're zeroing in on with Katherine is this may be the main mechanism of action by introducing foreign proteins...

Sasha Latypova

So let's talk about what *anaphylaxis* is. I also was under impression that anaphylaxis is only shock, the life-threatening condition where somebody immediately drops on the ground and you need antihistamines or EpiPen.

Now, it turns out Richet, who received Nobel Prize for it, himself said it's not just that.

And actually, at the time, there were some other scientists calling it *allergy*. And he said, "This is wrong. You shouldn't call it allergy because it's the same phenomenon…"

He has demonstrated that anaphylaxis is anything from mild rash to shock. And it has the same underlying mechanism.

Later on the science has demonstrated, well, there are different antibodies and different things that happen with mild versus not-mild, but the outcome is the same. The body gets sensitized by injection to whatever was injected and the injection specifically of proteins.

Proteins are, people don't quite understand what they are, but proteins are large molecules, large biological chemical structures, as opposed to small chemicals like salt or some small drug that you typically get as a pill. Proteins are large structures. They can be food proteins. They can be toxins from plants or animals... Injections of proteins, even milk and food proteins, produce the same result as injecting poison of Actinaria, as [Richet] was practicing with...

It does not have to be toxic at all or considered toxic. As long as you inject protein directly into the bloodstream, bypassing the digestive tract, that sets up the state of anaphylaxis.

By ingesting proteins [through the digestive tract], we can ingest almost anything. You can actually even ingest snake poison. That's used in bush medicine. I don't recommend it. But if you don't have abrasions or sores in the mouth, you can suck out poison, and it's safe...

Our digestive tract deals with proteins extremely well. It disassembles them and then we reassemble our own.

Now, when you inject foreign protein, our entire system is designed in such a way that we reject non-self proteins.

And so anything, even what you think is benign, like milk, will become poisonous and can kill somebody.

Jane Ruby

It's the injecting into the compartment...Once you put something directly into the main, the vascular system...you're going to go everywhere. And like you said, there's a huge surveillance system operating naturally. And when the body sees a protein, that's not its own printing, it reacts.

And so you're saying anaphylaxis is any of the reaction to that, but they know this, the mechanism of action I

think you've discovered that's relevant is they, knew this in the 17 and 1800s maybe, or they were coming to know it and they are using it actively. This is a slow kill, I think as Katherine has said. Right?

Sasha Latypova

Yeah, so what [Richet] found...working on these early attempts at vaccinations [is] that it's unpredictable which — so not 100% of the population injected will react that way.

This makes it even more sinister. It's unpredictable which people or animals when injected will go into the state of anaphylaxis.

So state of anaphylaxis requires to inject one injection and then the second one sets it off.

So, and in my article, I said, you know, "the second shot," why the second shot is so important. So the first shot will, after some period of time, he showed that it's around 20 days.

That's vaccine doses at 21 days.

So he showed that it's around 20 days. It can vary depending on the poison and the species. So you inject them once, they may not react. It may be just totally fine for them, you don't see any results, maybe somebody develops like mild rash or something.
And then 21 days later you inject even minute dose...what is considered completely not dangerous, tiny, tiny dose of the same substance and some of the animals — but it's unpredictable which ones — will go into violent illness, bad allergic reactions, or even shock and death.

And he's done it so many times, and he's shown you cannot predict this. There is nothing. And since then, the science still cannot predict this. We don't have any ability to say how a person will react to what everyone thinks is a safe ingredient, like peanut oil, or casein or yeast or, like these albumins that are made from wheat and cereal and soy and corn.

Are we surprised that everybody's having those allergies now? No, because these were vaccine ingredients. These were people who were *anaphylactized* over time with this.

Another sinister point of this whole vaccinology, is that they over time have developed, let's say, they call it "safer," but they're just less detectable anaphylactizing agents than what Richet was using...things that won't produce as many overt shocks, but will be underlying, sensitizing the population to commonly-occurring proteins like wheat, like peanut oil, like other nuts, you know, foodstuffs, now meat...
Pretty much everything you encounter or eat then becomes a mild poison to you. And because you're doing it continuously, it creates chronic inflammation, allergies, autoimmune diseases, destruction of microbiome, because the anaphylaxis is actually intestinal reaction. And so leaky gut...cancer pathways over time, obesity, especially in children, it's all related to that because their gut is now completely either destroyed or completely, I would say, out of whack. They can't properly digest food. So they grow obese, even from not such a bad diet.

And then…they gaslight you into, "Oh, you have this...genetic mutation, you have a hereditary autoimmune condition or you have, you know, your diet and lifestyle. Oh it's toxic food."

Now notice all over the place we have, on Tucker Carlson and everywhere: "Toxic food, we have to deal with toxic food."

It's not toxic food.

It's this.

Everyone is anaphylactized to normally occurring proteins...

Jane Ruby

...You need an initial exposure to a foreign protein to then have a more severe reaction, whether or not you have it the next time around. Because it takes time for the body, it probably puts a lot of energy into developing, setting up surveillance..."I know that thing over there is foreign protein, so I'm going to imprint that memory, whatever that is..." But then the next time you're exposed to it and your body goes into hyperdrive...

What you're suggesting by this work and this analysis is that this is a programmed intentional priming and programming...

Let's just talk about the *adjuvants* for a minute. All of these injections since 1950s when they were injecting, they've always had adjuvants, additives... These things that don't seem to make sense. For the most part, society has brushed it off. Aluminum, polysorbates. Now these antibiotics... Why are all these things added? The top-level response is, "Well, because we need to jump-start your immune system..."

Is that primarily one, maybe a major way that introduces foreign proteins...and "anaphylactize" the body?

Sasha Latypova

The adjuvants are also very, very sinister. ...I also found some older documentations and even articles in like *New York Times* discussing this issue. This is before pharma was advertising directly with them. So they were actually doing journalism on this topic.
For example, peanut allergy. It was introduced in Merck vaccine and the peanut oil was an adjuvant [NYT, Sept. 19, 1964[24]]...and it started producing allergic reactions. It was recognized at the time that this is anaphylaxis to the peanut oil. They continued by renaming it into Adjuvant 65, so that nobody can say what it is. And since then, FDA is giving [adjuvants that are food proteins] designations. It's called GRAS, generally [regarded] accepted as safe...or things that are considered, you know, common and safe.

For example, mRNA vaccines contain cholesterol. So what is going to happen if you are sensitized to cholesterol in your own bloodstream?...

...Some agents like the peanut oil are so anaphylactizing that after the first exposure, people become then sensitive to even breathing the oil that comes out of the peanut. And so they become so sensitive to this...

Once something like this is detected...[pharmas and FDA] go find some other anaphylactizing agent that's less detectable, for example, *albumins*, which produce gluten allergy over time, or rice or corn or soy, depending on what they're derived from.

And then you get gas-lit...It's very difficult to diagnose autoimmune condition or gluten intolerance. ...People go nuts through like these elimination diets, trying to figure out what's going on. What's an anaphylactizing agent?

[24]https://www.nytimes.com/1964/09/19/archives/peanut-oil-used-in-a-new-vaccine-product-patented-for-merck-said-to.html

And nobody tells them that this is from the vaccine...

Jane Ruby

Here's how I know you're on to something. Peanuts have been around for thousands of years. Why only in the last 50 years or so has this peanut allergy escalated to where you can't even breathe the molecules in an airplane or anywhere?

So it's intentional. It's part of the plan.

Sasha Latypova

Part of the plan. I know. Where I grew up, we had no allergies whatsoever. And I keep telling people, again, about toxic food and toxic chemicals in the environment. I'm not proposing to have toxic chemicals. I'd love to clean up any pollution and keep everything clean.

And organic food, I also love it.

But I'm telling you, I grew up for 20, 30 years in a place where we could light the creeks on fire because we had all this industrial pollution dumping into the water where we were taking the water for drinking. And we had leaded gasoline. We had, the agriculture was full of chemicals, just, they were dumping straight chemicals. It's Soviet agriculture.

The food, everybody ate sugar, fat. The only oil for cooking was seed oil and margarine because butter was too expensive. And we had not a single overweight kid. We had no allergies. I didn't know about food allergies at all, that they exist. We had no asthma, despite the air being a total, total awfulness. And no autism. I didn't know it existed. Actually, when I first saw *Rain Man*, I was like, "What is it? What does this guy have?"

Jane Ruby

Because you didn't have vaccines?

Sasha Latypova

Well, there were maybe three or four vaccines...When I come here and everybody is — and I go to the grocery store, here you can buy actually pretty decent food. Okay, avoid those middle aisles where all this, like, petroleum products are. But if you buy groceries, like normal groceries, it's all fine.

It's not toxic food. And it's not toxic environment. The environment most of the time is actually quite good.

So what is this whole propaganda? It's again, it's part of gaslighting. It's gaslighting into why "it's all this food that we need to worry about and spend money on," as opposed to removing the cause of anaphylaxis to the food...

Jane Ruby

Right. Part of the plan…I knew it was a crime because nobody in their right mind, you don't even have to be in the pharma industry. It's been talked about for generations that pregnant women have to be careful...

I'm a little focused right now on the drive to get the polio vaccine. There hasn't been a reported case of an indigenous wild, in-the-wild acquired polio, obviously, since I think, online I read 1979. So again, we have a non-issue, but there's this World Health and CDC push right now. And it bifurcates into the oral polio and the injection since 2000 in the United States.

Is it in these adjuvants, that they're adding these protein sensitizers?...

Sasha Latypova

Depending on how they authorize this...if they declared, in a particular location, they declared public health emergency of polio...We
have PREP Act declarations....I don't think they included polio specifically, but they included poisoning by pesticides and nerve agents, which I think what polio is today, because there is no virus. If there was a virus, it was eliminated. God knows when, 70s. But I don't believe there is a virus of polio. I think it's primarily poisoning by pesticides like DDT. Originally it was DDT and then later different other pesticides. And so we even have a PREP Act declaration for it.[25] So depending how they put this vaccine on, it can contain pretty much anything...

They can put just about anything into these vaccines because of almost bulletproof liability protection, especially in the US...There's no oversight of vaccines. That's what my colleague Katherine demonstrated. And that's what she's writing about. There's no effective regulation of vaccines. They are not regulated as pharmaceutical products.

They were not regulated at all until 1973. So they were just cooked up by CDC and distributed from disgusting things. Let's not go there yet. But in 73, FDA finally got mandate to regulate them, sort of. But we have traced all those regulations and they are completely ineffective. And nobody ever does any enforcement, especially now. There's no enforcement of any of those regulations. They're basically operating a system of, Katherine calls it, empty mailboxes,[26] where pharma companies write up their own reports, send them to the FDA. FDA sends them back, "Okay, you can go ahead, inject this vaccine..."

And in fact, FDA is even actively helping them. There are labs inside of FDA that develop these additives and develop different assays for pharma companies and share them with pharma companies. One of their labs actually works on SV40...how much of SV40 you can put in with what...

When you start reading and looking at it, you can't avoid the conclusion that they are working specifically to poison people.

Jane Ruby

The Covid shots were the door that opened to the rest of the vaccine reality, that it's part of the mass inoculation, eugenics, injuring people...

Sasha, how do we get the country and the world to see that vaccines are actually the vehicle?...Let's just start with our country in the United States to stop taking vaccines because they are the bioweapon. They've always been a bioweapon, not just Covid.

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[25]https://www.govinfo.gov/content/pkg/FR-2022-12-23/pdf/2022-28013.pdf

[26]https://bailiwicknews.substack.com/p/on-fda-buildings-as-virtual-mailboxes?utm_source=publication-search

Sasha Latypova

I think the education about anaphylaxis, that it's not just a shock, that it's actually all these food allergies can be traced back to the vaccine ingredients.

I think that that will give a lot of ground for people to understand, because just about any family I know... you can point to the vaccine injury or several, with respect to...having food allergies, having gluten intolerance, autoimmune conditions, obesity, and all sorts of things.

So my goal is to try to popularize this and to try to explain to people: this is what's going on. This is why you have all these things, because you have been injected directly into the bloodstream with the foreign protein.

And Richet said in his Nobel Prize acceptance speech and also in his book that the human body is constituted in such a way that it cannot accept foreign proteins directly. We are unique. Each human is unique, in a unique chemical balance with itself and the environment. And it's a product of time...we're so unique that we need to have our own self-proteins made from digestion. There's no other way. If you start introducing these foreign proteins...

The industry gaslights you into: "We synthetically make DNA. We synthetically make RNA. It's just like yours."

No, no, no. It's not like yours. The only DNA and RNA that you can accept is what you yourself make. Nothing else will substitute it.
And so what happens is that once that it's introduced, your body revolts and attacks those agents and attacks itself.

You're inducing, as if you were making a transplant, you start rejecting it.

Number two...anaphylaxis also explains those epidemics of what is considered infectious diseases.

Instead of just saying "viruses haven't been isolated," which, I agree, they haven't. But that's not sufficient.

It doesn't provide comfort to people [who ask] "But what makes us sick?...What about the disease?"

That becomes a stumbling block for a lot of people. They can't accept the narrative and they're saying, "Well, I need the explanation of what goes on."

Here's the explanation. Anaphylaxis explains the same thing. Anaphylaxis explains the plague and cholera very well because those diseases also happened at the time when people were crowding in the cities without sanitation, without plumbing, refrigeration, or air conditioning. So the animals were living in the same buildings, some small buildings with humans in cities. The sewage was flowing through the streets. There were rats and other pests like fleas and lice and all sorts of stuff.

And when — you can get anaphylaxis naturally, and people know it, for example, stung by a bee a couple of times, stung by Man o' War [jellyfish]. So those can still happen. It's very rare probability.

But at the time it was high probability because you have your sewer rats running around or lice or fleas biting people continuously...If enough people get in the same community, get anaphylactized by that rat, [then] bit them twice with the same protein that came from the local sewer. Guess what? The plague starts. Because normally people carry the plague bacteria and cholera bacteria in their intestines and it's no problem. But this is

when you get anaphylactized by an animal or an insect bite. And enough people in the area have gotten that exposure. That's when you have the epidemic.

So removing those vectors, making sanitation, pure water, air conditioning, refrigeration, removes all those problems.

Jane Ruby

Right. But it also brings back the problem of too many people on the planet, which is a myth, a myth about resources...It defeats the eugenicist attempt. They don't want clean water and clean air and they don't want you to live healthy and longer.

Sasha Latypova

Yeah. So notice that all of those concerns started percolating when all of these previous problems went away. Right around that time, the Club of Rome and the Trilateral Commission and all that, they started writing their documents when they realized, "Oh, wait, now we have people living healthy, living long. We can't have that."

So they started writing all these plans and putting all this vaccination programs in place. And this is when this all started.

So instead of the sewer rats, now we have CDC doing the same exact thing.

Jane Ruby

And the pharma companies...Take a moment or two to speak from your perspective about the relationship between the pharmaceutical industry, especially the bigger players that are obvious in this Covid thing, that are now also feeding at the trough of all...like Novavax, coming out with their new variant-related shot, and testing it in six-month-old babies, two shots and a booster.
I've often said that the pharma industry is really part of the DOD, not just our government, but the Department of Defense. Some of your thoughts on that and how they could get an institutional review board to stamp, if they did, a study with babies.

Or I guess they don't have to because it's a vaccine, they don't need human subjects review on giving babies three shots?...

Sasha Latypova
There are several factors here. So pharmaceutical industry ran out of returns on investment a long time ago, sometime around 2014. And this was because of patents expiring in traditional drugs.

They all started moving into the biologics, which is all these proteins...because of the IP [intellectual property] issues.

But now the biologics are also expiring of patents, although it's not as dramatic as the drugs because it takes longer time to develop a biosimilar...

They're all freaking out about that. The only major source of funding that they've had since 2020 or even before, like 2017, the only major source of funding is federal government through the military such as DARPA and BARDA giving them contracts to mostly make these poisoning systems: vaccines.

Vaccines is like a huge thing and then there are some minor other stuff. By 2020 it became, about 50 percent of the R&D [research and development] funding or even more in pharma coming from BARDA, through these contracts where you don't have to comply with pharmaceutical law.

Well, can you imagine? If a private business has a choice: "I can get free money from the government and don't have to comply, or I have to raise money from private investors, have all kinds of compliance, including SEC, but I also have to comply with every letter of the pharmaceutical law." The answer is very simple.

So they are all dropping normal programs and they are running into these military programs because the government is dangling these dollars in front of them. And they will do anything, you know, jump how high. They will do anything and they don't care.

And a lot of the time these components are coming directly from the DOD for these mRNA vaccines, for example. They don't even know what they're mixing, but they're doing it anyway.

More recently, I'm going to publish on this, but the federal government started even giving money to places like pharmacy chains, like Walgreens, to specifically hunt pregnant women and children....for participating in these clinical trials like Novavax, right? So you're saying, well, who is going to give their baby up for this experimentation? Well, guess what? Walgreens in poor neighborhoods offering $3,000 for your baby to be injected.

Jane Ruby

Yeah, it's a bribe...It's more than an over-inducement. No human subject review board would let you write an informed consent with a $3,000 stipend because nobody could—. You're right. If you can't make your mortgage payment, you're like, "I'll just take the baby and it must be safe. You know, let them give this to the baby."

Sasha Latypova

"It's a vaccine. It's safe. You know, the, Paul Offit says it's safe. CDC says it's safe. These anti-vaxxers, they're just stupid people, uneducated, right?"

And there we go and they bring their babies into the Walgreens for clinical trials...

[For discussion of transfer and shedding from Covid-vaccinated to Covid-unvaccinated, see full transcript.[27]]

Jane Ruby

And probably one of the most dangerous things that we always believed was dangerous, not that that's a new revelation, is a blood transfusion from an injected person, especially someone who's taken two, three, four or five shots and whatever's going on in their body, but it's in their main compartment. This dance going on and rejecting and anaphylactizing. And then you take, as an uninjected person, directly into your vascular system, right in the system.

[27]https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/09/2024.09.06-anaphylaxis-by-vaccine-jane-ruby-and-sasha-latypova-transcript.pdf

Sasha Latypova

Exactly. This was shown by Richet and it's in his book...

He has stated that previous research, his own research in 1910 and his colleagues has demonstrated that if you inject the blood from the animal that has been, they call it passive anaphylaxis. So if you inject the blood from the animal who has been anaphylactized into a healthy animal, you will create anaphylaxis.

But the medical establishment today and Red Cross, everyone denies this. This work received Nobel Prize. This was known 100 years ago.

Jane Ruby

But now you know why the Red Cross has never screened, has said "Not to worry." They're a federal agency. They're part of the operation.

Sasha Latypova

They're making huge amounts of money on this, first of all. And then, yeah, it's another vector by which they are going to get all those anti-vaxxers. Now, I personally would not accept blood transfusion...Only from, like, known, identified donor. But other than that, no.

Jane Ruby

I think the Jehovah's Witnesses, if that's the religious group that, I think they were on to something...And the Amish don't, I believe, as well...You don't know what you're getting when you directly take someone else's blood into your blood compartment. Very, very dangerous.

[For discussion of how to find work by Sasha Latypova and Katherine Watt at Substack; censorship by Twitter, Facebook, LinkedIn, YouTube, see full transcript.[28]]

Jane Ruby

...This has opened up a whole new can of worms that I want to continue to talk about and help you get the word out, Sasha, because I think it speaks to the broader issue of warning people. None of these are good. None of these are necessary. In fact, they're an attack on you. Any last words from you on this? What do you want people to know?

Sasha Latypova

I want everyone to please share this information with your friends and relatives who are still thinking about "injecting is fine and the vaccines are safe..."

Explain to them that this anaphylaxis phenomenon explains the infectious disease and explains the epidemic of chronic illness that we're experiencing. They have the same cause. And so that's very critical for people to understand...

[28]https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/09/2024.09.06-anaphylaxis-by-vaccine-jane-ruby-and-sasha-latypova-transcript.pdf

Jane Ruby

This is good news then for parents who maybe stumbled into it. They have a three, four, five-year old. They had, they got nailed the first year or two, but then they crossed over with everything that's happening. And now they've stopped. I mean, it's better than those who continue.

Sasha Latypova

It's better than those who continue. I have a friend who had a baby. She's two-and-a-half now. And they were forced into one shot in the hospital, but then refused everything else. The baby — while the parents are both fairly short, like five, seven, five, eight — the baby is 97th percentile, very tall, very beautiful, very talkative, hit all the milestones early.

It's a joy. The child is a joy. How wonderful healthy children are. I mean, I demand photos every day from them. I can't stop admiring how healthy and beautiful this child is. And everyone can have children like that. Imagine our society. Imagine what we can do. Imagine how smart people can be and creative. And we can have a joyful, harmonious world if we stop this evil.

Note on "epidemiologic transition"

Published Aug. 1, 2024

CDC's term for the intentional poisoning of the American population, conducted through vaccination programs, is "epidemiologic transition."

From March 2024 CRS report on CDC history[29]:

> "…Over time, CDC evolved in response to an epidemiologic transition that occurred throughout the 20th century, in which the leading causes of death in the United States shifted from infectious diseases to chronic diseases and injuries…"

[29]https://crsreports.congress.gov/product/pdf/R/R47981/2

Note on the long history of fraud in diagnosis, disease causality attribution and cause-of-death classification.

Published Aug. 10, 2024

(Comment on Sage Hana post: Aug. 10, 2024 - Diagnostics and Syndromes are Rockefeller Medicine Fuckery. Modern Medicine is Fifth Generation Warfare on YOU. Yeadon on PCR and other Diagnostics[30] (Sage Hana))

Digging around in the late 1800s, early 1900s history is yielding some early examples of the same plays from the general playbooks.

For example, paper by Dr. Joseph Kinyoun, first director of the Laboratory of Hygiene within the Marine-Hospital Service, which later became the Public Health Service, and the Hygienic Laboratory and MHS were the seedbeds for NIH, NIAID, CDC and FDA.

Kinyoun trained under Robert Koch and Louis Pasteur in Europe, and brought their infectious disease attribution techniques back to US.

NIH history[31]:

> "Within a few months [of Hygienic Laboratory set up in 1887], Kinyoun had identified the cholera bacillus in suspicious cases and used his Zeiss microscope to demonstrate it to his colleagues as confirmation of their clinical diagnoses. "As the symptoms . . . were by no means well defined," he wrote, "the examinations were confirmatory evidence of the value of bacteria cultivation as a means of positive diagnosis."

1896, Report of the Committee on the Causes and Prevention of Diphtheria,[32] by Kinyoun, offers an early look at the use of microscopic techniques to "diagnose" disease in asymptomatic or mildly-ill cases.

> "It is now almost a universally accepted fact that the bacillus diphtheriae is the sole cause of the disease. Formerly, the bacillus diphtheria, was supposed to cause only inflammation of the upper air-passages, which are accompanied by a pseudo-membrane. This belief is slowly changing, and the term diphtheria has a broader application; for it has been satisfactorily demonstrated that many of the inflammatory affections of the nose and throat not accompanied by a false membrane, were nevertheless caused by the diphtheria germ.
>
> While this is not being accepted as rapidly by the medical profession and laity as the health officer could wish, the number of adherents to this belief is gradually increasing.
>
> By reason of the microscopic and culture test, we have now two classes of diphtheritic infection to deal with, the one presenting the classical and typical symptoms - the clinical diphtheria - the other, where the symptoms are slight or absent, with the bacillus present, the so-called laboratory diphtheria."

The killers put the pretextual basis for federal disease control authorities in the wording of the enabling laws, right from the start:

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[30]https://sagehana.substack.com/p/diagnostics-and-syndromes-are-rockefeller

[31]https://history.nih.gov/display/history/A+Short+History+of+the+National+Institutes+of+Health

[32]https://pmc.ncbi.nlm.nih.gov/articles/PMC2329096/

March 1890, An act to prevent the introduction of contagious diseases from one State to another and for the punishment of certain offenses[33]:

> "…whenever *it shall be made to appear* to the satisfaction of the President that cholera, yellow-fever, small-pox or plague *exists* in any State or Territory…"

[33]https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/07/1890.03.27-51st-congress-ch.-51-marine-hospital-service-interstate-communicable-disease-control-quarantine-read-summarize-upload-link.pdf

Note on HHS addition of "protein" to biological product list

Published Aug, 21, 2024

(Comment on Aug. 21, 2024 - Similarities between "spike protein" and synthetic anthrax toxin. Real bioweapons are not viruses but chemical weapons.[34] (Sasha Latypova))

HHS-FDA Final Rule, published Feb. 21, 2020, effective March 23, 2020, added a regulatory definition for biological product subcategory "protein" under 21 CFR 600 and PHSA 351(i)/42 USC 262(i):

> "21 CFR 600.3(h)(6) - A protein is any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. When two or more amino acid chains in an amino acid polymer are associated with each other in a manner that occurs in nature, the size of the amino acid polymer for purposes of this paragraph (h)(6) will be based on the total number of amino acids in those chains, and will not be limited to the number of amino acids in a contiguous sequence."

85 FR 10057[35]

> "A. History of This Rulemaking
>
> The BPCI Act (2009) amended the definition of ''biological product'' in section 351(i) of the PHS Act to include a ''protein (except any chemically synthesized polypeptide).''
>
> After publication of the proposed rule, section 605 of the FCA Act (2020) further amended the definition of ''biological product'' in section 351(i) of the PHS Act to remove the parenthetical ''(except any chemically synthesized polypeptide)'' from the statutory category of ''protein.''

[34]https://sashalatypova.substack.com/p/some-similarities-between-spike-protein

[35]https://www.govinfo.gov/content/pkg/FR-2020-02-21/pdf/2020-03505.pdf

Note on lack of definition for term *disease*

Published Sept. 16, 2024

A 1974 SCOTUS ruling in *Marshall v. US*, a case about whether a thrice-convicted felon should be eligible for an experimental narcotics treatment program, is the source for Chief Justice John Roberts' ruling in 2020 *South Bay Pentecostal v. Newsom*, that "When [state legislators and executive/administrative] officials "undertake[ ] to act in areas fraught with medical and scientific uncertainties," their latitude "must be especially broad."

The 2020 *South Bay Pentecostal* ruling reinforced precedent of judicial non-review, which is also reinforced by provisions of 2005 PREP Act through which Congress explicitly prohibited judicial review of HHS Secretary acts pursuant to 'public health emergency' preparedness and response.

The Marshall court, citing 1968 *Powell v. Texas* decision, observed:

> "…there is no agreement among members of the medical profession about what it means to say that 'alcoholism' is a 'disease.'
>
> One of the principal works in this field states that 'alcoholism has too many definitions and disease has practically none.'…"

The lack of definition for the term *disease* (including *communicable disease*) is related to the lack of definitions (by measurable physical or chemical attributes) for the terms *virus* and *vaccine*.

Antibodies and surrogate endpoints: more pieces of the scientific and regulatory fraud puzzle.

Published Sept. 27, 2024.

Translation of July 12, 2020 German report: Misinterpretation of Antibodies, republished November 2020 by Tracey Northern.

Below is a translation of roughly the first half of a report published in German July 12, 2020: Die Fehldeutung der Antikörper[36]/The Misinterpretation of Antibodies (Corona_Fakten)

The full report was translated and republished in November 2020 by Northern Tracey, without live links or clear formatting of quoted sections: Nov. 2020 - The Misinterpretation of Antibodies[37] (Northern Tracey)

Because the originals are both a bit difficult to read for a few different reasons, I've edited roughly the first half of the translated, original report, to hopefully improve the clarity of the information. Readers interested in the second half can use the two links to investigate further.

Information about historic mischaracterization of antibodies by governmental scientific and public health officers relates to the hypothesis that vaccination is the intentional induction of anaphylaxis by repeated injection of foreign proteins, and that US-government directed and funded worldwide vaccination campaigns have been historically and still are intentional mass deception and mass poisoning events camouflaged as public health communicable disease-prevention campaigns.

Intentional mischaracterization of what antibodies are and how they function in living creatures are important parts of the medical-scientific and regulatory cover-ups carried out concurrently with mass vaccination/poisoning events.

Corona-Fakten, Stefan Lanka, Tracey Northern, Sasha Latypova and others challenging principles of immunology, toxicology, pharmacology, pathology, bacteriology, microbiology and related fields have identified the inherently self-contradictory premises of vaccination.

Stop taking vaccines.

Stop vaccinating babies and children.

Titer/titre, definition (Merriam-Webster[38]):

> 1) the strength of a solution or the concentration of a substance in solution as determined by titration[39]
>
> 2) a measure of the concentration of a substance (such as an antibody) in a blood sample that is obtained by subjecting the sample to serial dilutions (as with saline) to determine the maximum dilution at which the sample retains a specific activity (such as neutralizing an antigen) and that is often expressed as a ratio (such as 1:200)

[36]https://telegra.ph/Die-Fehldeutung-der-Antik%C3%B6rper-07-12
[37]https://northerntracey213875959.wordpress.com/2020/11/26/the-misinterpretation-of-antibodies/
[38]https://www.merriam-webster.com/dictionary/titer
[39]https://www.merriam-webster.com/dictionary/titration

July 12, 2020 - Die Fehldeutung der Antikörper[40]/The Misinterpretation of Antibodies (Corona_Fakten)

Written and published in German by pseudonymous Corona_Facts (on Telegram at Corona_Fakten[41])

A closer look at antibodies is more important today than ever. After showing in my other articles that there is no proof of the existence of a pathogenic virus, because none of the claimed pathogenic viruses have fulfilled Koch's postulates, the "antibody" card has now been played by the vaccination advocates.

Their claim (which has been drilled into heads for decades) that antibodies are the indirect proof of a pathogen, or offer protection against a pathogen X, is based on an error.

This assertion has been repeatedly exposed as false. Since being asked again and again what these antibodies are, I would like to show in this article that antibodies are no proof of protection, nor that they work specifically as in the key-lock theory.

What is a titer increase?

Dr. Stefan Lanka[42]:

> "The increase is nothing more than the body's reaction to poisoning. When the body is poisoned, holes are torn in the cells by these poisons and the cells are destroyed. The body's reaction when cells break down is to form sealing substances (globulins), small protein bodies that immediately expand in acidic environments, become flat and cross-link with their hydrogen sulphide groups (in which energy is stored) with other proteins and other things. These cause blood to clot and wounds to heal and they seal our cells when toxins are injected into the body.
>
> Even if you get a blow on a muscle, (forming a bruise) or a blow on the kidney (especially sensitive), or the liver, there is an immediate increase in titer. The body reacts to this by sealing the damaged cells and sealing growing cells. It's like a house that leaks until the windows are in and sealed.
>
> They called this an antibody and even a specific antibody, which is not true. The binding property of these hydrogen sulfide-type proteins is non-specific, they bind to all sorts of things. You can manipulate this in the laboratory by changing the acid level, adding detergents that change the mineral concentration to achieve a binding or not.
>
> The blood of a pregnant woman is full of globulins to seal the placenta, which is constantly growing, to accommodate the baby. The blood of a pregnant woman has to be diluted 40 times to avoid a massive positive result in tests, such as an HIV test."

*

The approval of vaccines is limited solely to so-called "seroconversion."

All vaccines for Europe are approved by the EMA (European Medicines Agency) in London. Their demand for

[40]https://telegra.ph/Die-Fehldeutung-der-Antik%C3%B6rper-07-12
[41]https://t.me/Corona_Fakten
[42]https://www.youtube.com/watch?v=KexlGm1ixW8&t

proof of effectiveness[43] is limited solely to so-called seroconversion.

Seroconversion shows the formation of measurable antibodies in the blood of vaccinated persons, which are equated to a protective effect.

However, when assessing immunity or the effectiveness of vaccinations, this decisive limitation is again put into perspective by the fact that (almost) all current vaccinations are developed primarily to form antibodies.

[5] *Correlates of Protection Induced by Vaccination*, Plotkin SA, Clinical and Vaccine Immunology. July 2010, p. 1055–1065[44]

> "Although mucosal and cellular immune responses are clearly important to protection by some vaccines, most vaccines licensed today depend for their efficacy on serum antibodies."

See also, [6] *Immunologic correlates of protection induced by vaccination,* Plotkin SA, 2001. The Pediatric Infectious Disease Journal. 20(1):63–75[45]

This is very important for the development and approval of vaccines, as they have to prove their efficacy in this context – which is done without exception (and in many cases exclusively) by determination of provoked antibodies.

Even long-standing STIKO [German Standing Committee on Vaccination] members do not always seem to be aware of this correlation when they question the usefulness of titres after vaccinations – after all, the proof of efficacy of the respective vaccinations is based on the detection of precisely these antibodies.

According to Prof. Ulrich Heininger, STIKO member:

> "For none of the generally recommended so-called basic vaccinations is a routine control of the vaccination success planned or even advisable..." [7-Heininger, 2017[46]]

or the blanket statement regarding the measles vaccination,

> "that a positive laboratory result does not certify protection" [8 - Heininger 2016[47]].

If the latter were the case, the vaccination could not have been certified as effective and therefore approved...

However, in medicine we have known for decades that circulating antibodies are not synonymous with protection against a disease, a fact that can be understood even by laypeople using short examples.

If antibodies do indicate protection, how do the following statements of the Robert Koch Institute (RKI), STIKO and Arzneitelegram [German medical journal] fit in?

1. The Arznei [Medical] Telegram April 2001 states: [1[48]]

[43]https://www.aerztezeitung.at/fileadmin/PDF/2017_Verlinkungen/State_Entwicklung_Impfstoffe.pdf
[44]http://cvi.asm.org/content/17/7/1055.full.pdf+html
[45]https://europepmc.org/article/med/11176570
[46]https://www.rosenfluh.ch/media/arsmedici/2017/04/Impfungen-und-Antikoerpertiter.pdf
[47]http://www.kinder-undjugendarzt.de/download/47.(65.)Jahrgang2016/KJA_4-2016_Web.pdf
[48]https://www.arznei-telegramm.de/html/2001_04/0104041_01.html

"Vaccine-induced titre increases are also unreliable substitutes for efficacy.
What benefit or harm the vaccinated person can expect cannot be deduced from such findings."

2. The RKI (Robert Koch Institute) writes: [2 - Epidemiological Bulletin (EpiBull) No. 30 2012 p.299[49]]

> "For some vaccine-preventable diseases (e.g. pertussis) there is no reliable serological correlate that could be used as a surrogate marker for existing immunity.
>
> Furthermore, the antibody concentration does not allow any conclusion to be drawn about a possible existing cellular immunity."

3. Prof. Ulrich Heininger, a long-standing member of the STIKO (permanent vaccination commission) writes [3 - *Child vaccination manual. The competent decision-making aid for parents*, 2004[50]]

> "It is neither necessary nor useful to determine efficacy by blood sampling and antibody determination after a vaccination has been carried out. On the one hand, even an antibody determination does not provide a reliable statement about the presence or absence of vaccination protection, and on the other hand, it is simply too expensive."

4. RKI, 2008 - Sick in spite of vaccination? [4 - Epidemiological Bulletin 2008; 24:193-195[51]]

An example of this was a 14-year-old boy who had received sufficient basic immunization in childhood and a booster against tetanus six months earlier when he developed tetanus.

Laboratory tests revealed antibodies so high that, according to the definition of antibody titres, he should have been protected. But he was not.

This example shows that the theory of antibodies as "protective magic bullets" is wrong.

The RKI then coined the term "non-protective" antibodies.

5. Prof. Heininger - STIKO (2017) [7 - Heininger U. 2017. Ars medici. 2017(4):172-75[52]]

> "The most important thing right from the start: For none of the generally recommended so-called basic vaccinations is a routine control of the vaccination success planned or even advisable."

6. Prof. Heininger - STIKO (2016) [8 - Heininger U. 2016. Children and adolescent doctor. 47(4):227[53]]:

> "...there are not only false-negative IgG antibody results (which would not bother us if the child received an MMR vaccination as a consequence), but unfortunately also false-positive results.
>
> This must be put to parents so that they understand that a positive laboratory result does not certify

[49]https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2012/Ausgaben/30_12.pdf?__blob=publicationFile
[50]https://www.amazon.com/Handbuch-Kinderimpfung-kompetente-Entscheidungshilfe-Eltern/dp/3720524965
[51]https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2008/Ausgaben/24_08.pdf?__blob=publicationFile
[52]https://www.rosenfluh.ch/media/arsmedici/2017/04/Impfungen-und-Antikoerpertiter.pdf
[53]http://www.kinder-undjugendarzt.de/download/47.(65.)Jahrgang2016/KJA_4-2016_Web.pdf, page not found as of Oct. 23, 2024

protection and that they are much better advised to give their child a second dose of MMR."

*

So again confirmation that a positive laboratory result is insignificant.

The question arises again and again as to how you know that antibodies offer circulating protection when the highest authorities themselves say that a titer increase cannot prove protection exists.

When people have high antibody levels, do they still fall ill?

If no one can say exactly at what titer level there is real protection, why is the approval of a vaccine based on that exact reading?

Personally, this makes me more than a little suspicious.

The following points are of crucial importance in this discussion:

First, we cannot always be sure that the question of immunity can be clarified by means of an antibody determination for each vaccine (see below).

Second, the antibodies that show up in routine tests are not automatically those that provide protection (immunity), but sometimes only those that indicate that (apart from the measured protective antibodies that are not decisive for immunity, and which are certainly not measured) protective antibodies have been produced.

The measured ones are then a so-called surrogate parameter of immunity.

This complicated hypothesis is based, on one hand, on the fact that the immune response produces numerous different antibodies with different functions and, on the other hand, that the determination of the actually-decisive antibodies in some vaccinations would be too time-consuming for routine diagnostics.

Or to put it simply, the connection between antibodies and immunity is a myth.

Third, each 'immunity' is based on statistics and therefore relative whether it protects in the individual case or not.

The true reasons for the state of the body being "symptom-free" lie buried in other justifications.

[6] Plotkin SA. 2001. The Pediatric Infectious Disease Journal. 20(1):63–75[54]

> "Thus protection is a statistical concept. When we say that a particular titer of antibodies is protective, we mean under the usual circumstances of exposure, with an average challenge dose and in the absence of negative host factors."

Fourth, the question of protection from what exactly, is meant from the point of view of orthodox medicine, is also crucial.

[54]https://europepmc.org/article/med/11176570

For example, it is claimed that in the case of HiB and measles, much lower antibody levels protect against contracting the disease oneself (protection from disease) than is necessary to prevent transmission to others (protection from infection).

As there is still no scientific proof of the measles virus, the question naturally arises as to how the claim of protection from measles by antibodies can be claimed when the pathogen has not yet been proven. It's a fallacy.

So the horse is being put before the cart here: "I'm measuring some 'antibodies,' so I'm indirectly claiming to have a pathogen."

The measurable antibody titers after vaccination only shows the conflict of the immune system with the antigens, which are mostly coupled to adjuvants. Without these adjuvants there would be no antibody formation.

[KW note: in light of Richet's work on anaphylaxis as a disease state that can be induced by parenteral injection (into humans and animals) of foreign proteins and other complex, non-self molecules, it would be more accurate to say that any injection of non-self biological material into an animal or human can induce antibody formation.]

Here it becomes clear that the immune system is much more complex and does not function exclusively through antibody formation.

Herpes sufferers develop circulating antibodies against the herpes virus. Nevertheless, herpes can flare up again and again by weakening the immune system... And this occurs even when herpes antibodies are detectable.

Someone who is HIV-positive is also not happy about having circulating antibodies against HIV.

The hypothesis of antibodies does not work from start to finish.

If they can offer protection, how is it that people who have a sufficient titer still fall ill?

And how is it possible that the logic of antibodies in HIV was turned 180 degrees, such that high antibodies are deemed counterproductive?

Link to RKI Frequently Asked Questions[55] page

> "Q: What should be done if there are no antibodies against measles after a double vaccination?
>
> A: "If two vaccinations against measles are documented, protection against measles can be assumed with a high degree of probability, even in the absence of or borderline antibody levels."

No antibodies are required; protection through vaccination is always assumed, without providing any evidence for this. The phantom is always assumed, you don't even want to think in other directions. This is not science.

[55]https://www.rki.de/SharedDocs/FAQ/Impfen/MMR/FAQ_Uebersicht_MSG.html#:~:text=Sind%20zwei%20Impfungen%20gegen%20Masern,Impfung%20h %C3%A4lt%20wahrscheinlich%20lebenslang%20an.

To claim an "antibody" you need a "body"

As I have already pointed out in my other articles, there is still no evidence of [measles virus[56]] | [SARS[57]] alleged pathogenic viruses.

So if I don't have any evidence for a body, how can I claim to have defined specific antibodies and above all, how in God's name can I test for them?

You know the answer: it is simply not possible.

What does all this mean for the vaccinated person?

Since there is no scientific research on how often this phenomenon occurs where vaccinated individuals develop 'non-protective antibodies,' the possibility of disease still remains for each vaccinated individual.

A complete vaccination record and also the detection of antibody titres, as is often done for example with rubella or hepatitis B, is no guarantee.

Could the non-protective antibodies, invented off the cuff, explain the situation where after vaccination (e.g. against measles, mumps, rubella or whooping cough etc.) the vaccinated individual may have antibodies, but still fall ill (with measles, mumps, rubella or whooping cough etc.)?

Could they be the reason (apart from the alleged mutations that undermine vaccination protection) for the epidemics despite high vaccination rates, in which, more often than not, a large percent of the sick were sufficiently vaccinated?

Circulating antibodies alone therefore do not provide reliable protection; this has been orthodox medical knowledge for many decades.

On the other hand, the proof of efficacy in the approval of vaccines is based solely on the proof of the allegedly (sometimes?) protective antibody titres.

*

DIMDI, the German Institute for Medical Documentation and Information: Antibody titre is only a supplementary measurement.

A half truth from orthodox medicine – but still!

DIMDI, Cologne 2009, *Surrogate endpoints as parameters of benefit assessment*[58]

> "Antibodies are surrogate endpoints, i.e. substitute measurement quantities invented on the basis of random correlations...
>
> The use of surrogate endpoints is [...] not unproblematic.

[56]https://telegra.ph/Gerichtsprotokolle-best%C3%A4tigen-Es-existiert-kein-wissenschaftlicher-Nachweis-f%C3%BCr-das-Masernvirus-07-06
[57]https://telegra.ph/Alle-f%C3%BChrenden-Wissenschaftler-best%C3%A4tigen-COVID-19-existiert-nicht-07-03
[58]https://impfen-nein-danke.de/u/hta250_bericht_de.pdf

> In the past, there have been many situations in which relying on surrogate endpoints was misleading or had fatal consequences despite strong correlation with the clinical endpoint.
>
> This problem has been known for more than 30 years. [...] Some products that were approved on the basis of surrogate endpoints had to be withdrawn from the market at a later date because the benefit-risk balance was reversed in studies with mortality or morbidity endpoints."

*

So we have been dealing with problematic "substitute markers" for decades, which have repeatedly led to completely wrong results and assumptions.

Despite strong correlation (correlation is no scientific proof, only an indication) these were misleading and had fatal consequences.

It is time to correct this false hypothesis about antibodies.

Working aid on the topic of antibodies:

Stefan Lanka and Veronika Widmer from The Vaccination Lie: Does Vaccination Make Sense?[59] (July 2005)

…Commentary on (wrong) question: What are antibodies?

Correct question: What is measured if antibodies are claimed?

According to Pschyrembel, antibodies are "a possible reaction of the immune system," "Antibodies do not occur naturally."

Was this formulation chosen because it is known that people with a high "antibody titre" can fall ill in the same way as people without "titre" remain healthy?

Today's school of medicine distinguishes between the formation of foreign antibodies (pathogenic bacteria, toxins from viruses) and the body's own antibodies (tumour cells).

While we are told that after a vaccination the organism is protected by the formation of antibodies, conventional medicine also describes cases in which the presence of antibodies has adverse effects on the organism. For example, conventional medicine refers to allergies, AIDS, transplant rejection and autoimmune diseases.

The Robert Koch Institute explains that: An increased total immunoglobulin concentration in the serum indicates in the majority of cases an allergic disease. However, elevated levels can also occur in cases of parasite infestation or malignant tumours, for example.

In the case of inhalation allergies, IgE levels are moderately to greatly increased, depending on the symptoms and the number of allergens causing the allergy. A normal IgE does not rule out an allergy.

If antibodies are diagnosed after a vaccination, conventional medicine tells us that the person concerned is now protected.

[59] https://archive.org/details/Dr.StefanLanka-MachtImpfenSinn/page/n5/mode/2up

However, it is concealed that people are ill despite the presence of antibodies and people without antibodies remain healthy.

HIV-antibodies detected by a test produce a diagnosis of fatally ill – or at least – will become fatally ill.

Rubella antibodies detected by a test provide a diagnosis of – protected – to the affected person.

A contradiction in terms.

"Anti" bodies have never been detected.

Bodies, the immunoglobulins, which among other things play a role in the coagulation and cross-linking of proteins, have, however, been proven.

The word "anti" assumes that the immunoglobulins can only bind to certain proteins. All experiments ever performed, however, rule this out.

Whether or not binding takes place depends on the environment and state of the proteins: Whether acidic or basic, i.e. oxidized or reduced.

Every scientist who has carried out such experiments or studied them knows this.

Antibody tests: The procedure in the laboratory

First, the blood is separated from its cells and the larger proteins. This is done, for example, by a centrifuge. 99% of all tests performed are carried out with the patient's serum, the remaining blood liquid.

Now the laboratory technician is told what is to be detected by the antibody test. For this purpose, the so-called supernatant is then filled with corresponding, pharmaceutically produced, patented substances whose composition is kept secret (the government and the Paul Ehrlich Institute under its supervision keep strict secrecy).

If there is a measurable reaction, the test is evaluated as "positive." Up to now, it has been claimed that if antibodies were detected, immune protection has been proven.

The indirectly and not quantitatively determined amount of "antibodies" is then called a titer.

In the case of AIDS, however, a death sentence is pronounced, if necessary, because it was claimed that the antibodies are now indicative of the presence of the AIDS virus.

So it is not surprising that there is no scientific standard for titres and that the measurements are never comparable.

It is even less surprising then that there are no scientific criteria whatsoever as to when a titer can, should, may etc. be called "immune protection."

The laboratory technician is told that the test kit contains one or more proteins exactly corresponding to the shape of the microbe. If the laboratory technician would think about it, he would realize that under the appropriate conditions the form of the proteins could not correspond to that of the claimed microbe, because

the proteins are no longer in their natural environment. This is called denaturation of the proteins.

According to the delusional logic of compulsion, these unknown proteins are then named "antigens" by which the antibodies can be detected. The test kit also contains: e.g. dyes and substances that serve to produce a "positive" signal for reproduction.

The apparatus, into which the whole thing is then placed, is calibrated again with substances whose composition is kept secret and which are monitored by the aforementioned Paul Ehrlich Institute.

The fact that there are about 5% people in the entire population in whose blood, under laboratory conditions, little or no immunoglobulins can be detected, is not discussed and not investigated. These people are then called "non-responders" after vaccination and are poisoned with more and more vaccines according to delusional logical compulsion.

Blood group AB was invented for these 5% and according to compulsive logic, blood groups A and B, in addition to blood group 0 (40% of the population), for which little or no proteins that could clump in the test tube are found under the appropriate laboratory conditions.

The contradictions that arose from the dogma of blood groups were first dismissed by the discovery of a rhesus factor and later by the continuous introduction of thousands of sub-blood groups.

Stefan Lanka: Facts that refute claims about antibodies and a specific immune system.

1. Because there are so-called autoimmune diseases and so-called allergies that occur at lightning speed. In psycho-neuro-immunology this is called facilitation.

Comment: It cannot be the case that "specific" antibodies react against the "foreign" and then suddenly against "your own" proteins.

2. Changing "foreign" intestinal bacteria exist side by side with immune cells that are supposed to carry out the specific defense.

Comment: If there were specific antibodies, intestinal colonization would not be able to change.

3. Humans, mammals, bony fish and sharks exist. They produce immunoglobulins.

Comment: If there were specific antibodies, the offspring would be destroyed and breast milk would be toxic.

4. New proteins appear during the development of humans and animals, during shock and with age.

Comment: Since according to the immune hypotheses, which have never been verified but always falsified, "foreign" and "own" proteins are recognized in the thymus in early childhood and "antibodies," if the forming immune cells are sorted out against "own" proteins, proteins that appear later, such as hormones during puberty etc., would automatically lead to allergies, autoimmune diseases, destruction and death. This is not the case.

In principle, there cannot be "anti" bodies against viruses that do not exist. Here, the claim of the existence of specific antibodies and specific tests clearly turns out to be a crime and, consequently, genocide.

Comment: Since immunoglobulins are detected that are able to bind other proteins, there is "body." But not "anti." But globulins that first complete themselves in the oxidized, i.e. acidic environment (via reduced S-H groups, which in the oxidized state combine to form disulfite groups (–S-S-) and thus bind the protein chains together, which first makes up the complete immunoglobulin) are then able to bind proteins that are intended for transport, conversion or recycling.

Comment from Karl Krafeld:

An antibody can only be claimed if the body has been proven. Evidence (including through tests) of many virus antibodies is claimed without the virus being scientifically proven.

Orthodox medicine knows its own nonsense that it habitually spreads: "Antibodies form in infectious diseases and the detection of antibodies is evidence of protection against the disease."

According to orthodox medicine, HIV positivity should be the best protection against AIDS.

Every test measures what the test measures, but no one knows exactly what the test measures.

The tests react quite unspecifically to proteins, according to the coffee grounds reading principle: Is Eduscho or Tschibo better for coffee grounds reading?

In any case, no test can detect antibodies if the underlying body has never been detected…

*

To read the rest of the June 12, 2020 Corona-Fakten analysis, please see Northern Tracey translation[60] or the German original.[61]

[60]https://northerntracey213875959.wordpress.com/2020/11/26/the-misinterpretation-of-antibodies/

[61]https://telegra.ph/Die-Fehldeutung-der-Antik%C3%B6rper-07-12

Probit, probability unit as related to public deception campaigns, vaccines and other biological and chemical weapons.

Published Jan. 27, 2025

Working last week to track the development and use of specific result, potency and other key undefined and pseudo-defined terms from the 1902 Virus-Toxin law to the 1938 Food, Drug and Cosmetic Act, 1944 Public Health Service Act and beyond, I learned the word 'probit,' and the terms probit line, probit slope, probit function and probit model.

The earliest terms applied by military-public health officers to give the false public impression that specific results or potency for viruses, serums, toxins and antitoxins can be observed, measured, defined and described, were immunity unit or antitoxin unit.

Both "units" were derived, by dilution and arbitrary assumptions, from the median minimum lethal dose of a toxic, heterogeneous, unstable mixture of foreign (xeno- or non-self) biological substances, when injected into a group of living test subjects such as guinea pigs, mice, rabbits and dogs.

Probit is a portmanteau of probability unit, coined by Chester Ittner Bliss in 1934.

Wikipedia:[62]

> "The idea of the probit function was published by Bliss in a 1934 article in Science[63] on how to treat data such as the percentage of a pest killed by a pesticide. Bliss proposed transforming the percentage killed into a "probability unit" (or "probit")."

The terms probability unit and probit are related to biological product nomenclature such as immunity unit (in use by 1905); antitoxin unit (by 1909); international unit (by 1931); and international antitoxic unit (by 1946).

Probability unit is also related to toxicology and biological and chemical warfare nomenclature:

> LD50 - median lethal dose, dose of a drug or microbe that will kill 50% of the subjects receiving it, expressed as mass of substance administered per unit mass of test subject, ie mg of substance per kg body mass);
>
> ID50 - median infective dose, dose that has a 50% probability of producing a specified response to infection, considered as symptoms or signs of disease or death;
>
> TCID50 - tissue culture median infective dose; dilution of a virus required to infect 50% of a given cell culture.
>
> ED50 - median effective dose, dose of a drug or microbe that has a 50% probability of producing any precisely definable effect;
>
> Ct50 - measure of intensity of exposure; function of concentration and time, not of dose that actually penetrates the body; concentration applies as much to pathogens as to chemical agents; if concentration

[62] https://en.wikipedia.org/wiki/Chester_Ittner_Bliss

[63] https://www.science.org/doi/10.1126/science.79.2037.38

(C) is expressed in mg-m3 and time (t) is in minutes, the Ct is mg-min/m3

LCt50 (median lethal exposure intensity; function of concentration and time).

The related quantities LD50/30 or LD50/60 are used to refer to a dose that will be lethal to 50% of the dosed population within (respectively) 30 or 60 days.

One of the source documents is a 1970 report by World Health Organization consultant, titled Health Aspects of Chemical and Biological Weapons.[64]

At. p. 85:

Specification of toxicity and infectivity

The LD50 (lethal dose 50) of a drug or a microbe is the dose that will kill 50% of the subjects receiving it.
It may also be defined as the dose that has a 50% probability of killing any particular individual.

Correspondingly, and more generally, one can specify an ED50 (effective dose 50) as the dose that has a 50% probability of producing any precisely definable effect, for infective agents the term ID50 (infective dose 50) is used for the dose that has a 50% probability of producing a specified response to infection, considered in this report as symptoms or signs of disease or death.

Neither the LD50 nor the ED50 gives sufficient information in itself to form a guide to the relation between dose and effect.

The additional information needed is provided by the "slope of the probit line", which can always be calculated from the data required for the accurate determination of an ED50 (Finney, 1952, 1968).

This figure is dimensionless, so that its meaning is independent of the units of dosage.

At p. 88

Influence of local meteorological factors on the effectiveness of an attack with chemical weapons

…It appears that the probit lines of very toxic agents have high slopes.

It is legitimate therefore to take the critical distance as that at which the Ct corresponds to an LD50. This Ct is referred to as the LCt50. The probability of death will amount almost to certainty for an agent of high probit slope (5-10) when the Ct is only a little larger than the LCt50...

*

Vaccination — parenteral (outside the digestive tract) injection of mixtures of foreign biological material and synthetic chemicals — can be understood as maximizing exposure intensity or Ct: inserting the maximum concentration of poison into the living subject in the minimum amount of time.

[64] https://iris.who.int/bitstream/handle/10665/39444/24039.pdf

See also, 2011 WHO manual for the establishment of national and other secondary standards for vaccines:[65]

> Biologicals are "substances which cannot be fully characterized by physico-chemical means alone, and which therefore require the use of some form of bioassay."
>
> Biological tests (bioassay). A biological test is a laboratory procedure for the estimation of the nature or potency of a material by means of the reaction that follows its application to some elements of a living system (examples include animals, tissues, cells, receptors and enzymes). The potency of the material being measured is often defined in International Units or, in some circumstances, may be defined in terms of International System of Units (SI), by comparison with the reaction of the system to a biological reference preparation.
>
> International biological measurement standards (commonly referred to as WHO International Standards, IS) are substances, classed as "biological" according to the criteria outlined above, which are provided to enable the results of biological assays or immunological assays to be expressed in the same way throughout the world. The value assignment by the World Health Organization is in terms of an International Unit (IU) or another suitable unit. The unitage is attributed to a first international standard in an arbitrary manner after an international collaborative study has been completed.

[65] https://iris.who.int/bitstream/handle/10665/70669/WHO_IVB_11.03_eng.pdf?sequence=1

Anaphylaxis, allergens, immunogenicity, vaccines.

1980 GAO report to Sen. Abraham Ribicoff, Sen. Edward Kennedy and others, about allergenic products and vaccines.

Published Oct. 16, 2024

I found a 1980 General Accounting Office report while working on Part 5 of the 1798-1972 series, from a footnote (FN 298) in Terry S. Coleman's 2016 paper, Early Developments in the Regulation of Biologics.[66]

- 1980.06.06 GAO Answers to Questions on Selected FDA Bureau of Biologics Regulation Activities HRD 80-55 Ribicoff Kennedy[67]

As with all the other records I've collected, the 1980 GAO report is a forked-tongue blend of truth, lies, and mischaracterizations, and supports two of the main conclusions Sasha Latypova and I have drawn from our work:

All vaccines, and most if not all other heterogeneous, unstable products classified as biological products, have always been intentionally toxic to recipients — primarily through induction of anaphylaxis, also known as allergenic reactions and immunogenic effects.

The inherent toxicity of biological products, including all vaccines, has always been intentionally covered up through laws and regulations written to enable deniable mass poisoning to be carried out worldwide through vaccination programs.

That mirroring between the purported mechanism of action for vaccination or immunization (introducing a foreign substance into the bloodstream to elicit a systemic defensive response from the organism while characterizing the defensive response as beneficial to the organism) and the known mechanism of action for anaphylaxis (introducing a foreign substance into the bloodstream and observing the elicited, systemic defensive response as the organism suffers from the inflicted harm) is why Charles Richet's anaphylaxis work was so compelling to me when I read his Nobel lecture.

I had already identified the legal inversion of truth: publicly presenting the issuance of licenses to injure and kill without facing criminal or civil liability, as lawmaking and law enforcement.

Anaphylaxis as the basis for vaccination is a structurally-identical scientific inversion of truth: injury promoted as a form of protection.

Vaccination proponents cannot refute the anaphylactic, scientific theory of harm, because it's identical to the immunogenic theory of benefit, except the harms are observable in reality, while the claimed benefits are projected illusions.

In the same way, vaccination proponents cannot refute or even discuss the existence of federal, state and international legal instruments rendering the harms of mass poisoning by vaccination legally unstoppable through biological product law, public health emergency law and pandemic preparedness law, because the

[66] https://www.fdli.org/wp-content/uploads/2017/01/FDLJ-71-4-early-developments-in-regulation-biologics-5221114-open.pdf
[67] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/10/1980.06.06-gao-answers-to-questions-on-selected-fda-bureau-of-biologics-regulation-activities-hrd-80-55-ribicoff-kennedy-pagination-corrected.pdf

programs are built on the legalized manufacture, distribution and use of poisons masked as medicines. Without those laws in place, the acts themselves are evidently acts of criminal fraud, mutilation and homicide.

Without providing a detailed summary or analysis of the 1980 GAO report — available for interested readers to consider more fully[68] — here's a brief email exchange between me and Sasha Latypova prompted by the report.

Sasha Latypova

Just started reading this - great find. They basically say, "Oh yeah, we have 1,800 poisoning agents in biologics and everything else, and sheesh, we'll just keep using them because reasons.

KW

Exactly. Looked at it more. Allergenic product entered the law in 1970, at the same time Congress added vaccine to the biological product law for the first time. Allergenic product was defined by NIH in 1970 regulations as "products that are administered to man for the diagnosis, prevention or treatment of allergies."

Then it shows up in the 1972 NIH regulations in each separate vaccine section, with language such as this section for adenovirus vaccine -

> "(d) Extraneous protein. Extraneous protein capable of producing allergenic effects on human subjects shall not be added to the final virus production medium..."

Another example -

> "Additional Standards for Bacterial Products...Pertussis Vaccine...(a) Propagation of bacteria. Human blood shall not be used in culture medium for propagating bacteria either for seed or for vaccine. The culture medium for propagating bacteria for vaccine shall not contain ingredients known to be capable of producing allergenic effects in human subjects, except blood or blood products from lower animals other than the horse. When blood or a blood product is used, it shall be removed by washing the harvested bacteria. The bacterial concentrate shall be free of extraneous bacteria, fungi, and yeasts, as demonstrated by microscopic examination and cultural methods"

And in a miscellaneous section at the end, with language such as

> "(a) Extraneous allergenic substances. All manufacturing steps shall be performed so as to insure that the product will contain only the allergenic and other substances intended to be included in the final product. (b) Cultures derived from microorganisms. Culture media into which organisms are inoculated for the manufacture of Allergenic Products shall contain no allergenic substances other than those necessary as a growth requirement…"

I'm trying to think through more why Congress, when it pretends to be concerned at all, focuses on efficacy rather than safety concerns, when doing investigations about NIH lack of data, and so forth.

[68] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/10/1980.06.06-gao-answers-to-questions-on-selected-fda-bureau-of-biologics-regulation-activities-hrd-80-55-ribicoff-kennedy-pagination-corrected.pdf

I think it relates to the 1967 Iron Mountain Report[69] on substitutes for war and Silent Weapons for Quiet Wars[70] (1979) principles.

From Iron Mountain report:

> "…In the case of military "waste," there is indeed a larger social utility. It derives from the fact that the "wastefulness" of war production is exercised entirely outside the framework of the economy of supply and demand. As such, it provides the only critically large segment of the total economy that is subject to complete and arbitrary central control.
>
> If modern industrial societies can be defined as those which have developed the capacity to produce more than is required for their economic survival (regardless of the equities of distribution of goods within them), military spending can be said to furnish the only balance wheel with sufficient inertia to stabilize the advance of their economies.
>
> The fact that war is "wasteful" is what enables it to serve this function. And the faster the economy advances, the heavier this balance wheel must be. This function is often viewed, oversimply, as a device for the control of surpluses…"

Slowly making several generations of a country's people sick and dying early, is a very good way to quietly and deniably destroy the productive capacity of the country, by diverting the wealth to drugs and disability payments for people who can't be working to produce goods and services and generate true wealth. Goes along with de-industrialization, off-shoring of manufacturing, lots of other methods.

So what Congress was really interested in is, how efficacious are these poisons at destroying the productive capacity of the people who are injected with them and driving up health care expenditures to eat up a larger portion of overall national spending of human time and money?

And Congress members could, when they bothered at all, disguise that interest as questions about how efficacious these poisons are at obtaining the undefined "specific results" listed in the statutes going back to 1902 and the regulations going back to 1903 related to dating requirements for labels — "the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results."

Specific results eventually developed into potency definitions by 1947, i.e. "is interpreted to mean...specific ability...to effect a given result," with result still undefined, which is the definition for potency to this day. See 21 CFR 600.3(s)[71].

[69] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2022/12/1967-report-from-iron-mountain-substitutes-for-war.pdf
[70] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2022/12/1979.05-silent-weapons-for-quiet-wars-original-document-copy-29-p.pdf
[71] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-600/subpart-A/section-600.3

Methods of deceit underlying pathology, virology and genetics

Published Nov. 6, 2024

Jamie Andrews of the Virology Control Studies Project, interviewed by Sasha Latypova, condensed transcript
Video posted Oct. 25, 2024 and transcript: Video[72]; Transcript[73] (PDF)

Virology Control Studies Project on Substack[74] (Jamie Andrews)

Related

- June 15, 2024 - Perhaps the Most Important Work of Our Time: The Elusive "Virus", The Control Experiment, & Jamie Andrews75 (Conspiracy Sarah) - Includes many of the slides described by Jamie Andrews in the interview transcript below.
- Nov. 2, 2024 - The Spanish Flu Hoax & The Rosenau Contagion Study[76] (Jamie Andrews)

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Notes from KW

1. In conducting research to attempt replication, expose and thereby discredit many of the scientific protocols purporting to support conclusions drawn by pathologists, virologists and geneticists, Jamie Andrews and his colleagues have used living cell lines taken from human embryos through abortion, just as earlier researchers (including John F. Enders, Thomas H. Weller and Frederick C. Robbins as early as 1949,77 and Alex Jan van der Eb and Frank Graham in 197278 at pp. 77-82) also used cell lines and organs taken from human embryos through abortion.

Cell lines and organs taken from human embryos are taken by intentionally dismembering and killing living human beings. Abortion is a grave mortal sin, and I pray and hope that all scientists, physicians, mothers and fathers will stop intentionally killing human beings, and stop supporting and conducting all research using organs and cell lines taken from human embryos.

2. Andrews accepts claims made by suppliers of biological materials that I believe are not true and cannot be true. For example, at p. 7 of the transcript below, Andrews states:

"We can guarantee that there is no pathogen in the dish, because we have bought all of the reference material guaranteed to be uncontaminated. They negatively test and heat sterilize every single part to this. They heat sterilize the fetal bovine serum. They heat sterilize and negatively test the cell line and then they also put penicillin and streptomycin in, antibiotics, to get rid of bacteria and fungi contamination."

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[72] https://sashalatypova.substack.com/p/conversation-with-jamie-andrews-the
[73] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/11/2024.10.25-jamie-andrews-interviewed-by-sasha-latypova-transcript-with-kw-notes.pdf
[74] https://controlstudies.substack.com/
[75] https://conspiracysarah.substack.com/p/perhaps-the-most-important-work-of
[76] https://controlstudies.substack.com/p/the-spanish-flu-hoax
[77] https://pubmed.ncbi.nlm.nih.gov/17794160/, Jan. 28, 1949, Cultivation of the Lansing Strain of Poliomyelitis Virus in Cultures of Various Human Embryonic Tissues, *Science*
[78] https://wayback.archive-it.org/7993/20170404095417/https:/www.fda.gov/ohrms/dockets/ac/01/transcripts/3750t1_01.pdf - US-FDA CBER Vaccines and Related Biological Products Advisory Committee Meeting,[78] discussion of "adventitious agent testing, tumorigenicity testing, and issues related to residual cell substrate DNA of novel and neoplastic cell substrates used to manufacture viral vaccines, May 16, 2001, van der Eb testimony, transcript at p. 77-82

To the extent suppliers assert that cell lines have been "heat sterilized," I think they are making a false representation, because I think sterilizing a cell line with heat sufficient to kill non-cell-line living cells (so-called contaminants), will also kill the human embryonic kidney cells themselves, leaving them non-viable: not capable of dividing and growing in the petri dish.

The intrinsic heterogeneity and instability of living creatures — the irrepressible dynamism of organic life over time and in relation to God, surrounding living creatures and the non-living material world — is the same theoretical and practical hurdle that renders establishment, compliance and enforcement of true biological product purity and stability standards impossible.

I point this out only to emphasize that the diabolical deceptions carried out by physicians, pathologists, biologists and virologists for the past century have many, many layers.

3. I've added headers to the transcript, indicated by [brackets], to help readers orient to the topics discussed during the interview.

Jamie Andrews of the Virology Control Studies Project, interviewed by Sasha Latypova, transcript excerpts.

[1. How Jamie Andrews began investigating the scientific foundations of disease pathology and virology]

Sasha Latypova

Hello, everyone. Today I have an exciting guest. I would like to introduce you all to Jamie Andrews. I was very interested in his Virology Controls Project and work with the different PCR labs. Jamie, maybe say a couple things about you, your background and how you got into this project, what motivated you.

Jamie Andrews

Hi, Sasha. Thank you very much for having me on and for letting me introduce the project to you and all of your listeners.

My name is Jamie Andrews. I moved to France about six years ago from the UK, just looking to kind of escape what was going on in the UK, politics-wise [...] what happened with Brexit [...] I started to see the kind of UN agenda walls kind of slowly creeping in [...]

This project was born out of the fact of what happened in 2020. We had a vaccine passport here for nearly a year. In fact, just over a year, which saw me and more importantly, my kids banned from society. It was just over a year, which was a third of my eldest son's life at the time, not being able to partake in society at all: restaurants, theaters, cinema, anything like that, we were completely banned because we refused to take [vaccines]...But this was the setting for me to start to look at causation, start to actually challenge, "Well, if this supposed deadly pathogen is transmitting from person to person --"

My scientific background is practically none. I have a degree in geology, but that was 20 years ago. I know how to handle data. I know how to look at data, to compartmentalize it and to read published, peer-reviewed journals. But apart from that, it's been 20 years since I had any sort of accreditation, that was in geology. And to be honest, I very much saw what was the problems with, again, the UN's claim about anthropogenic climate change, because data didn't stack up to me then, even as an undergrad. So I was skeptical coming in whenever I saw the moniker of UN, the World Health Organization.

Immediately alarm bells started to ring that, "Hang on a second, what's happening in front of my face, and what's happening on the news." There was just a direct in-comparison between the two. It was incompatible: what was going on in front of my eyes and what the news said was happening.

This was no much more prevalent than in India where — my wife has Indian heritage and I knew a couple of people during 2020 that were working on the streets, in charitable agencies working with people that were in quote-unquote, "the most unsanitary conditions."

I was getting daily updates through, what the news was saying was peaking transmissible pathogens. And on the streets of New Delhi, I had a friend who was giving me daily reports saying, "Look, nothing's happening." They were saying there was this deadly pathogen there, but people living in malnutrition environments, diseased, supposedly, very poor and literally, sat on the streets next to each other with rubbish and all of the most what you would think of as conducive pathogenic-encouraging situation and these people weren't dying. If there was a transmissible agent, it just should have been—

SL

It was the same in San Francisco. I have friends there and I have properties nearby. When we looked at it, all the homeless population in San Francisco, which is kind of a similar situation, we thought, they would be dropping dead left and right. And there's nothing. There's nothing at all.

JA

It's strange, isn't it? The homeless population are supposedly immune. This led me to going and just typing into Google Scholar, I didn't really know what I was looking for. I have an A-level in biology, but past that I had kind of nothing to do with the area of biosciences whatsoever. It was to do with geology and that kind of mass spectrometry, really, they rely on, carbon dating and things like that.

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[2. Disease contagion studies; Milton J. Rosenau, (Director of US Public Health Service Hygienic Laboratory 1899-1909)]

The machinery and the mechanisms involved in virology, I had not a clue. But I started to look and [found] what turned out to be contagion studies.

They did actually give people what they considered to be virus directly up the nose. In some of the older ones, at the turn of the 20th century, such as the [Milton J.] Rosenau studies[79] which were conducted by the US Navy, where they took people who were displaying the symptoms or basically very unwell with what they considered to be the Spanish flu and they took all of their fluids, the BALF [bronchoalveolar lavage fluid], the mucus, the sputum, and did everything that they could to healthy people to try and infect them.

And lo and behold, this was a real kind of change for me in my life, was realizing that they all failed.

It was just this mind-blowing moment of going, "I've looked for causality, expecting there to be [causality]." And this isn't just with the influenzas and the coronaviruses. They've done it with all manner, with smallpox, with

[79] https://jamanetwork.com/journals/jama/article-abstract/221687

polio, with every single communicable disease and turned up nothing.

For me, it was a very eye-opening moment and a very liberating moment because it was "Okay, well, maybe disease doesn't work like this." That kind of led me to looking at, because we all saw that the pandemic, the scamdemic during 2020 was actually enabled by the PCR test. Really, that was the pure vehicle for trying to claim that somebody was sick.

They came up with all of these very inventive things such as asymptomatic transmission, where the symptom of you being sick with a deadly pathogen was you didn't have any symptoms...

[3. Reagents, equipment and methods for cell culture isolation of viruses and PCR (polymerase chain reaction).]

JA

So, I think everybody could see that the PCR test, on the face of it was not showing what it was claiming to be showing.

Now, up until this very point, really, although people have kind of pointed out that — and there were some anecdotal evidences with John Magufuli, for instance, who was the president of Tanzania, who did a press release that said that he PCR-tested a goat and a papaya and all manner of things that came back with positives.

It's still only really been anecdotal evidence.

The project that I formed about a year ago, just over a year ago, is finding people that are coming from biomedical backgrounds. Some of them are still working in there, but all of the people that I've consulted with and worked with are all published, peer-reviewed biochemists or microbiologists or even virologists and geneticists that were skeptical of the claims that were made.

We really wanted to go out and prove it, actually take the evidence.

One of the names that kind of came about in 2020 to me was Dr. Stefan Lanka, who did some control experiments during 2022 showing that the cell culture isolation of viruses was essentially fraudulent.

I took that as a benchmark to try and replicate his results and then further them because he actually, the story goes that he did the genetic sequencing, that he managed to take a control culture and genetically sequence it and build the SARS-CoV-2 genome out of essentially a cell line which shouldn't have SARS-CoV-2 in it.

Hence you have falsified their, the big genomic sequencing. That's what we're currently doing. We are currently in the process of genetically sequencing some control cultures...

What we did was we designed an experiment that took, Stefan Lanka's work took the exact protocol for the original isolation of SARS-CoV-2, which was funnily enough done in monkey kidney cells. It's not done in human cells. It's done in a monkey cell, which is rather strange, because the in vitro isolation...

Virologists have always said that you cannot just take a sample direct from a sick person and centrifuge it down and get virus. They can't supposedly purify a virus in such methods. There's supposedly not enough. You would have to have swimming pools' worth of fluids to be able to do this, according to them.

Their get-around clause with this — and this is the gold standard for supposedly isolating a virus — is to add more stuff.

It sounds as if it's contrapuntal to what they're trying to do, adding more stuff if you're trying to isolate it and get it something on its own. But that is what they do.

They claim to do this by growing it in cell lines. They take cell lines taken from banks, which sell reference materials. They are supposedly sterilized cell lines. They grow the cells out and then they inoculate them with the fluids of a sick person.

And when these cell lines break down, which is called the cytopathic effect, they say that that is caused by a pathogen, therefore they know that the pathogen is in their dish and they can then centrifuge it out and they have enough because they've supposedly grown it in this cell culture.

The issue is that when Stefan Lanka conducted these, he showed that, and actually it's kind of funny because the person that invented this method, the cell culture isolation, was a guy called John Enders. He did this in 1954, and he did it with measles, which was the very first "virus" he isolated.

In his un-inoculated culture, i.e. the one without any sample in, the cell line still broke down.

SL

The cells die outside of bodies, so there is no perpetual living cell line.

JA

That's right. All of this when you actually scratch beneath the surface is very well documented. That "starving cell lines causes them to die," it's quite obvious when you look at it on the face of it. There's a few key things to do with PCR that hopefully I can kind of point out.

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[4. Negative control study: growing cell line in nutrient medium without addition of allegedly pathogenic material, but following virus isolation protocols]

[One] is the fact that, if you have not isolated something, it's very difficult to find something.

What we have here in this top slide, in this plate is the negative control of our study.

We have the cell line. It's a human embryonic kidney [HEK] cell line which is supposedly the most robust clinical cell line to use. The hardest to break down. We chose to try and give ourselves the highest hurdle, to strong man, steel man the results that we were getting by taking the most robust cell line: the human embryonic kidney cell.

You grow them out in what's called fetal bovine serum. It's a nutrient medium. It's the fluid from around the heart of a baby cow and it contains all of the nutrients for a cell line to grow.

You take a pellet of the cell line and you grow them out to what's called confluence within a dish.

You want to get them to grow out, but not too much, so that they occupy enough of the dish, but still have room to grow. So here we have objective verification in these cell cultures. We use a thing called [Thermo-Fisher Scientific] Countess, which counts the amount of viable cells. So just living to dead cells.

Here you can see the cell viability counter saying that we have a very confluent dish. There's 95% good healthy

cells and still 5% left for them to grow into. They're not starving each other out, which they can do if you "overgrow" them, which was some of the problems that people say that Stefan Lanka had with his cell culture isolation. They claimed that he overgrew them. I don't necessarily believe that, but we wanted to just show that we were taking note of some of the problems that people claimed that they had and making sure that we kind of ticked all the boxes with that.

So this is our negative control to show that when cells are given the necessary medium, they grow and they stay healthy. And this is taken at Day 4. What you do is you incubate this and you grow them out. You leave them in an incubator, they grow out.

Now, in every single isolation-of-a-virus protocol, when they inoculate these cell cultures with a sample [of alleged infectious material], they remove the nutrient medium.

We have followed a standard protocol for isolating a virus. It's an adenovirus, which is because they use slightly different cell lines for isolating different viruses.

For the HEK, they isolate SV40, lentiviruses and adenoviruses. So we followed a protocol that is in a published and peer-reviewed literature where they reduce the nutrient medium to 2%, which is a very, very standard reduction. You will find that in practically every single viral isolation protocol.

When they removed the nutrient medium, we, this is the test, we fluctuated the amount of fetal bovine serum and left it in for four days. You can see that the cell line has died. You have these huge gaps in it. You also have what's called cincture and clumping where the cells die, the cell walls break down and they move together and clump and form plaques.

There's all sorts of morphology, which was noted by the contract research organization who did this. We employed the independent research. We blinded the outcomes. And this was done by this contract research organization who pointed out that, a lot of these morphologies that we see in cytopathic effect, i.e. the supposed breakdown of cell lines caused by a pathogen, were noted in all of these cell cultures.

If you look at the bottom here, the cell viability counter that we were talking about before has noted that, it should, that should actually say 34%, is a typo, but 34%, is dead at Day 4 [after] inoculation.

SL

How do they justify the removal of nutrients from the cells?

JA

That's an interesting question. What they call it is a maintenance medium. They accept that 10% fetal bovine serum is a what they call growth medium. Then they say, if you remove it down to 2%, because they do a wash when they put it in, so [the wash] lowers the overall concentration down, they call it a maintenance medium.

Well, it's just a misbranding, really. It's not a maintenance medium. It's starving the cells. Which is what we found, because we did this in over 90 cultures, 90 separate cell plates and we received cytopathic effects to the exact degree mentioned by the American Society of Microbiology, that if you have any cytopathic effect within two days and up to six days, you have a virus in your dish.

So we have achieved the standards according to the American Society of Microbiology without putting a pathogen in the dish.

And we can guarantee that there is no pathogen in the dish, because we have bought all of the reference material guaranteed to be uncontaminated. They negatively test and heat sterilize every single part to this. They heat sterilize the fetal bovine serum. They heat sterilize and negatively test the cell line and then they also put penicillin and streptomycin in, antibiotics, to get rid of bacteria and fungi contamination.

So they claim that it's solely a cause of a virus, but it contains, funnily enough, also the antibiotics are known nephrotoxic. So amphotericin, gentamicin, somewhat penicillin and streptomycin, are all known to cause renal disease.

And most, 90% of the cell lines that are used in these cell cultures are kidneys. They're kidney cells. So they are knowingly using nephrotoxic ingredients such as antibiotics. And then when the kidney cells die, they're saying, "Oh, look, it must be because of a pathogen and not because of the ingredients."

This is what a control study really does is, it's a very basic thing of just removing the independent variable and showing that the ingredients cause the observable effect that they claim is made by a virus.

Here, just very quickly, we put it down to 1%. They will consider 1% a starvation medium. They do have this in a few protocols, but we show that actually there's not a lot of difference between the cytopathic effect, between what they call a maintenance medium [2%] and a starvation medium [1%].

They are putting most of their cell cultures in this 2% medium which is causing the death.

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…[5. Positive control study: Growing cell line in nutrient medium with addition of sputum from asymptomatic, healthy human subject, also following virus isolation protocols]…

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[6. PCR tests, genetic sequencing; looking for an object that has not been isolated or identified.]

How this kind of plays out to genetics and PCR is that, and this is where the end of the road is, because every single virologist, and as you pointed out before, they will readily admit that starvation of cells does occur. And they will also actually readily admit that you don't necessarily have a virus.

You have to verify that you have a virus with other means. And those other means are actually genetics, eventually whole genome sequencing. They will usually just PCR test it. They will PCR test with certain things.

But here is the problem. If you have not isolated this virus, i.e. if the observable effects are happening irrelevant to whether you put a pathogen in, how do you know what you're looking for within genetics when you test them?

Because even if you take what they're saying is happening, [...] even if you accept that everything works in the way that they say it does, [in] which a nucleotide sequence is representative within PCR, so they take small nucleotide sequences which are supposedly specific to a virus or specific to whatever you are looking for, with the PCR test, bacteria and people and anything with a genetic sequence.

How do you know if you have never ever purified and isolated the thing that you are looking for?

How do you know what to look for when you are PCR testing it?

It's like saying, "I am looking for a new color that's never been seen before," if that makes sense. "Go out and

find me this new color that's never been seen before. " "Okay, what does it look like?" "Well, I don't know."

It's kind of impossible to say that, because you have no benchmark for what it should look like originally, that you can all of a sudden then find it in this soup.

And the other thing to note is the fact that, we've already seen that this is slightly easier, but within the cell culture, there is human embryonic kidney cell, there is fetal bovine serum, there's all manner of different cell lines.

For SARS-CoV-2, you are starting with, knowingly, the genetics of a monkey, knowingly, the genetics of a cow, knowingly, the genetics of a human sample. You already have a mixture, a wash of three different animals in this dish.

And geneticists will even say this, and they will agree with this, that a mixture of samples is very difficult because it's all stirred into one, because it's all a mixture.

The way that the genetic sequencing works is they break it down into very, very small fragments to then build it back up.

So when you're breaking it down into these very small fragments, how do you know that this one comes from a monkey, this one comes from a cow, this one comes from a person, and this one comes from a virus?

Well, it's very difficult, especially when they claim that, say, a monkey shares 99% of the same genotype as a person.

So here you have kind of the beginnings of seeing all sorts of problems, which are fascinating.

SL

Yeah, and I keep telling people, genetics is just as fake science as virology. You can go for a long time explaining that. PCR is funny: it's a collision of two fake sciences…

*

[7. Fluorescent dyes and PCR]

JA

That's right. I've got a video…

I'll just stop it there for the moment, because I just wanted to kind of run very quickly through...the basics of what is occurring in PCR.

In both of the methods of PCR, they use fluorescent dyes. They actively say that they are knowingly putting in a fluorescent dye whether that's in RT-PCR [Reverse Transcription Polymerase Chain Reaction] where they claim — and she's just explaining it now — that they put it in with a quencher and it binds to a specific nucleotide sequence. And then when they go through these cycles of amplifying it, the dye expresses.

If I am to break it down of exactly what they're doing within PCR, to make it simple so that people can understand, if you look at this picture at the bottom, this is a PCR machine broken down into its very, very simple, and it is actually a very simple machine when you look at it.

The reagents is where they claim the complexity is happening, but what they will knowingly tell you is that they take a sample of what they want to genetically sequence, or they find the target primers, target nucleotide sequence, and they put a fluorescent dye in it. They put a fluorescent dye knowingly in it. Then they put this sample in a thermocycler and heat it up. And when the dye fluoresces, the cameras pick up the fluorescence. They are putting a fluorescing dye in.

SL

And then picking up fluorescence.

JA

When it fluoresces, they say all of this story about why it fluoresced. When you look at it in those very, very simple terms, it is actually quite stupid. Because all of it is unseen. All of it is very complex in what they're saying. Is it happening? Because on the surface of it, they're literally just shining a camera and picking up the fluorescence. That's kind of going into the PCR. That's the core principles of what's occurring.

It's a very, very simple set of mechanisms. The only complexity is what's happening beyond the naked eye, beyond what anybody can see, where they say that the nucleotide sequence is binding up to the specific base pairs, and the reason why it's amplifying is because of da-di-da-di-da....It is just the story. To what degree that occurs, we don't know. You can't say with any specificity.

So just at the very core principles of what's occurring with PCR and whole genome sequencing, because this is even the most accurate, genome sequence, where they have.

For instance, the Wu Fan assembly80 for SARS-CoV-2, whole genome sequencing, Illumina sequencing, next generation sequencing, nanopore sequencing, all does the same thing, just a lot more times.

It's still a fluorescent dye. It's still taking these small packets. It's still, whenever it's fluorescing, they have the same thing. They just do it. Sometimes the reads, the small reads that you get out of it are half a billion reads that you get out of it, which is why it takes quite a long time.

Here we have actually part of the control experiments that we've done. We have actually done some controls and I would just go through some of the manuals.

Because it's quite enlightening. It's enlightening to me, when I start to actually look at things, the things that they give you, because more often than not, they do actually tell you just how spurious this stuff is.

The primers that we used in the control experiments that we did, we bought the most accurate primers available. So it's RT-PCR, reverse transcriptase polymerase chain reaction, which is all done in one supposed vial where they put it in, it reverse transcribes it from DNA to RNA, and then it has three genes. It supposedly doesn't just measure one nucleotide sequence. It measures three that are supposedly specific.

This is the most accurate PCR that money can buy. And yet in the manual, it specifically says this product is not intended to be used for therapeutic or diagnostic purposes in humans or animals. So anybody that has been given any sort of medical intervention based on a PCR test alone should very much read the manual. It's like buying a soft drink and on the soft drink it says, "Please do not consume this soft drink..."

[80] https://www.nature.com/articles/s41586-020-2008-3

SL

This part, this is a regulatory, so what people don't quite understand about diagnostic tests. It's actually, it's okay to have this statement because they never approved it as a standalone diagnostic test. You can have diagnostic tests, and I worked in the industry of CROs, contract research organizations, where we have our own tests that we made, on assays we made ourselves and validated, which we sell to professionals who then make a certain type of decision. And we were selling it to pharma companies to make their decisions about their drugs. It's not even patient diagnostics. And FDA allows you to do that.

But now this means that, what they were doing during this pandemic is forcing this analytical technique as if it's a diagnostic test on everyone. And nobody of course was told this. It's never been validated to diagnose any disease or condition.

JA

That's right. Who is making—? It's kind of plausible deniability, right? It's not on me and everybody's standing back going, "Well, we said it was for research use only" and so on and so forth.

But yet the frontline medics are kind of going, "You've appeared in hospital, you have some sort of respiratory problems, but we don't know what it is. Is it bacterial? Is it whatever?" And they do this PCR test and then start treating people on it.

SL

And even worse now, they send them to people's homes. It's absolutely terrible what they're doing.

JA

That's right. With the [Virology Control Studies] project, we hope to kind of unstitch what they're doing and show this. This is the types of questions that you need to ask to back yourself, legally, if you find yourselves in these positions in hospital, if you have family members that are unfortunately unwell, that you need to be able to back yourselves that—. Medics will, if they don't know what's wrong with you, which is seemingly nine times out of 10 these days is, their go-to is to kind of blame viruses and inject you with all sorts of stuff which as a lot of us are finding out is not a good thing to do…

Here's the other very important part to this is, is that, they claim to have a negative control as part of these tests. Now, the negative control here, they say, just contains nuclease-free water. That's not actually a negative control, because a negative control would be a healthy human sample. Because nuclease-free water is obviously not going to fluoresce, right? Because it's water. It's going to dampen down any fluorescence. So, of course, you're going to get a blank result out of that.

That's not showing that it's working. That's showing that when you put water in a machine, it doesn't—.

Interestingly enough though, interestingly enough during 2020, some of the very first few batches of accredited primers that were sent out were actually amplifying the negative control because the primers were so fluorescing that the negative controls were amplifying.

They use this down the bottom as their scapegoat. They say it's a thing called primer-dimer, which is where the primer attaches to itself. And it's quite actually a common thing when you read places like ResearchGate. ResearchGate have a lot of new lab techs and things to PCR and to the world of genetics saying, "My negative

control keeps amplifying. Can somebody help me out?"

These are the kind of rescue methods for basically failing these tests, is the fact that they just say, "It's primer dimer. Try putting less primer in."

Whereas actually on the surface of these things, it's maybe you should actually look as to why these things are failing. Because if a negative control amplifies, the test is junked, right? You have to legally junk it because that's what a negative control is there for.

This is quite eye-opening to me as a layman, is that working hand in hand with a lot of these accredited microbiologists and accredited geneticists involved in the project, I've worked with them very closely for about two years. And every single one of them has echoed the same sentiment to me in terms of finding out about their daily practices at the bench which was, they all get the remit. They all get the work in from above.

Pfizer comes in, they want to clinically test this drug or whatever. They know before they conduct the experiment what the experiment should look like. They know, for instance, on a PCR test that it should be amplifying here, the graph should look like this, and it should be an exponential curve here, here, and here.

When it doesn't happen in the way that they've preconceived, they don't say, "Oh, it's wrong, so we haven't found what we're looking for." What they do is they chuck everything out, make a few tweaks in terms of the protocol, and then run it again until they get the results that they conceived that they wanted in the first place.

To me as a layman, that was really jaw-dropping because it's kind of like, well, that's not really science, is it? That's not trying things and then if you don't get the results saying, "We haven't got the results, we don't think it works that way."

That is just changing your methodology until you find what you thought you wanted in the first place. And they all said the same thing. They all said that basically that's it. You're just employed to essentially do this kind of paint-by-numbers type thing of creating the image that you had in your head of what a positive result should look like before you start.

It's just been quite an interesting learning process from somebody kind of outside of the commercial science, if you want to even call it science. I'm not entirely sure whether it would fall under that bracket if you actually broke down what they're doing on a day-to-day basis.

*

[8. Cycle thresholds, manual baseline adjustments and PCR]

JA

…A lot of people that are challenging PCR rightly point out that, we've all heard about cycle thresholds [CTs], the amount that's being, the amount that's being amplified.

So here we have, they consider, there's a few different channels on here. So this is the FAM [fluorescein amidite] channel. So it's 40 cycles they consider as a positive result. 40 cycles is quite high. They claim that you're talking about only a couple of molecules of target nucleotide sequence at 40 cycles, so right here again in the most supposedly accurate primers kit, that they are saying that they will accept anything up to this 40-cycle threshold.

I'll just point out something that became interesting for us is that the positive control — so a positive control in science is what you are meant to be looking for. So it's meant to be purified the-thing-that-you-are-testing, right?

In PCR, it's a thing called an oligonucleotide, which is about 200 different chemicals that are all whizzed together and that they claim is purified target sequence. So purified nucleotide sequence that you're looking for.

And just again, as a layman, I would have thought that if you were testing the purified target thing that you were looking for, that would you really need it to amplify once, twice? I don't know.

To me, it's kind of like I've developed this test for an apple and the positive control that I have is an apple. You shouldn't think that it should be difficult to find the apple when the positive control is fully what you're looking for.

Yet here in this target, in this primer sequence, it's anything under 27, 27 cycles, which is actually not even that strong a positive indication, even in a test of sputum.

So it's quite strange to me that they can accept just such a kind of low degree. I've got a couple of videos here…

Just to recap on the first one is that he states that when you're moving this threshold about, it does actually change the CT value. So there can be a manual threshold change which will affect the whole thing, the readout of what you're getting…

Okay, that's enough of that sitting through it. But it's just to highlight the fact that they know that there are some manual threshold levels that affect the results that can be turned up or down, literally like a dial to reject or accept what they class as noise.

But we actually found this out through, it was complete happenstance. Unfortunately, every single other experiment that we've done, we've blinded the outcomes to the contract research organization.

Whereas when we came to PCR test these cultures, unfortunately, the person was let on to what we were trying to do. So we were getting them PCR tested for SARS-CoV-2, but they knew that the cultures that we were handing them couldn't possibly contain a virus.

And they were very suspicious about this, of course, as you would be. I had to have about an hour's-long meeting with the CEO as to why I was bothering doing this, which was very unorthodox because every single other time it's been very cursory, the information that they've wanted. You know, just "yes, sir, no, sir, three bags full, sir. Here you go. Here's the results of your experiment. Can we be paid now, please?"

So we, during this we spoke to the CSO, the Chief Scientific Officer who actually got put in touch with a geneticist that we were working with in our project and we were doing some investigation ourselves and they had run, trying to set up to use some of these primers on their machine.

They were actually borrowing a machine that wasn't known to them and so hadn't set up the channels correctly. There's three channels in this case, and they were used to only using two channels. They actually gave us the results back and we got a positive on one channel and a negative on another channel, which shouldn't happen.

The channels are just the fluorescent dyes. If you have the target sequence in there, they should all be positive or all should be negative. And then you just get the mixture and that's what provides the curves that you see, the amplification curves.

And we asked this geneticist, the independent, the contract research organization geneticist, "Do you have any idea?" Because they had done somewhere in the region of about 50,000 PCR tests during 2020.

And they said, "Oh, yeah, that's just the baseline threshold. You just need to up the baseline threshold on the

hex channel, the channel that was negative."

So she said, she admitted that this baseline channel, because it was set so low, was inhibiting the positive from coming through. It was essentially rejecting everything that it was calling noise. It was calling this noise floor low. What they admitted to is that, and when you actually study the literature, is that there is between the setting of the threshold and the baseline correction you can change the outcome by three to 15 cycles.

A lot of people think when they're just talking about thresholds, when it comes to PCR, "Oh, 35 cycles, it's not very accurate." Well, it's a little bit more complex than that, because 35 cycles doesn't necessarily mean 35 cycles, because if you've set the baseline correction, low or higher to that, it could mean anything from 20 to 45, or it could be 15 to 45, depending on how aggressively you've set the kind of internal thresholds to reject or accept what they call the noise floor.

So we got our results back here and "unfortunately," they said "I'm so sorry Mr. Andrews, but they've come back negative, unfortunately. Viruses do exist and whatever."

We had a look at these and these that are plotting on here are the positive control. We talked about just a little bit before. The positive control is meant to be purified what-you're-looking-for. And also within the manual, it says that anything over 27 is a fail.

Well, this is the cycle threshold read off of because you have to take where it becomes exponential is where you take the readout. Well, this was at 35 to 36 cycles, i.e. it's a failed test. It wasn't negative. What we think that they've done is they've turned up this baseline correction so high that the noise floor has pushed the positive control into giving a failed result.

It's very eye opening to us for a few for a few reasons. It was a bit of a gut punch because it came back negative. It wasn't negative. It failed. But we learned two very valuable things.

[One,] that you've definitely got to blind the outcomes to people if you want them to try and do some sort of unbiased science because they will change the results to fit what they want.

And secondly, the fact we've uncovered this seemingly volume knob in PCR testing which is very much a parameter that is accessible to a geneticist to manipulate the outcome of what's going on…

…If you want to get into the real, the funny side of PCR is, and actually how, just crap this stuff is really, the PCR thermocycler and some of these, the Quant 7, the most up-to-date thermocyclers, you're talking about $20,000 to $30,000 for one of these machines.

But when you actually break it down, as we talked about before, it's just a camera and a heating module.

They take a Peltier module, which is just a very simple, you can buy them for a few dollars from China, and you heat them up and then you reverse the polarity on the battery that runs them and they cool down very quickly, and that's all a PCR thermocycler is. Actually the digital side of it is really not rocket science. It's not a full computer processing power. It does very rudimentary things compared to even your basic laptops.

They have managed to put an entire PCR thermocycler into a battery-operated machine that you can use. And it's one time, and this was released by Pfizer, I think in 2022, called the Lucira. It literally is in your hand. It's a single-use PCR machine.

Now, they say it's actually LAMP [loop-mediated isothermal amplification], which the only difference is, the

reagents are exactly the same. The method of doing it is exactly the same. But in LAMP, RT-LAMP, they only heat it once. They heat it once at a consistent temperature, whereas in PCR, it just does cycles. But it has all of the working parts of the Quant 7 Thermo-Fisher Scientific in a pocket battery-driven device, machine.

That that's how crap the machine, the machinery is, when you actually start to scratch away at the surface of it.

I want to dispel the illusion that what is going on is this miraculous stuff and I want to pull away the curtain and it is the Wizard of Oz behind there pulling all of the gears and saying "This is very complex stuff."

And again, I have a little video of it occurring…

The big thing that I want to point out with that is, I don't know if you caught it right at the end there, but they admitted that the thing that they were looking for when they said, "Oh, the sample comes down and it mixes" and it does all the, they showed the loop-mediated stuff with all of the very complex nucleotides being knocked down in a big long row.

But then they said that the sample comes down and it mixes with that and it turns acidic. And the acidity makes the reagent turn yellow. So they fully admitted that actually what they're looking for is acidity.

SL

It's all this hocus pocus genetics. It's just a story. It's acidity. They're looking for acidity.

JA

And it kind of gets even worse than that because I've just bought one of these. This is an exact same thing, but it's reusable. So this benchtop thing, you get the reagents in this — in the little card. You get all the little reagents in a circle in the card, and then you can put them in and reuse this machine. It works on the same technology.

And in the manual, it says, "Avoid acidic foods before you use it." I wonder why that is. I wonder why you shouldn't eat acidic foods. Is it because it's looking for acidity?

And there's fair science that say when you are expressing symptoms, especially respiratory symptoms, that your mucus turns what?

SL

Acidic. It's a product of any kind of inflammation.

JA

I'm not saying that that's exactly how it works because I haven't actually, I'm due to receive this machine in a few weeks' time. I can tell you a little bit more when I do some of the testing on it.

But is it as stupid as just, it's measuring acidity? Because I think that we can all see that it is measuring something. People are sick, they test, it comes back positive. I think there is certainly some sort of correlation between where things test and where things don't.

Just at the bottom here that the World Health Organization have just approved this technology to be used, the LAMP-mediated thing, so these home PCR kits, they're trying to to take slowly the rapid antigen tests off of the market and replace them with these reusable desktop PCR machines because everybody knows that the antigen

tests are junk.

There is some semblance of it telling you whether you're sick or not. But if it is just as stupid as it is measuring acidity, it a) should be easy to show and b) easy to prove in a court of law or anything like that, that if they're basing this stuff off of fraudulent indications, they're claiming it's indicating one thing, whereas actually it's provably not…

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[9. Stefan Lanka, German court ruling on evidence of the existence of measles virus.]…

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[10. Innocence project, forensic DNA, inability of geneticists to distinguish human DNA from dog DNA.]

JA

…It's fair enough to start picking holes in that but one of the eye-opening things in my investigation and doing the R&D [research and development] for this project that I came across was a project called the Innocence Project, which was set up by one of the lawyers on the OJ Simpson trial, and another one called Greg Hampikian, who during the OJ Simpson trial, they were so put off by some of the forensics evidence, that they started to kind of dig into the National Institute of [Standards and] Technology [NIST], the kind of three-letter agency that was involved in forensics genomes, making sure that what was going on in court was, was it based on good science, all of genetic forensics evidence?

This Innocence Project, and Greg Hampikian, and the name is escaping me now. I've said his name so many times, but I can't remember. It'll come back to me. They went to the three-letter agencies looking for what is essentially a blinded test for forensics genetics sequencing. They asked the National Institute of Technology if they had any blinded tests of accuracy, to which jaw-droppingly, they said "No. We don't. We've never actually tried to blind known outcomes to genetics labs to test whether it's accurate."

They forced — this group, the Innocence Project — forced the National Institute of [Standards and] Technology to do it.

Here, if you read at the top, a 2013 survey by the National Institute of [Standards and] Technology[81] asked analysts from 108 labs to look at a three-person mixture and determine if a suspect's DNA was present.

They took this DNA petri dish, they put three people in, and they said, "We know the perpetrator of this crime. Can you tell us which one it is, A, B, C, or they're not in the dish?"

70% of the analysts said the suspect might be in the mix. 24% said the data was inconclusive. And just 6% arrived at the truth: the suspect was not in the sample. So out of 108 different labs, 6%, it was eight labs, got the correct answer.

They say it's 99% accurate, all this DNA stuff. But actually when you blind the outcomes, when you know the outcome, and I've asked this of maybe a couple of hundred geneticists. Now I do the same thing every time. It's "if I took a DNA sample, if I took a pool of a hundred animals, and I, they were known to me, but you didn't know which animals they were. And I took the sample of one animal. Could you tell me what that animal was?"

[81] https://nvlpubs.nist.gov/nistpubs/ir/2021/NIST.IR.8351-draft.pdf

And every single one of them goes, "Yeah, of course I could."

And I just say one simple thing: "Could you show me a paper where you do this?"

And it doesn't exist. It doesn't exist. They are complete—, it's like garlic to a vampire. They don't like being blinded. In fact, the entire forensics geneticists' union or whatever it is, have actively rallied against being blinded to the outcomes.

They want to know basically who they think the perpetrator is before they start any of these genetic sequencing.

Here it says the same, Innocence Project.

> "Greg Hampikian, a biology and criminal justice professor at Boise State University and director of the Idaho Innocence Project, was a defense expert in the trial and felt sure the analysts had reached their conclusion because of unconscious bias. They knew a great deal about the case, including that the detectives believed Robinson was guilty.
>
> To test his suspicions, Hampikian and cognitive neuroscientist Itiel Dror of University College London sent the DNA data to 17 other analysts and asked them to interpret it without any information about the case. Only one agreed with the original analysts."[82]

Again, less than a 10% outcome when you blind the outcomes to even within forensic science which, I have to tell you, Sasha, I have no interest about getting into because the implications for showing that potentially forensic DNA testing is not as it says it is, is mind-blowing. Absolutely mind-blowing.

SL

It should be because...there are famous, and I can send you references to that, there are news stories in articles saying that people do these blinded tests sent out for the results. These forensic supposedly DNA tests cannot tell the difference between a dog and a human.

So they send dog DNA—. There are numerous examples. There are also examples where, for example, people who received bone marrow transplant, they have different DNA now. So their DNA changes.

It's also not clear whether sampling from one part of the body produces the same results sampling from another part of the body.

Because not only they don't do these validation tests, they also don't do the repeat test. For example, if this first experiment with 108 labs was repeated, would it be the same 6% that come back with correct answer or a different 6% or 3% or no? What does it look when you test, retest?

JA

That's right. Essentially, there is no repeatability within it, even on first go, because you — and I've come under quite a lot of flak for kind of just even pointing this out — because people go, "Are you trying to tell me that—?"

It's astounding to people that work in, say, engineering and mechanical engineering are things that, aviation. I was chatting to a bloke on Twitter that's in aviation and insurance, so they quite clearly have, when things go

[82] https://www.themarshallproject.org/2015/06/24/the-surprisingly-imperfect-science-of-dna-testing

wrong, it's very evident that they go wrong. The plane falls out of the sky.

The problem with a lot of biology is that, well, there is nothing tangible to go by. It's not like a failing system. You can't really see its working parts. You are totally kind of reliant on what's happening within the petri dish and unless you specifically go and you specifically benchmark test it against something that's happening in reality, like, for instance knowing an animal that you've chosen or knowing a person that you've chosen and reverse engineering it, there's no way of easily showing that.

So it's eye opening to a lot of people that these things haven't been done before within these areas of science that, to an engineer, for instance, they just say, "Well, they must have done it because if they haven't, that's mental."

But it's mental. It's mental. That's it. They haven't done it. Not only have they not done it, is that when they in the very, very rare instances that they do do it, they fail massively, massively badly…

This is the background that we have going on, there's quite clearly a lot of holes in this thing. They tell us on the surface "It's 99.9 accurate, we never get anything wrong and this is exactly how it works."

Whereas I hope that you can see that they openly tell you that some of the things that they're measuring are just the fluorescent dye that they're putting in, that it turns acidic and they're measuring acidity, that there are just wholesale volume knobs to turn up and down the positive or negative results that they're getting.

And then even when you come out right out the back, even when they're very confident in saying it, that actually when you blind test the results they can't tell the difference between a lizard or a dog or a human being. That's kind of it in in a nutshell the background towards what is the, I would say, pseudoscience of, you know, genetics.

SL

Those two are pseudo-sciences, the virology and genetics, and then the PCR test, it's combined. This is fascinating and I hope more people subscribe. Is Substack your primary?

JA

Yeah, Substack is where we're going to be releasing all of the results. It's an open-source project. We welcome people getting on board. The whole point is, is that we're trying to dispel the mysticism around science.

There's this thing that scientists are this protective breed in white lab coats and everything that goes on behind closed doors is very, very technical and you can't understand it as a layman. I want to lift the lid on that and I want to bring people into the laboratories.

So we're doing all of these experiments. We're trying to show them in as communicable and easy a way as possible. We are even going as far as taking video. We have video to release of the experiments taking place in a couple of the CROs. We're releasing every single piece of material to the general public as they want it to use in an open-source manner in any way that they want to use them.

Whether it is people being unfairly dismissed from work or people trying to be forced into taking vaccinations or people in school trying to not have vaccine mandates at school for their kids.

Take this work and use it to defend yourself and say, "Look, this science is not settled. You cannot force us to do anything," otherwise you're going—.

I want to empower people to be able to defend themselves, both knowing how fraudulent this science is, and also, to make sure that people trying to enforce all of these ridiculous politics on people, are legally liable for what they're doing.

That's the project that I'm running. It's available on Substack, putting all of the information out there. And if you sign up for free, the email addresses, we're keeping them. The final, all the experiments, the whole genome sequencing that we're doing at the moment, the PCR testing will all be put up into one manuscript that we will be emailing to everybody in one kind of large piece of paper.

We're very aware that there is not a single scientific journal that will publish this. And I don't want it published. It's about an open-source and a decentralized way of getting people moving forward and unstitching the problems that we're seeing in science today and the problems of why 2020 occurred...

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Pesticides and vaccines; microbiology and pathology nomenclature; scientific, medical and legal deceit and deceivers.

Published Dec. 24, 2024

I think the attached paper is important, and may be useful for those responding to the polio vaccine defense being mounted currently, as public vaccine hostility grows: Nov. 1953 - Public Health Aspects of the New Insecticides[83] (Morton Biskind, American Journal of Digestive Diseases)

I found a reference to it in my files when I did a search on organophosphate, because I'm trying to untangle what was happening in the late 1940s and early 1950s that made the Enders-Weller-Robbins-Peebles; Watson-Crick and Salk-Sabin mis-direction research need to be in the forms those mis-directions were.

For deconstruction of some of those scientific deceits and the pseudo-scientific methods used to perpetrate them, see the work of Stefan Lanka and Jamie Andrews, linked below, including Lanka's 2015 paper (Dismantling the Virus Theory[84]); Lanka's 2020 4-part series (The Misconception Called Virus); Andrews' 2021 report (The Lansing Strain of Polio[85]); and Andrews' November 2024 interview with Sasha Latypova (Virology Control Studies Project).

The reference in my files was a Feb. 8, 2003 report by Jim West published at Weston Price: Feb. 8, 2003 - Pesticides and Polio: A critique of scientific literature.[86] Jim West was writing in 2003 about Morton Biskind's 1953 paper.

Morton Biskind's work was suppressed and then allowed to partially surface with Rachel Carson's Silent Spring in June 1962, but Carson's work focused on organochlorine compounds, especially DDT, not organophosphates like parathion and cell debris from cells and tissues used in vaccine production.

Organophosphates include DNA, RNA and ATP.

Their main benefit for the killers, as far as I can tell currently, is that they are not persistent. They break down, especially within humans and animals, into constituent molecules that cannot be clearly traced back to the source of the poisoning.

So they can be sprayed on people and animals, coated on food, used as additives for food and drugs, and injected directly through vaccines.

And then the neuro-muscular and other damaging effects can be falsely attributed to viruses such as poliovirus, followed by vaccine production and vaccination programs built on the false foundation of the virology, using the false isolation and propagation methods described in the Enders papers.

*

[83] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/12/1953.11-paper-biskind-morton-public-health-aspects-of-the-new-insecticides-american-journal-digestive-diseases.pdf
[84] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/12/2015.06-dismantling-the-virus-theory-stefan-lanka-wissenschaftplus.pdf
[85] https://viroliegy.com/2021/10/27/the-lansing-strain-of-polio/
[86] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/12/2003.02.08-jim-west-report-biskind-pesticides-and-polio.pdf

Oct. 27, 2021 - The Lansing strain of polio[87] (Jamie Andrews, ViroLIEgy):

> "The Lansing strain of Polio is one of three strains used in the Polio vaccine.
>
> It was created through the emulsified brain and spinal cord of an 18-year-old boy from Lansing, MI. The emulsified goo was injected into the brains of monkeys which then had their brains and spinal cords emulsified and transferred into other monkeys 15 times. This process was repeated into cotton rats and eventually into the white mouse.
>
> This continually passaged goo was widely used for Polio research and was the one used by John Franklin Enders during his Polio tissue/cell culture experiments which lead to the discovery of the "cytopathogenic effect" still used today to indirectly state that a "virus" is present in the cell culture soup.
>
> Below are two full studies from 1939 by Charles Armstrong which detail the grotesque Lansing strain transfer from boy to monkeys to rats to mice.
>
> - 1939.09.22 PHS Public Health Reports Experimental transmission of poliomyelitis to the eastern cotton rat[88] (Charles Armstrong)
>
> - 1939.12.29 PHS Public Health Reports Successful transfer Lansing strain poliomyelitis virus from cotton rat to white mouse[89] (Charles Armstrong)
>
> No purified/isolated "virus" is ever presented in either paper nor is pathogenicity proven.
>
> Beyond creating experimental disease in some animals through brain injections of ground up tissue goo, the only outcome from these studies was that they ultimately led to cheaper test animals being used for Polio experimentation..."

*

Nomenclature

From my reading of the work by Lanka and Andrews, about the work of Armstrong, Enders and others — viewed in the light of how lawyers, legislators, military officers, public health officers, drug companies, physicians and university researchers have (since 1902) constructed a legalized system to covertly deceive, poison and kill lots of people — I don't think it's correct to say that "viruses don't exist."

I think virus is one of many terms used to denote cell products made and used by living cells, tissues, organs and organisms; and cell fragments of dying, disintegrating and dead cells and tissues.

Other terms include proteins, lipids, peptides, nucleic acids, amino acids, enzymes, neurotransmitters, hormones, organophosphates, organochlorines, alkaloids, toxins, antitoxins, toxoids, rickettsia, antigens, toxigens, antibodies, endotoxins, exotoxins, endosomes, exosomes, pathogens, immunogens, viroids, virions, prions, prodrugs, receptors, sugars, salts, terpenes, flavonoids, steroids, fatty acids, cytokines, phages, phagocytes,

[87] https://viroliegy.com/2021/10/27/the-lansing-strain-of-polio/
[88] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/12/1939.09.22-phs-public-health-reports-armstrong-experimental-transmission-of-poliomyelitis-to-the-eastern-cotton-rat-armstrong-paper-at-1719.pdf
[89] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/12/1939.12.29-phs-public-health-reports-armstrong-successful-transfer-lansing-strain-poliomyelitis-virus-from-cotton-rat-to-white-mouse.pdf

lymphocytes, macrophages, dendritic cells, acellular life, non-cellular life.

That list of terms is not exhaustive. The authors of scientific literature over the last few centuries have invented hundreds of words to describe things they've seen or speculated about during their investigations into microscopic life forms and how they live, use energy, reproduce, exchange information with each other, weaken and die.

I agree with Lanka's main point as I understand it. Viruses, understood as cell products and cell fragments, don't cause disease.

Cell products and cell fragments are caused by disease, understood as poisoning; viruses are the result of disease, the body's response to disease.

Cell stress, cellular efforts to regain equilibrium or homeostasis, and cell fragmentation and death: all result from living organisms' responses to acts of poisoning.

Poisons can be produced in nature by non-self living cells and larger, more complex living plants, insects, fish, reptiles and mammals. Bee venom, for example.

Poisons can also be produced by men using methods of synthetic chemistry developed for manufacture of pigments, dyes, fertilizers and pesticides. The organochloride Paris green, for example, was first manufactured in 1814 for paints but widely used to kill insects and rodents by 1867.

Where poison is found, traces or signatures of cell fragments of living, dying and dead creatures are also found.

Where poison is used on more than one person at a time, for example, by spraying crops, animal herds and human settlements, or conducting vaccination campaigns, outbreaks of disease are found.

Virus is one among many names for the infinite diversity of cell products and cell fragments that result from defense mounted by a self against non-self organisms, cell products and cell fragments introduced into the self.

During the 20th century and up to the present, the two primary routes of administration to get natural and synthetic chemical poisons into humans and animals, are pesticides (herbicides, insecticides, rodenticides, biocides...) and vaccines in injectable, oral and spray forms.

Poliomyelitis is one among many names for diseases (individual cases and outbreaks within populations) of brain, spine and nerve disorders caused by mass poisoning.

In 1840, the symptom cluster was called Heine-Medin disease. In 1885, another form was called Strumpell's disease II. Polio has also been described using the terms infantile paralysis, flaccid paralysis, Theiler's encephalomyelitis, Guillaine-Barre syndrome, multiple sclerosis, myasthenia gravis, meningitis, hepatitis, encephalitis, amyotrophic lateral sclerosis, amyloidosis, chronic fatigue syndrome, autism spectrum disorder, and sudden infant death syndrome.

Polio has not been eradicated. It has been renamed. Many times.

*

Lanka and Andrews, as far as I know, do not attribute the "misinterpretation" of viruses to intentional, vicious, willed deceit.

My views differ from theirs on that point. I think that the deceit surrounding the term virus, the field of virology, and the derivative field of vaccine manufacturing, is intentional. Private and public research funding organizations and university, corporate and government scientists, physicians and publishers who have published papers purporting to describe methods to isolate viruses, methods for using isolated viruses to produce vaccines, and methods to demonstrate the induction of immunity by vaccines, did not "forget how to science," to borrow a phrase from Sage Hana.[90]

They didn't fund, conduct or report on negative or positive control studies, because their goal was not scientific knowledge. Their goal was to deceive the public, to facilitate public poisoning for as long as possible.

Lawyers, legislators, military officers and civil administrators built communicable disease control and biological product law and vaccination policy and programs on those false scientific foundations. They didn't forget how to law. They intentionally built law to legalize deception and poisoning, to enable scientific and medical fraud to be reproduced and deepened over many decades; to block attempts to expose the scientific misconduct and fraud as such; and to block attempts to stop all vaccination programs.

*

In 1937, Congress appropriated funds for the Public Health Service "for investigations to determine the possibly harmful effects on human beings of spray insecticides on fruits and vegetables." Pesticide spraying and chemical weapons had already been used for many decades and some of the harms were already understood. With this budget item, Congress brought pesticide application and the study of the harmful effects officially into US government law and programs. Source: 1937 Congressional act.

In July 1939, the Journal of Experimental Medicine published a paper by Rockefeller Institute investigator Leslie T. Webster. Webster assumed that "rabiesvirus" caused disease symptoms; purported to demonstrate the "immunizing potency" of antirabies vaccine by injecting poisonous substances into inbred W-Swiss white mice; and used measurement of "antibodies" as a surrogate endpoint or proxy assumed to indicate immunity. Source: 1939 Webster paper.

As Sasha Latypova has reported, no later than 1913, Charles Richet and others investigating induction of anaphylaxis by parenteral (outside the digestive system) injection of complex non-self biological materials (bacteria, plant and animal proteins and lipids, for example) knew that "white mice and some breeds of rats do not experience anaphylaxis.91" Source: Sept. 6, 2024 interview of Sasha Latypova by Jane Ruby.

The scientific misconduct methods described in the 1939 Webster paper formed the foundation for all subsequent demonstrations of the alleged potency of vaccines, including procedures vaccine company executives claimed had been performed by in-house scientists, and procedures US government officials claimed had been performed by scientists working in the National Institutes of Health Division of Biologics Standards.

The forms of scientific misconduct in virology and in vaccine manufacturing and regulation, and the forms of cover-up mechanisms adopted to shield the misconduct from public view, have changed during the past 85 years.

The substance has not.

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[90] https://sagehana.substack.com/p/they-didnt-forget-how-to-science

[91] https://bailiwicknews.substack.com/p/on-vaccination-as-intentional-induction

In September and December 1939, Charles Armstrong published two papers in the US Public Health Service journal Public Health Reports.

Introductory paragraph, Sept. 22, 1939 Armstrong paper:

> "Through the courtesy of Dr. Max Peet, of the Department of Surgery, University of Michigan, we received on August 28, 1937, a sample of brain and cord from an 18-year-old boy, one of several bulbar cases of poliomyelitis which occurred at Lansing, Mich., during that summer. A strain of virus was recovered from the material which has now been through 15 monkey passages and which clinically, and pathologically as reported by Surgeon R. D. Lillie, is apparently a strain of poliomyelitis. Neutralization tests with this virus have not been done."

Armstrong stated, without evidence, "a strain of virus was recovered," and attributed the presence of what he called poliovirus to transmission of disease from person-to-person.

In truth, Armstrong was describing cells, cell products and cell fragments produced by the 18-year-old boy's human body in response to poisoning from pesticides, from vaccines (vaccines bearing smallpox, diphtheria, tetanus, pertussis and influenza labels were in use by 1937) or from the combined effects of pesticide exposure and vaccination.

These three 1939 papers — one by Webster and two by Armstrong — set the frame for the next 85 years of scientific, medical and legal misconduct and deception of the public to believe false premises.

The public was led to believe the false premise that viruses cause disease, when in truth, poisons cause disease, and sub-visible substances found in sick organisms (variously termed viruses, toxins, antitoxins, antibodies, proteins, enzymes etc.) result from poisoning. They are part of the healing process.

The public was led to believe the false premise that vaccines cause immunity to disease, when in truth, vaccines are poisons, and cause disease.

*

In 1953, Connecticut physician Morton Biskind published a paper, Public Health Aspects of the New Insecticides, in the American Journal of Digestive Diseases.

Biskind wrote:

> "In 1945, against the advice of investigators who had studied the pharmacology of the compound and found it dangerous for all forms of life, DDT (chlorophenothane, dichlordiphenyl-trichloroethane) was released in the US and other countries for general use by the public as an insecticide...
>
> Soon after the introduction of DDT for widespread use as a household, public health and agricultural insecticide, it became evident that virtually all forms of insects were propagating strains completely resistant to this compound...
>
> One after another new compounds were introduced...
>
> In addition to numerous variants of DDT itself, in widespread use appeared chlordane, toxaphene...benzene hexachloride,...lindane...heptachlor, and finally...the incredibly deadly aldrin and dieldrin, both chlorinate naphthalenes....

> In addition, the organic phosphorous compounds, closely related to the "nerve gases" of chemical warfare and lethal for man in minute doses, have also been widely used in agriculture — parathion, tetraethylpyrophosphate,... hexaethyltetraphosphate...malathion and others...
>
> In man, the incidence of poliomyelitis has risen sharply; there has been a striking increase in cardiovascular diseases, in cancer, in atypical pneumonias and especially interstitial pneumonitis in babies and children, in retrolental fibroplasia among premature infants, in conditions involving excessive fatigability and muscular weakness, in hepatitis and in obscure gastrointestinal and neuropsychiatric disorders often attributed to a new "virus" (or "virus X")." Source: 1953 Biskind paper.

*

In 1949 and 1954, medical scientists led by John F. Enders published a series of three papers, purporting to build on the virus isolation and propagation work of Charles Armstrong, using the so-called "Lansing strain" of the alleged polio virus and alleged strains of measles virus.

- 1949.01.28 - Cultivation of the Lansing Strain of Poliomyelitis Virus in Cultures of Various Human Embryonic Tissue[92] (John F. Enders, Thomas H. Weller and Frederick C. Robbins, Science, paywalled by AAAS)

- 1949.08.24 - Cultivation of Poliomyelitis Virus in Cultures of Human Foreskin and Embryonic Tissues[93] (Thomas H. Weller, Frederick C. Robbins and John F. Enders, Proceedings of Society for Experimental Biology and Medicine, paywalled by SagePub)

- 1954.06.01 - Propagation in Tissue Cultures of Cytopathogenic Agents from Patients with Measles[94] (John F. Enders and Thomas C. Peebles, Nature, paywalled by SagePub)

In 2002, Maurice Hilleman cited Enders' January 1949 paper as "the breakthrough technology...of cell culture propagation of viruses that led to the development of poliovirus and a large number of other vaccines."

Hilleman's career included work at the company now known as Bristol-Myers Squibb developing a vaccine purportedly against the disease named "Japanese B encephalitis," service at the Walter Reed Army Institute of Research as chief of the Department of Respiratory Diseases (1948-1957) followed by work at Merck as head of the virus and cell biology department at West Point, PA, where he developed "most of the forty experimental and licensed animal and human vaccines for which he is credited." Sources: 2002 NIH-NIAID Jordan Report, Vaccines and the Vaccine Enterprise: Historic and Contemporary View of a Scientific Initiative of Complex Dimensions (Hilleman); Wikipedia.

*

In 1931, Joseph Smadel graduated from Washington University School of Medicine. In 1933, he was a member of a team that claimed to recognize an outbreak of St. Louis encephalitis, attributing the outbreak to mosquito-borne encephalitis virus. Smadel then worked at the Rockefeller Institute in New York City.

In 1940, Smadel joined the US Naval Reserve and went on active duty with the US Army Medical Department Professional Service School (MDPSS) in August 1942. By 1953, The MDPSS had been renamed the Walter Reed Army Institute of Research (WRAIR). Smadel was assigned to the European theater as Chief Virologist in

[92] https://www.science.org/doi/10.1126/science.109.2822.85
[93] https://journals.sagepub.com/doi/abs/10.3181/00379727-72-17359
[94] https://journals.sagepub.com/doi/abs/10.3181/00379727-86-21073

May 1943. After the war, Smadel served as director of the WRAIR Department of Virus and Rickettsial Diseases.

In early 1954, Smadel was tasked with writing the production protocols for the polio vaccine.

In 1956, Smadel transferred to the NIH as associate director, and in 1963, just before his death, was appointed as chief of the NIH Division of Biologics Standards, Laboratory of Virology and Rickettsiology (LVR).

Sources: Wikipedia, citing Jane S. Smith, Patenting the Sun: Polio and the Salk Vaccine, The Dramatic Story Behind One of the Greatest Achievements of Modern Science and a short biography of Smadel published by WRAIR.

Smadel's production protocols for polio vaccines were based on the scientific misconduct protocols for isolating viruses and measuring vaccine potency published in 1939 by Armstrong and Webster, and on the scientific misconduct protocols for isolating viruses published in 1949 and 1954 by Enders et al.

Smadel's production protocols were used, or asserted to have been used, by the manufacturers of polio vaccines during mass vaccination campaigns that began in April 1955.

Smadel's production protocols for the polio vaccines were then published as pseudo-regulations for biological product manufacturing, in the Dec. 12, 1956 Federal Register (21 FR 9890).

The new pseudo-regulations, Additional Standards for Polio Vaccines, were codified at 42 CFR 73.100 to 73.105, including 73.105, Equivalent methods, authorizing the US Surgeon General to permit "modification of any particular manufacturing method or process or the conditions under which it is conducted" and providing "that compliance with any test, method or procedure otherwise required...shall be waived as to such material to the extent the Surgeon General of the Public Health Service determines that the production or processing of such material has proceeded to a stage at which it is impossible to comply with any such requirement..."

*

In 1957, Eleanor McBean published The Poisoned Needle, compiling evidence of the scientific misconduct historically underpinning virology and vaccination programs, with particular emphasis on the poliovirus and polio vaccine campaigns conducted by the US Public Health Service and

McBean's work was suppressed.

*

In 1959, J. Anthony Morris was hired as a virology and vaccine researcher at the NIH Division of Biologics Standards (DBS). He worked there from 1959 until 1972, serving as the "influenza control officer" under Joseph Smadel, director of DBS Laboratory of Virology and Rickettsia (LVR) and Roderick Murray, DBS Director.

Roderick Murray served as DBS Director from the division's establishment in 1955 (as an upgraded version of the precursor Laboratory of Biologics Control during the polio vaccination campaign) until DBS functions, authorities and employees were transferred to FDA and renamed Bureau of Biologics in 1972.

In 1971, Morris filed an employment grievance against NIH leaders, alleging harassment and scientific misconduct: "that he had been harassed and pressured to leave the DBS because of his doubts about the potency and efficacy of commercial influenza vaccine."

Morris's complaints led to a GAO investigation commissioned by Sen. Abraham Ribicoff (who had served as HEW Secretary in 1961 and 1962), NIH internal investigations, and a series of reports in *Science* magazine written by Nicholas Wade.

Morris later transferred to the FDA Bureau of Biologics when the DBS authority to oversee biologics non-regulation was "concurrently redelegated" to FDA by memorandum dated Feb. 18, 1972 and published Feb. 25, 1972 (37 FR 4004).

Morris was fired in 1976. His firing was attributed, by the officials who fired him, primarily to insubordination: he raised objections about the impotency and harmfulness of influenza vaccines within government departments and publicly, based on his clinical investigations.

In Wade's Feb. 25, 1972 report in *Science,* he described an order issued by Joseph Smadel, to Morris, instructing Morris to pass vaccines during lot release procedures, based solely on the test results manufacturers submitted to DBS, without conducing independent testing to validate the procedures or confirm the results.

> "...Morris was recalled to the witness stand and related how when he had first taken over the duties of influenza control in 1960 he had frequently opposed the release of subpotent vaccines but was overruled by his then supervisor, LVR chief Joseph Smadel. For a time, Morris refused to sign the [manufacturer-submitted potency test] protocols of the bad vaccines [to authorize "lot release"], and Smadel signed them instead.
>
> Then, in a memorandum dated 18 September 1962, Smadel ordered Morris to pass vaccines on the basis of the manufacturers' tests alone:
>
> "The manufacturer will provide full data on the potency assay of his lots which are submitted for release. Furthermore, release by the DBS will be on the basis of data submitted by the manufacturer and not on the basis of results obtained in this institution."
>
> Three days later Smadel wrote to Morris concerning specific vaccine lots:
>
> "In view of the fact that these lots are to be released, there is no purpose testing these two in the LVR. Therefore, discard your mice which were vaccinated with lots X and Y."
>
> Morris was obliged to destroy all his animals, about 2000 mice.
>
> Over the years Morris had continued to protest with DBS leadership the release of subpotent vaccines,
>
> But, as [Roderick] Murray [DBS director] himself testified, the operating instructions laid down in Smadel's 18 September memo were continued in force after Smadel's death in 1963.
>
> Under the terms of Smadel's directive...Morris's job as influenza control officer was simply to check that the vaccine lots were potent according to test results provided by the manufacturers. All vaccine testing subsequently carried out by Morris was done for the purposes of his own experiments."

*

By the mid-1960s, two tests were presented to the public as demonstrations of vaccine potency: the mouse test, built on Webster's 1939 scientific misconduct, and the chicken cell agglutination (CCA) test.

March 28, 1972 - GAO report, Problems Involving the Effectiveness of Vaccines:

> "Tests to determine potency
>
> To determine whether individual lots of manufacturers' vaccines meet the established potency standards, DBS requires manufacturers to perform certain laboratory tests on the lots. DBS performs similar tests in its laboratories for selected lots.
>
> During 1966, 1967 and 1968, DBS required the manufacturers to determine the potency of their vaccines by means of mouse potency tests, which involved inoculating one group of mice with the manufacturers vaccines and another group with the DBS reference vaccine. After inoculation, each group of mice was injected with the influenza virus and the protective ability afforded by each vaccine was compared.
>
> Late in 1968 DBS changed the required test to the chicken cell agglutination (CCA) test, which determined virus concentration by measuring the ability of the virus to clump red blood cells. This ability is proportional to the number of virus particles. The test is performed on both the manufacturers' vaccines and the DBS reference vaccine, and the results are compared to determine whether the manufacturers' vaccines achieve the potency standard established by DBS."

The Smadel memo, however, had ordered DBS employees to release vaccine lots based solely on manufacturer claims in submitted protocols, and remained in force after Smadel's death.

Manufacturer claims themselves are based on the pseudo-regulations first published in December 1956, which were based on the production protocols written by Joseph Smadel in early 1955 during the preparation for the polio vaccination campaign.

Smadel's production protocols were based on the scientific misconduct protocols published by Armstrong in 1939 and Enders et al in 1949 and 1954.

*

By 1980, GAO had written another report on regulation of biological product manufacturing, which had been housed in the FDA Bureau of Biologics since 1972, titled Answers to Questions on Selected FDA Bureau of Biologics Regulation Activities:

> "Upgrading test methodologies.
>
> BoB officials believe that the test methods they use are the best currently available. BoB also recognizes that results from certain tests are more variable than others; however, they are continually working to improve or develop tests for better ensuring that vaccine are safe, pure and potent. While we did not attempt to determine if better tests were available, BoB told us about several tests they were improving or developing.
>
> One test generally recognized by FDA and others as having certain deficiencies was the chicken cell agglutination (CCA) test. Manufacturers and BoB used this test between 1968 and 1977 to measure influenza vaccine potency. The test assessed virus concentration by measuring the ability of the virus to

clump chicken red blood cells. The test measures vaccine potency in terms of CCA units; the higher the CCA value, the greater the vaccine's potency. Clinical studies on a specific influenza vaccine, however, showed that increases in the vaccine's CCA content did not necessarily result in an increase in antibody response (associated with increased effectiveness) in humans."

*

Viruses do not cause disease for individual people (cases) or across populations (epidemics, pandemics).

Vaccine products are heterogeneous, unstable mixtures of cells from human, animal, plant, bacteria and other living creatures, cell products and fragments of dead or dying cells, mixed with synthetic chemicals and metals.

The forms of scientific misconduct and deceit in virology and in vaccine manufacturing and regulation, and the forms of cover-up mechanisms adopted to shield the misconduct and deceit from public view, have changed during the past 85 years.

The substance has not.

Germ theory, contagion theory, virology, antibodies and anaphylaxis: Tracey Northern's work.

Published Jan. 8, 2025

...I urge readers to read Tracey Northern's work.

Tracey Northern, "Independent researcher since 1985 into cancer, vaccines and more recently germ theory and virology," published a blog called *Northern Tracey's Scribblings* between 2020 and 2023, which has been archived in html format.

- 2020-2023 - Northern Tracey Blog Posts[95] (Archive.org) - "Notably, as of 2024, online memorials indicate that Northern Tracey has passed. Additional information is not immediately forthcoming."

Northern read, thought about and translated a very large volume of scientific misconduct literature into plain English, bringing Stefan Lanka's work deconstructing germ theory, contagion theory and virology — and the work of those who preceded him historically — to a broader audience in more readily understandable form.

I encourage Bailiwick readers who haven't already read Northern's work and are interested in better understanding the scientific and medical misconduct that has reinforced, and been reinforced by, legal and political misconduct in the virology, communicable disease control and vaccination era (roughly 1798 to present) to start with these four:

- May 7, 2021 - The Germ Theory, an Idiots Guide[96] (Northern Tracey)
- May 14, 2021 - Contagion, Fact Checked[97] (Northern Tracey)
- May 25, 2021 - Going Viral, A Recipe for Disaster[98] (Northern Tracey)
- June 30, 2021 - The Amino Age and The New abNormal Doctors[99] (Northern Tracey)

It's important to understand scientific and medical misconduct and deceit because — in the communicable disease control, biological product and vaccination context — scientific and medical misconduct and deceit are integrated with political and legal misconduct and deceit.

All of these connected forms of misconduct and deceit are ongoing within Congress, federal and state public health, epidemiology and military programs, drug manufacturing, and the professions of medicine and law.

Understanding the forms used in the past to deceive, sicken and kill people, can help targets recognize the same patterns of behavior as new scientific terms for old poisons are introduced and new legal cover-up methods are put in place, so as to more confidently stop taking vaccines and other biological products, and stop vaccinating babies and children.

[95] https://archive.org/details/northern_tracey_blog_posts_2020-to-2023
[96] https://northerntracey213875959.wordpress.com/2021/05/07/the-germ-theory-an-idiots-guide/
[97] https://northerntracey213875959.wordpress.com/2021/05/14/contagion-fact-checked/
[98] https://northerntracey213875959.wordpress.com/2021/05/25/going-viral-a-recipe-for-disaster/
[99] https://northerntracey213875959.wordpress.com/2021/06/30/the-amino-age-and-the-new-abnormal-doctors/

As Lydia and I wrote in August, introducing a series of reports about legalized production, distribution and use of unregulated poisons under US biological product law:

> …These developments are important, because the scientific disciplines of microbiology, bacteriology, virology, immunology, and epidemiology developed in a mutually-reinforcing way with the development of communicable disease, quarantine and biological product law.
>
> Scientific and statistical fraud have historically enabled legal fraud, and legal fraud has historically enabled scientific and statistical fraud.
>
> Among other examples, lawmakers have relied on authoritatively-delivered but false claims made by scientists and statisticians, to build public support for and compliance with federal public health programs and products, from the roots in the late 1700s and early 1800s, through modern global pandemic preparedness and response programs, Covid-19 and the current avian influenza fraud...

Will continue thinking through the changes made from 1902 law Section 4 to 1944 law Section 351(d) and the addition of Section 352, and how they fit together with the scientific misconduct of the late 1930s and enabled the scientific misconduct, vaccine production, non-regulation and use of the unregulated 1948 DTP combination vaccines and then into the faked (pesticide poison and vaccine-driven) epidemics to drive the 1955 polio vaccines, mid-1960s MMR vaccines, late-1960s influenza vaccines and into the 1972 transfer from NIH to FDA.

Chapter 3

US-FDA non-regulation of biological products and vaccines, 1972 to present

42 USC 262-263, 21 CFR 600-680

Coordinated federal government diversion of research and public understanding to obscure epidemic of vaccine injury.

Published Dec. 4, 2024

I recently received a question from a reader wondering "Why 1972?"

Reader wrote:

> I was reading one of your pieces and I think you mentioned you and another woman (or maybe just you) will be doing a deep dive into the health policy changes starting from 1972 on. I said to myself, "Why 1972?"
>
> I went to the HHS website and found this: Histories of FDA-Regulated Products[100]
>
> Particularly this stood out to me: "In 1972, the regulation of biological products was transferred to the FDA from the National Institutes of Health, just a year after the FDA's National Center for Toxicological Research was established."
>
> Knowing the craziness and confusion that can happen in departments when they are given new responsibilities, I wondered if they were completely unprepared for this change. Did they have enough staff or funding to take on this new responsibility? Would it require new technology they didn't typically have in their reach? They had just taken on the responsibility of the newly founded "National Center for Toxicological Research" a year earlier. It sounds like the FDA was just being used...

*

For a year or so, I've been working on two series of reports.

One series is about biological product law since US federal government biological product regulatory simulations transferred from the Department of Health, Education and Welfare (HEW)-Public Health Service (PHS) National Institute of Health (NIH) Division of Biologics Standards (DBS) to the HEW-PHS Food and Drug Administration (FDA) Bureau of Biologics in 1972.

The other series — co-researched with Lydia Hazel — is about biological product law as it developed from origins in the Marine Hospital Service in 1798 and the 1902 Virus-Toxin law (also known as the Biologics Control Act, incorporated into the 1944 Public Health Service Act at Sections 351 and 352), up until the transfer from NIH to FDA in 1972.

*

I use 1972 as a turning point year because it's the year biologics non-regulation was transferred from NIH and FDA.

I had already done several reports (mostly published between Dec. 2023 and July 2024) on the 1972-to-present records.

With Lydia Hazel's help, I've been working on the pre-1972 series for several months. There are now four parts

[100] https://www.fda.gov/about-fda/fda-history/histories-fda-regulated-products

of the pre-1972 series published and the last one, Part 5, is in progress.

As a result of my research, I don't think it's correct to attribute what FDA has not done or has pretended to do since 1972, to FDA's sudden receipt of the biologics program and lack of preparedness.

What happened is that the NIH Division of Biologics Standards came under a small amount of public scrutiny in 1971, due to an employee grievance filed by J. Anthony Morris, and members of Congress worked with HEW, NIH and FDA officers to conduct fake investigations, write whitewash reports and then quietly, laterally move the entire DBS program and all of its on-paper employees from the NIH organizational structure to the FDA organizational structure, without substantially changing how the non-regulation regulatory charade worked, and still works today.

*

Prompted by the reader's mention of the FDA National Center for Toxicological Research as established in 1971, I looked into that organization further.

The FDA National Center for Toxicological Research was set up at the U.S. Army Chemical Corps chemical and biological weapons development site at the Pine Bluff Arsenal (Pine Bluff, Arkansas).

At the Pine Bluff Arsenal, chemical and biological weapons military research had been conducted since World War II, in cooperation with the US Army Biological Warfare Laboratories at Camp Detrick (Maryland) and Dugway Proving Grounds (Utah).

In 1969, President Richard Nixon issued a statement pretending to ban chemical and biological warfare research [101] but characterizing some biological research, including "immunization" programs, as "defensive measures" that would continue.

One of the methods for legally and administratively enabling chemical and biological warfare research to continue was to change the names, administrative housing and political cover stories for federal agencies engaged in the work.

In 1971, the Pine Bluff Arsenal US Army Chemical Corps chemical and biological weapons research and development moved from the Department of Defense to the FDA National Center for Toxicological Research under the Department of Health, Education and Welfare and the Public Health Service, and was rebranded as "toxicological" research.

The conclusion I've drawn from the legal history is that FDA departments (and other federal public health and military divisions) ostensibly studying the toxic effects of chemical and biological agents for the purpose of preventing and treating diseases and disorders caused by these agents, are, in truth, studying the toxic effects of chemical and biological agents to find more efficient and difficult-to-trace methods of poisoning people, primarily by inserting pathogenic organisms and toxins into routine and emergency vaccines and injecting those vaccines into babies, children and adults.

*

[101] https://2001-2009.state.gov/documents/organization/90920.pdf

Similarly, I think most NIH departments and research programs should be understood as vaccine injury cover-up enterprises.

Key players have known for more than a century, and still know, that the most significant source — not the only source but the most significant source — of harm to human and animal health was and is vaccines.

Key players have also known for a very long time that published research purporting to demonstrate therapeutic benefits of vaccination is scientifically unsound.

Public Health Service, HEW/HHS and NIH have established and run programs to pretend to be looking for sources of the observed damage (disease, infertility, premature death), and to centralize and control research funding and publications, to achieve an overarching goal: suppressing proper public understanding of vaccine development and manufacturing, vaccine contents and the biological effects of vaccination.

Public health and military officers work to suppress public understanding, because vaccines are insurmountably heterogeneous mixtures of unstable substances toxic to living creatures. Vaccines cannot be purified; they cannot be stabilized; they cannot protect or heal the recipient.

Vaccinators and targets who understand those things stop vaccinating babies and children, and stop taking vaccines themselves.

Legalized FDA non-regulation of biological products effective May 2, 2019, by Federal Register Final Rule, signed by then-FDA Commissioner Scott Gottlieb.

Published Dec. 19, 2023

Related Sage Hana reporting and analysis: Dec. 18, 2023 - Brook Jackson's November, 2021 Whistleblowing BMJ Article Reprinted[102]

Note: Brook Jackson's litigation is related to legalized FDA non-regulation of clinical trials. The information below is related to legalized FDA non-regulation of biological product manufacturing. Legal paper trail documents are provided after the text at the online version[103] for readers interested in digging deeper.

Under the 1944 Public Health Service Act, biological products were defined as "any virus, therapeutic serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound)."

In 1970, the biological products definition was amended to add, after the word "antitoxin," several new products, including "vaccine, blood, blood component or derivative, allergenic product." [42 USC 262].

Until May 2, 2019, FDA inspectors were required to inspect all establishments or facilities producing biological products at least once every two years, and held eight enumerated inspection duties.

The relevant section, 21 CFR 600.22, read:

> "The inspector shall:
>
> (a) Call upon the active head of the establishment, stating the object of his visit,
>
> (b) Interrogate the proprietor or other personnel of the establishment as he may deem necessary,
>
> (c) Examine the details of location, construction, equipment and maintenance, including stables, barns, warehouses, manufacturing laboratories, bleeding clinics maintained for the collection of human blood, shipping rooms, record rooms, and any other structure or appliance used in any part of the manufacture of a product,
>
> (d) Investigate as fully as he deems necessary the methods of propagation, processing, testing, storing, dispensing, recording, or other details of manufacture and distribution of each licensed product, or product for which a license has been requested, including observation of these procedures in actual operation,
>
> (e) Obtain and cause to be sent to the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research (see mailing addresses in § 600.2(c)), adequate samples for the examination of any product or ingredient used in its manufacture,
>
> (f) Bring to the attention of the manufacturer any fault observed in the course of inspection in location, construction, manufacturing methods, or administration of a licensed establishment which might lead to

[102] https://sagehana.substack.com/p/brook-jacksons-november-2021-whistleblowing
[103] https://bailiwicknews.substack.com/p/legalized-fda-non-regulation-of-biological

impairment of a product,

(g) Inspect and copy, as circumstances may require, any records required to be kept pursuant to [21 CFR] 600.12,

(h) Certify as to the condition of the establishment and of the manufacturing methods followed and make recommendations as to action deemed appropriate with respect to any application for license or any license previously issued.

Since May 2, 2019, FDA inspectors have had none of those duties, and are not required to inspect biological product manufacturing facilities at any time intervals.

Prior to the rule change, 21 CFR 600.21, Time of inspection, read:

> The inspection of an establishment for which a biologics license application is pending need not be made until the establishment is in operation and is manufacturing the complete product for which a biologics license is desired.
>
> In case the license is denied following inspection for the original license, no reinspection need be made until assurance has been received that the faulty conditions which were the basis of the denial have been corrected. An inspection of each licensed establishment and its additional location(s) shall be made at least once every 2 years. Inspections may be made with or without notice, and shall be made during regular business hours unless otherwise directed.

Effective May 2, 2019, the last three sentences of 21 CFR 600.21 were removed.

There is currently no legal requirement for an initial FDA inspection; no minimum interval for subsequent FDA inspections, and there are no legal consequences for compliance failures, such as establishment or product license denial or revocation.

The legal mechanisms through which FDA regulation of biological product manufacturing disappeared, included a Direct Final Rule and a Proposed Rule, simultaneously issued by Federal Register notice on Feb. 26, 2018, and an April 2, 2019 Final Rule, issued by then-FDA Commissioner Scott Gottlieb.

To summarize: On April 2, 2019, effective May 2, 2019, FDA Commissioner Scott Gottlieb changed the federal regulations governing inspection of licensed facilities manufacturing biological products including 'vaccines', from at least every two years to unspecified times; eliminated provisions about what would happen if a licensed facility failed an inspection; and eliminated all inspection duties for FDA inspectors.

A commenter submitted a pithy comment in response to the Feb. 26, 2018 notices, reprinted in the Final Rule document published in the Federal Register April 2, 2019:

> "One comment expressed concern that the risk-based inspection frequency will not be without negative health consequences. The comment also stated that ''[R]isk Management is an identified known weak element to a majority of biological and medical device companies'' and that the management and mitigation of risk without FDA oversight for a number of years is going to be a high-risk endeavor…"

On the continuing effort to fit a square peg (legalized manufacturing and use of biological weapons) into a round hole (FDA drug, device and biological product regulation).

Published Jan. 3, 2024

Meryl Nass, promoting David Gortler's work: Dec. 26, 2023 - David Gortler is the most knowledgeable person challenging the FDA on the COVID vaccines today. Here is his analysis--lawyers please pay attention/Brownstone.[104]

My reply:

It is not true that any Covid vaccines have been licensed.

All FDA activity that appeared to be license-related, pertaining to all biological products manufactured since May 2019, has been fraudulent, performative, charade, pretextual, and any other word or phrase that means not real, not substantive, not legally relevant.

See Dec. 19, 2023 - Legalized FDA non-regulation of biological products effective May 2, 2019, by Federal Register Final Rule, signed by then-FDA Commissioner Scott Gottlieb.[105]

And all biological product development, manufacturing and use since February 4, 2020, has had additional layers of non-regulation and liability exemption (license-to-kill) through the PHE-EUA-MCM-PREP structure and the Defense Production Act structure.

Until litigants properly identify the toxic products as unregulated poisons, biochemical weapons, or other accurate terms, no court cases are going to move things along toward ending the 'vaccination' and 'biological products' programs in their entirety and bringing the medicalized mass murder chapter of American history to a close.

Litigation that erroneously identifies the toxic products as regulated biological products or vaccines is a waste of time and money, and only serves to extend the mass murder programs.

[104] https://merylnass.substack.com/p/david-gortler-is-the-most-knowledgeable

[105] https://bailiwicknews.substack.com/p/legalized-fda-non-regulation-of-biological

Regulatory simulations at home and abroad: Mutual Recognition Agreements

Published March 8, 2024. First in series on legal links connecting domestic and international non-regulation of non-medicines.

Introduction

Sasha Latypova and I have documented how American pharmaceutical companies have contracted with the US Department of Defense, Department of Health and Human Services and many other federal agencies, divisions and officials, under authorities granted by Congress and US presidents through the 1938 Food Drug and Cosmetics Act, 1944 Public Health Service Act, 1950 Defense Production Act and related statutes, implementing regulations and executive orders, to intentionally, with complete legal impunity, poison recipients of vaccines and other drugs and biological products since January 2020, through the deployment of non-regulated, intentionally toxic medical countermeasures (MCM) under public health emergency (PHE) legal conditions.

Recently, I've been looking at international Mutual Recognition Agreements, and how they fit into the global legal system that enables poisons-labeled-as-medicines to enter interstate commerce in the US, and also enter international trade, unimpeded by American drug safety regulations and also unimpeded by regulatory systems in other countries.

Mutual Recognition Agreements are mechanisms through which regulatory agencies in one country can legally rely on the claimed validity of another country's regulatory reviews and decisions, to authorize import and use of the allegedly regulated product in the importing country.

International MRAs were put into place in the 1990s, and should be understood as working together with the gutting of US biological product regulation under non-emergency conditions, which predates Covid.

So far, I've identified at least four examples of such rule changes promulgated by FDA officials since 1973 that I hope to describe in future installments of this series.

One of those is the elimination of scheduled FDA inspections of biological product factories and inspector duties, effective May 2, 2019. (*See* Dec. 19, 2023 report)

Mutual Recognition Agreements and the gutting of US-FDA biological product regulation should also be understood as working together with the Public Health Emergency-Emergency Use Authorization-Medical Countermeasures system, which guts regulatory functions under emergency conditions.

These are examples of redundancies built into kill box laws, layer upon layer, allowing the killers to assure themselves that they will be able to legally continue to kill even if some of the enabling laws and regulations were to be acknowledged and repealed or nullified by Congress, American state governors and lawmakers, and/or state and federal judges.

The takeaway message is this: Stop taking vaccines.

Every layer of kill box law identified, supports the actionable conclusion that governments are intentionally sterilizing and killing off their populations, and that vaccines and other biological products are the class of weapons they prefer to use. The killers prefer biological weapons packaged as medicines because it's very difficult for targets to see needles, nasal sprays and skin patches as weapons.

It's very difficult for targets to see pharmacists, nurses and doctors as armed military contractors. It's very difficult for targets to see neighborhood retail pharmacies and doctors' offices as killing floors.

Memoranda of Understanding and Confidentiality Commitments

During a recent interview, the topic of Memoranda of Understanding or MOUs between the US Food and Drug Administration (FDA) and drug regulators in other countries, came up.

The MOUs I have on file are mostly internal to the United States. They are contracts between different agencies to share information about "medical countermeasures" development, regulation and production among themselves and keep the information out of public view.

- March 2014 - MOU among Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and participating federal agencies[106]: Department of Health and Human Services; HHS Office of the Assistant Secretary for Preparedness And Response (ASPR); HHS-CDC; HHS-NIH; HHS-FDA; Department of Defense; Department of Homeland Security; Department Of Veterans Affairs and Department Of Agriculture covering "information-sharing exchanges" and confidentiality. MOU 225-13-0028.
- Feb. 2016 - MOU between US-FDA and US Centers for Disease Control and Prevention (CDC)[107] "for coordination regarding emergency use instructions for medical countermeasures." MOU 225-16-008.

I also have some confidentiality agreements between the US-FDA and other countries, contracting to share information about drug, device and biological product regulation among themselves and keep the information from the public.

- Sept. 2003 - US-FDA and Swiss Agency for Therapeutic Products (Swissmedic), Confidentiality Commitment[108]
- August 2017 - US-FDA, European Commission Directorate-General for Health and Food Safety, and European Medicines Agency Confidentiality Commitment.[109] EMA/490709/2017, supplementing 2005 and 2010 agreements.

While looking at the domestic drug regulation MOUs and international drug regulation confidentiality agreements, I found another form of international contract: Mutual Recognition Agreements.

[106] https://bailiwicknewsarchives.files.wordpress.com/2024/03/2014.03.11-mou-225-13-0028-medical-countermeasures-phemce-hhs-aspr-dod-dhs-fda-cdc-nih-usda-va-information-sharing-and-confidentiality-13-p.pdf
[107] https://bailiwicknewsarchives.files.wordpress.com/2024/03/2016.02.22-mou-225-16-008-medical-countermeasures-fda-cdc-emergency-use-instructions-information-sharing-and-confidentiality.pdf
[108] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/03/2003.09.05-fda-swiss-agency-for-therapeutic-products-swissmedic-agreement-confidentiality-commitment.pdf
[109] https://bailiwicknewsarchives.files.wordpress.com/2024/03/2017.07.31-fda-ema-confidentiality-agreement-us-signed-partly-replace-2005-and-2010-agreements.pdf

Mutual Recognition Agreements

Mutual Recognition Agreements or MRAs are international treaties or trade agreements governing the import and export of regulated, manufactured consumer products.

MRAs have been negotiated and signed to enable regulators representing different countries to share information about their regulatory reviews, keep the regulatory information confidential from the public, and defer to each others' legal decisions concerning regulatory compliance, without conducting independent evidentiary collection and assessments.

Political and economic momentum for MRAs developed in the mid-1980s, exemplified by a May 7, 1985 European Council resolution "on a new approach to technical harmonization and standards," followed by EC Resolution 90/C 10/01,[110] "on a global approach to conformity assessment" adopted Dec. 21, 1989, accompanied by the founding of the International Committee for Harmonisation in 1990.[111]

The US-European Union Mutual Recognition Agreement was negotiated in 1997 and 1998, signed in London on May 18, 1998, and entered into force Dec. 1, 1998.[112]

The MRA covers several manufacturing sectors, including telecommunication equipment, electromagnetic compatibility, electrical safety, recreational craft, pharmaceutical Good Manufacturing Practices (GMPs) and medical devices.

US-FDA inserted the 1998 MRA sectoral annex provisions on pharmaceutical GMPs into the US Code of Federal Regulations at 21 CFR 26,[113] by Federal Register Notice of Final Rule published Nov. 6, 1998.[114] (63 FR 60122)

US and EU officials negotiated an "amended sectoral annex for pharmaceutical good manufacturing practices [cGMP]," signed on Jan. 19, 2017, which entered into full force July 11, 2019 after a transition period.[115]

Among other provisions relevant to the non-regulation of the non-medicines known as Covid-19 vaccines, Article 9 of the 2017 sectoral annex for GMP "relieved" the "qualified persons" in EU countries who receive drug products imported from the United States of "responsibility for carrying out" batch testing controls,[116] under Article 51, Paragraph 2 of EU Directive 2001/83/EC,[117] Community code relating to medicinal products for human use, as adopted by European Parliament and European Council Nov. 6, 2001.

The US-FDA currently has signed, in-force MRAs covering pharmaceuticals intended for human use with at least 29 countries in Europe.[118]

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[110] https://bailiwicknewsarchives.files.wordpress.com/2024/03/1989.12.21-ec-resolution-90c-1001-global-approach-conformity-assessment-.pdf
[111] https://www.ich.org/page/history
[112] https://bailiwicknewsarchives.files.wordpress.com/2024/03/1998.05.18-us-eu-mutual-recognition-agreement-mra-effective-1998.12.01-pharmaceutical-gmp-sectoral-annex-pharma-p-34-of-78.pdf
[113] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-26
[114] https://bailiwicknewsarchives.files.wordpress.com/2024/03/1998.11.06-63-fr-60123-fda-final-rule-mutual-recognition-agreement-us-eu-revisions-21-cfr-26-regulations-1997.06.20-effective-1998.12.07.pdf
[115] https://bailiwicknewsarchives.files.wordpress.com/2024/03/2017.01.19-us-eu-mra-mutual-recognition-agreement-cgmp-amended-sectoral-annex-pharma-effective-2017.11.01-fully-in-force-2019.07.11-vaccines-therapeutic-biotechnology-derived-1.pdf
[116] https://bailiwicknewsarchives.files.wordpress.com/2024/03/2023.05.31-ema-qa-mutual-recognition-agreement-mra-human-veterinary-can-i-stop-batch-testing-yes-relieved-of-responsibility-effective-2019.07.11.pdf
[117] https://bailiwicknewsarchives.files.wordpress.com/2024/03/2001.11.06-eu-directive-200183ec-medicinal-products-for-human-use.pdf
[118] https://bailiwicknewsarchives.files.wordpress.com/2024/03/2023.05-list-of-fda-european-union-eu-mutual-recognition-agreements-fda-vaccines-not-covered-therapeutic-biotechnology-derived-covered.pdf

Effective May 30, 2023, more than half of the participating countries expanded the scope of the Mutual Recognition Agreements to also include animal (veterinary) drugs. Biological products for poisoning livestock are being rapidly developed and deployed on ranches and farms in the US and worldwide.

Sasha Latypova reporting: Oct. 25, 2023 - Genetic Vaccines in Animals/Food Supply, Part 1 - Merck Sequivity[119]; Nov. 2, 2023 - Genetic Vaccines in Animals and Food Supply - Part 2[120]; Nov. 28, 2023 - Animal vaccines Part 3[121]

Most European countries were folded into the US-EU MRA treaty through the European Union, with each country's government recognizing the treaty and the amended sectoral annex between November 2017 and November 2019.[122], [123]

Although Switzerland and United Kingdom are not member-states of the European Union, both are also parties to MRAs with the United States, effective Nov. 1, 2017 for the UK Medicines and Healthcare products Regulatory Agency (MHRA), and July 27, 2023 for the Swiss Agency for Therapeutic Products (Swissmedic).

Related Bailiwick reporting and analysis: Feb. 15, 2023 - European Commission regulations implementing the global pharma-military kill box; April 13, 2023 - Vaccine production facilities are indistinguishable from bioweapon production facilities, and vaccines are indistinguishable from bioweapons; April 4, 2023 - Government by silent immobility: an effective ruling innovation developed by the globalists, capitalizing on natural human aversion to hard work, conflict and pain; Sept. 26, 2023 - On the European Union lawmaking process; Nov. 8, 2023 - Sasha Latypova and Katherine Watt discussing non-regulation of non-medicines known as 'vaccines,' and other US military biochemical weapons; Dec. 6, 2023 - More on the workings of the war machine running on public health emergency determinations, PREP Act license-to-kill declarations, and EUA countermeasures.

[119] https://sashalatypova.substack.com/p/genetic-vaccines-in-animals-and-food
[120] https://sashalatypova.substack.com/p/genetic-vaccines-in-animals-and-food-078
[121] https://sashalatypova.substack.com/p/animal-vaccines-part-3
[122] https://www.fda.gov/international-programs/international-arrangements/european-union-eu-mutual-recognition-agreement
[123] Nov. 1, 2017 - Austrian Agency for Health and Food Safety; Croatian Agency for Medicinal Products and Medical Devices; French National Agency for Medicines and Health Products Safety; Italian Medicines Agency; Malta Medicines Regulatory Authority; Spanish Agency of Medicines and Medical Devices; Sweden Medical Products Agency; March 1, 2018 - Czech Republic State Institute for Drug Control; Greece National Organisation for Medicines; Hungary National Institute of Pharmacy and Nutrition; Romania National Agency for Medicines and Medical Devices; June 1, 2018 - Ireland Health Products Regulatory Authority; Lithuania State Medicines Control Agency; Sept. 14, 2018 - Portugal National Authority of Medicines and Health Products; Nov. 16, 2018 - Belgian Federal Agency for Medical and Health Products; Danish Medicines Agency; Finnish Medicines Agency; Latvia State Agency of Medicines; Feb. 7, 2019 - Poland, Main Pharmaceutical Inspectorate; Slovenia Agency for Medicinal Products and Medical Devices; April 29, 2019 - Bulgarian Drug Agency; Cyprus Ministry of Heath - Pharmaceutical Services; June 10, 2019 - Luxembourg Ministry of Health, Division of Pharmacy and Medicines; Netherlands Healthcare Inspectorate; June 26, 2019 - German Central Office of the Federal States for Health Protection for Drugs and Medical Devices; July 11, 2019 - Slovakia State Institute for Drug Control; Nov. 28, 2019 - Estonia State Agency of Medicines

Terms, phrases and organizations involved in worldwide regulatory and manufacturing deception surrounding vaccines and other biological products.

Published April 25, 2024

I'm still working to better understand (and better write about) the legal mechanisms that have enabled the US Food and Drug Administration (FDA), US Centers for Disease Control and Prevention (CDC), European Medicines Agency (EMA), World Health Organization (WHO) and other US federal agencies, national drug regulators, and regional and supranational organizations, to construct a worldwide regulatory deception through which mercenary pharmacists and nurses can legally mutilate and kill people, using manufactured, distributed pharmaceutical products that are intentionally toxic poisons.

As I've written [elsewhere], a lot of the legal mechanisms are suspensions, waivers, exemptions and exclusions from drug manufacturing quality control rules, known as current Good Manufacturing Practice (cGMP); along with suspensions/waivers/exemptions/exclusions of clinical trial conduct rules (including Institutional Review Board and informed consent rules), known as current Good Clinical Practice (cGCP); laboratory rules (cGLP); distribution rules (cGDP); and other rules.

For Emergency Use Authorization (EUA) countermeasure products, exemptions are legally justified by emergency declarations issued for specific communicable disease outbreaks (public health emergencies). Public health emergency declarations and determinations are issued unilaterally without any legal requirement for validated evidence that morbidity and mortality are attributable to a communicable disease pathogen, and without any legal mechanisms for legislatures, courts, or political subdivisions (states, tribes, municipalities) to challenge, counteract or otherwise "call the bluff" of lying government officials who promulgate groundless emergency declarations.

For biological products as a general class — at all times, not only during declared emergencies — the exemptions are legally justified by claims that manufacturers have assessment equipment and techniques, and an honorable disposition toward product users, sufficient to self-police product safety, purity and potency without independent, public verification of their claims, and that deregulation saves time and money for regulators, product manufacturers, and taxpayers without endangering consumer health and safety.

These legal non-regulation structures have become more visible since January 2020 through Covid-19 — a simulation of a deadly global pandemic, conducted through prearranged policy coordination (false information, non-validated diagnostic testing/surveillance, social/psychological/economic behavior manipulation, lockdowns, masking, hospital homicide, product review and vaccination programs) among individuals representing the World Health Organization, US-FDA, US-CDC and affiliated co-conspirator government agencies and non-governmental organizations.

For context, I began to understand FDA's deceptive role in EUA product non-regulation in early 2022, and have learned and written more about public health emergency law since then.

I learned about the FDA's deceptive role in non-regulation of the broader class of biological products — in which vaccines are a putative subcategory, and EUA vaccines are a putative sub-sub-category — in December 2023. I've been learning and writing more about biological product law since then.

To repeat a key point: a lot of the legal mechanisms that enable health care workers to mutilate and kill people with impunity using EUA countermeasures (including vaccines) under declared emergency conditions, and to also mutilate and kill people with impunity using non-EUA biological products and vaccines under routine, non-

emergency conditions, are suspensions, waivers, exclusions and exemptions from clinical trial conduct rules and drug manufacturing quality control rules.

Because of that legal framework, one of the best ways to understand what's happened, is to draw the negative or adverse inferences[124] that can be drawn from the *absence* of valid regulatory and quality control records.

'Smoking gun' documents, through which identifiable regulators and vaccine factory employees would disclose which toxic ingredients were added to which batch on which date and time, with foreknowledge as to subsequent molecular stability or decay, and foreknowledge as to harmful biological effects on recipients, are unlikely to appear.

Instead, ingredients and processing techniques are redacted from publicly-available regulatory review and manufacturing contracts. Package inserts are blank. When asked for unredacted, complete, accurate clinical trial and manufacturing quality control compliance records, regulators and manufacturers simply and accurately state that they cannot produce such records, because they are not legally obligated to produce such records, and therefore those records do not exist.

If entities with subpoena power — Congress members, state Attorneys General, state legislative investigatory commissions, or well-informed private attorneys using well-aimed litigation — someday decide to request clinical trial and manufacturing quality control evidence from pharmaceutical companies and FDA regulatory divisions involved in the development and production of drugs and biological products during, prior to and subsequent to Covid, I anticipate that they will receive responses similar to the July 2018 response that Informed Consent Action Network received from the Department of Health and Human Services in response to ICAN's request for records of HHS vaccine safety assessments between 1986 and 2018:

> "The [Department]'s searches for records did not locate any records responsive to your request."

*

In the meantime, since Congress members, AGs, state lawmakers, and private attorneys have been silent and immobile on the subject of legalized non-regulation of EUA countermeasures, vaccines and biological products, it falls to individual men and women in every country, to stop worldwide vaccination programs by clearly understanding how vaccine and biological product regulatory deceptions work; by drawing the adverse inferences from the non-existence of complete, accurate, unredacted, public regulatory and manufacturing records; and by confidently declining vaccine and biological product recommendations, endorsements and offers made by public health officials, product regulators, manufacturers and health care workers.

It may help build understanding and confidence, to know the names of key organizations running the regulatory deception programs, and some of the legally-undefined terms for the intrinsically unstable, and therefore physically-indeterminate, compounds categorized as "biological products."

Organizations whose members conduct regulatory deception campaigns, primarily through promulgation of official reports, guidance documents and regulations:

- World Health Organization Expert Committee on Biological Standardization.[125] "…commissioned [1947] to coordinate activities leading to the adoption of international requirements for the production

[124] https://en.wikipedia.org/wiki/Adverse_inference

[125] https://www.who.int/groups/expert-committee-on-biological-standardization

and control of vaccines and other biologicals and the establishment of international biological reference materials."

- WHO International Conference of Drug Regulatory Authorities (ICDRA, 1980)[126]

- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use[127] (ICH, 1990) - "…bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceuticals and develop ICH guidelines…"

- Pharmaceutical Inspection Co-operation Scheme[128] (PIC/S) - "...established in 1995 as an extension to the [European Free Trade Association] Pharmaceutical Inspection Convention (PIC) of 1970...PIC/S is a legally non-binding co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. It is open to any Authority having a comparable GMP inspection system. On 31 December 2021, PIC/S comprised 54 Participating Authorities (PAs) from all continents."

- International Coalition of Medicines Regulatory Authorities[129] (ICMRA, 2013) - "An international executive-level coalition of key regulators from every region in the world. It provides a global strategic focus for medicines regulators and gives strategic leadership on shared regulatory issues and challenges. Priorities include coordinated response to crisis situations. Members of the ICMRA include: Therapeutic Goods Administration (TGA), Australia; National Health Surveillance (ANVISA), Brazil; Health Products and Food Branch, Health Canada (HPFB-HC), Canada; China Food and Drug Administration (CFDA), China; European Medicines Agency (EMA) and European Commission - Directorate General for Health and Food Safety (DG - SANTE), European Union; French National Agency for Medicines and Health Products Safety (ANSM), France; Paul-Ehrlich-Institute (PEI), Germany; Ministry of Health and Family Welfare, India; Health Product Regulatory Authority (HPRA), Ireland; Italian Medicines Agency (AIFA), Italy; Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), Japan; Ministry of Food and Drug Safety (MFDS), Korea; Federal Commission for the Protection against Sanitary Risks (COFEPRIS), Mexico; Medicines Evaluation Board (MEB), Netherlands; Medsafe, Clinical Leadership, Protection & Regulation, Ministry of Health, New Zealand; National Agency for Food Drug Administration and Control (NAFDAC), Nigeria; Health Sciences Authority (HSA), Singapore; Medicines Control Council (MCC), South Africa; Medical Products Agency (MPA), Sweden; Swissmedic, Switzerland; Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom; Food and Drug Administration (FDA), United States."

- US FDA Center for Biologics Evaluation and Research (CBER, formerly Bureau of Biologics) - "the Center within FDA that regulates biological products for human use under applicable federal laws."

- US FDA CBER Office of Vaccines Research and Review (OVRR) - "allergenic products, infectious disease vaccines and live biotherapeutic (probiotic) therapies."

- US FDA CBER Office of Biologics Research and Review (OBRR) - "blood and blood products, including plasma derivatives and their recombinant analogues."

[126] https://www.who.int/teams/regulation-prequalification/regulation-and-safety/regulatory-convergence-networks/icdra
[127] https://www.ich.org/
[128] https://picscheme.org/en/about
[129] https://www.icmra.info/drupal/en

- US FDA CBER Office of Tissues and Advanced Therapies (OTAT) - "cell, tissue and gene therapies as well as therapeutic vaccines for various disease indications."

- US FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) - "responsible for supporting applications for licensure of vaccines." (House Report 106-977, Oct. 12, 2000)

- US CDC Advisory Committee for Immunization Practices (ACIP) - "Develops recommendations for U.S. immunizations, including ages when vaccines should be given, number of doses, time between doses, and precautions and contraindications."

Some of the terms and phrases used in official reports, plans, guidance documents, recommendations and regulations promulgated by the organizations listed above and their military and corporate pharmaceutical counterparts:

- allergen
- allergenic product
- analogous product
- antigen
- antitoxin
- arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound)
- attenuated infectious vaccine
- bacteria
- biopharmaceutical
- biosimilar
- biosimilar biological product
- biotechnology
- biotechnology product
- blood, blood component or derivative
- cell therapies
- cells pulsed with immunogen
- cellular therapy products
- component of pathogen
- conjugates
- crude or purified antigens isolated from killed or living cells
- crude or purified antigens secreted from living cells
- diagnostic antigen
- emerging technology in the context of the pharmaceutical and related industries
- first interchangeable biosimilar biological product
- fraction of pathogen
- gene
- gene therapies
- genetically-modified organism (GMO)
- human blood and blood components
- human cellular and gene therapy products
- human somatic cell therapy and gene therapy
- immunogen
- immunotoxin
- intentionally altered genomic DNA

- living vectored cells expressing specific heterologous immunogens
- microbial culture
- microbial derived proteins
- monoclonal antibody
- parasite
- pathogen
- peptide
- plasma-derived pharmaceutical
- plasma-derived product
- plasmid
- plasmid DNA vaccine
- polynucleotides
- polypeptide
- protein
- recombinant nucleic acid molecules
- recombinant or synthetic carbohydrate, protein or peptide antigens
- recombinant protein
- reference product
- regenerative medicine therapies
- regenerative medicine advanced therapy
- somatic cell therapy
- synthetic biological product
- synthetic nucleic acid molecules
- therapeutic biological product
- therapeutic biotechnology
- therapeutic biotechnology-derived biological product
- therapeutic recombinant DNA-derived product
- therapeutic serum
- toxin
- toxoid
- vaccine
- virus
- well-characterized platform technology
- well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products
- whole, inactivated pathogen

*

Stop taking vaccines.

Interpret public statements, reports, guidance documents and regulations by World Health Organization Expert Committee on Biological Standardization, ICDRA, ICH, ICMRA, PIC/S, US-FDA, FDA-CBER, CBER-OVRR, CBER-OBRR, CBER-OTAT, CBER-VRBPAC, US-CDC, CDC-ACIP and pharmaceutical company officials as presumptive lies and misrepresentations.

Pray the Rosary.

Statutory and regulatory definitions for drugs, biological products, and biosimilars

Information to support further reporting on regulation and non-regulation of biological product manufacturing, sample testing, lot-release, use.

Published March 12, 2024.

This overview is focused on the development of biological product definitions, statutes and regulations since July 1944, when Congress established the Regulation of biological products program under the Public Health Service Act at Section 351, codified at 42 US Code 262.[130]

Biological product manufacturing regulations may be found at 21 CFR Subchapter F,[131] Parts 600 to 680 and related sections of the Code of Federal Regulations as they have developed, especially since 1973.

Key points:

Chemical drugs are produced by quantifiable, predictable, controllable chemical and physical manufacturing processes involving the breaking and forming of chemical bonds; they tend to have smaller molecular structures than biological products.

Biological products are produced by non-quantifiable, unpredictable, uncontrollable biological processes, such as replication and division within living cells and organisms, with widely variable effects on other living organisms when introduced into a recipient. Biological products tend to have larger molecular structures than chemical drugs.

Chemical drugs manufactured using predictable, measurable chemical reactions can be produced and assessed for compliance with purity, potency, activity, safety and efficacy standards.

Biological products manufactured using biological processes cannot.

Drugs vs. Biological Products - Generally

Small Molecule Drugs	Biological Products
Generally low molecular weight	Generally high molecular weight
Usually made by organic or chemical synthesis	Made with/from live cells/organisms → *inherent & contamination risk*
Fewer critical process steps	Many critical process steps
Well-characterized	Less easily characterized
Known structure	Structure may or may not be completely defined or known
Homogeneous drug substance	Heterogeneous mixtures → *May include variants*
Usually not immunogenic	Often immunogenic

Slide: November 2013 - Biosimilar Biological Products, Clinical Investigator Course, FDA[132]

[130] https://www.law.cornell.edu/uscode/text/42/262
[131] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F
[132] https://bailiwicknewsarchives.files.wordpress.com/2024/03/2013.11.13-fda-biosimilar-biological-products-slide-deck-small-molecule-biological-

I. Statutory definitions of "drug"

A. June 30, 1906 - Pure Food and Drug Act, PL 59-384,[133] 34 Stat. 768.

Through the Pure Food and Drug Act, Congress prohibited adulteration and misbranding of drugs, and established civil and criminal penalties for manufacturers producing and distributing adulterated and misbranded drugs.

Congress delegated authority to promulgate and enforce rules and regulations to the Secretary of the Treasury, Secretary of Agriculture, Secretary of Commerce and Labor, and US district attorneys, including "collection and examination of specimens."

Biological products, including "viruses, therapeutic serums, toxins, antitoxins, or analogous products" had been listed in a different Congressional act, signed in 1902 (see below) and were not covered by the Pure Food and Drug Act.

Congress defined "drug" to include

> "...all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals."

B. June 25, 1938 - Federal Food Drug and Cosmetics Act, PL 75-717,[134] 52 Stat. 1041.

Through the Food Drug and Cosmetics Act (FDCA), Congress repealed and replaced the 1906 Pure Food and Drug Act, and codified federal food and drug regulation at 21 USC Chapter 9,[135] Sections 301 et seq.

Congress defined *drug* at 21 USC 321(g).

> The term "drug" means
>
> (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
>
> (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
>
> (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
>
> (4) articles intended for use as a component of any article specified in clause (1), (2), or (3) but does not include devices or their components, parts, or accessories.

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product-comparison-chart.pdf

[133] https://bailiwicknewsarchives.files.wordpress.com/2024/03/1902.07.01-biologics-control-act-pl-57-244-32-stat-728.pdf

[134] https://bailiwicknewsarchives.files.wordpress.com/2024/03/1938.06.25-food-drug-cosmetics-act-pl-75-717-52-stat-1040.pdf

[135] https://www.law.cornell.edu/uscode/text/21/chapter-9

C. Current FDCA Section 201/ 21 USC 321(g)(1)[136]

The term "drug" means

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C).
A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim.

A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

D. Drugs@FDA Glossary of Terms,[137] last updated Nov. 14, 2017

A drug is defined as:

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
- Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

[136] https://www.law.cornell.edu/uscode/text/21/321
[137] https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms

II. Statutory and regulatory definitions of biologics, biological products and biosimilars intended for use in humans, domestic animals

A. July 1, 1902 - Biologics Control Act or Virus-Toxin Act,[138] 32 Stat. 728.

Through the Biologics Control Act, Congress regulated "sale of and interstate traffic" in viruses, serums, toxins and analogous products, and delegated authority to promulgate and enforce rules and regulations to the Secretary of Treasury, in consultation with the Surgeon-Generals of the Army, Navy and Marine-Hospital Service.

> "No person shall sell, barter, or exchange...any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention and cure of diseases of man...unless (a) such virus, serum, toxin, antitoxin, or product has been propagated and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary of the Treasury [and] ...that the Surgeon-General of the Army, the Surgeon-General of the Navy, and the supervising Surgeon-general of the Marine-Hospital Service, be...constituted a board with authority...to promulgate...such rules as may be necessary in the judgment of said board to govern the issue, suspension, and revocation of licenses for the maintenance of establishments for the propagation and preparation of viruses, serums, toxins, antitoxins, and analogous products..."

[See Chapter 1 above for more detail about how definitions of 'virus,' 'toxin,' 'serum' and analogous products developed in regulations after the Congressional adoption of the Virus-Toxin Act in 1902]

B. March 4, 1913 - Virus-Serum Toxin Act,[139] 37 Stat. 832.

Through the Virus-Serum Toxin Act, Congress regulated preparation and sale of "virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals," and delegated authority to promulgate and enforce rules and regulations to the Secretary of Agriculture.

> "...It shall be unlawful for any person, firm or corporation to prepare, sell, barter, or exchange...or to ship or deliver...any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture..."

C. July 1, 1944 - Public Health Service Act[140] (PHSA) Section 351, *Regulation of biological products*. PL 78-410, 58 Stat. 702.

Through the PHSA, Congress codified regulation and licensing of biological product manufacturing at 42 USC 262.

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[138] https://bailiwicknewsarchives.files.wordpress.com/2024/03/1902.07.01-biologics-control-act-pl-57-244-32-stat-728.pdf
[139] https://bailiwicknewsarchives.files.wordpress.com/2024/03/1913.03.04-virus-toxin-serum-act-agriculture-37-stat-832-domestic-animals.pdf
[140] https://bailiwicknewsarchives.files.wordpress.com/2024/03/1944.07.01-public-health-service-act-pl-78-410-58-stat-682.pdf

PHSA Section 351, Regulation of biological products (1944):

> "Section 351(a) No person shall sell, barter, or exchange, or offer for sale, barter, or exchange...any virus, therapeutic serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man unless (1) such...product has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license..."

Notes

Congress did not place regulation of biological products under the Food Drug and Cosmetics Act, or under the Food and Drug Administration.

Instead, Congress placed regulation of biological products under the control of the Public Health Service, which is a branch of the US military.

Congress provided a list of biological product categories to be regulated under 42 USC 262, but did not provide legal definitions of the specific products to be regulated, instead describing them generally as products "applicable to the prevention, treatment or cure of diseases or injuries of man."

Between 1937 and 1972, biological product regulation was housed in the National Institute of Health Division of Biologics Standards [and preceding organizational divisions and laboratories].

In 1972, biological product regulation was moved to the FDA Bureau of Biologics, now called the Center for Biologics Evaluation and Research, or CBER.

D. Oct. 30, 1970 - Heart Disease, Cancer, Stroke, and Kidney Disease Amendments of 1970.[141] PL 91-515, 84 Stat. 1297.

Congress added *vaccine* to the list of biological products subject to manufacturing regulation under the Public Health Service Act.

Section 351 of the Public Health Service Act [42 USC 262] is amended by inserting, after "antitoxin", each time such word appears, the following: "vaccine, blood, blood component or derivative, allergenic product."

As of 1970, biological products listed by Congress as subject to federal manufacturing regulation under 42 USC 262 included:

> "Any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of diseases or injuries of man."

[141] https://www.congress.gov/91/statute/STATUTE-84/STATUTE-84-Pg1297.pdf

E. Nov. 20, 1973 - Department of Health, Education and Welfare, Food and Drug Administration, Notice of Reorganization and Republication, 38 FR32048[142]

Through this Federal Register notice, FDA Acting Associate Commissioner for Compliance William F. Randolph announced the consolidation and re-publication of federal regulations governing biological product manufacturing.

Sections included 21 CFR 600, Biological Products: General; 21 CFR 601, Licensing; 21 CFR 610, General Biological Products Standards; 21 CFR 620, Additional Standards for Bacterial Products; 21 CFR 630, Additional Standards for Viral Vaccines; 21 CFR 640, Additional Standards for Human Blood and Blood Products; and three other sections.

FDA defined several terms at 21 CFR 600.3, but did not define the term *vaccine*.

> 21 CFR 600.3 (h) - Biological product means any virus, therapeutic serum, toxin, anti-toxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man.
>
> 21 CFR 600.3(h)(1) - A virus is interpreted to be a product containing a minute living cause of an infectious disease and includes but is not limited to filterable viruses, bacteria, rickettsia, fungi, and protozos.
>
> 21 CFR 600.3(h)(2) - A therapeutic serum is a product obtained from blood by removing the clot or clot components and the blood cells.
>
> 21 CFR 600.3(h)(3) - A toxin is a product containing a soluble substance poisonous to laboratory animals or to man in doses of 1 milliliter or less...and having the property, following the injection of non-fatal doses into an animal, of causing to be produced therein another soluble substance which specifically neutralizes the poisonous substances and which is demonstrable in the serum of the animal thus immunized.
>
> 21 CFR 600.3(h)(4) - An antitoxin is a product containing the soluble substance in serum or other body fluid of an immunized animal which specifically neutralizes the toxin against which the animal is immune.

[142] https://bailiwicknewsarchives.files.wordpress.com/2024/03/1973.11.20-38-fr-32048-fda-biological-product-regulation-baseline-21-cfr-600-to-680-42-usc-262.pdf

F. Nov. 18, 1997 – National Defense Authorization Act FY1998,[143] PL 105-85, 111 Stat. 1915.

Congress amended 50 USC 1520a,[144] Restrictions on the use of human subjects for testing of chemical or biological agents.

In the wake of the Gulf War (1990-1991), during which DoD forced soldiers to submit to batteries of vaccines and toxic exposures in theatre, including burn pits, Congress defined "biological agents."

> 50 USC 1520a(e) ...The term ''biological agent'' means any micro-organism (including bacteria, viruses, fungi, rickettsiac, or protozoa), pathogen, or infectious substance, and any naturally occurring, bioengineered, or synthesized component of any such micro-organism, pathogen, or infectious substance, whatever its origin or method of production, that is capable of causing—
>
> (1) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;
>
> (2) deterioration of food, water, equipment, supplies, or materials of any kind; or
>
> (3) deleterious alteration of the environment.

Notes

The November 1997 NDAA section on biological agents is one of the main Congressional two-part maneuvers through which Congress appeared to be terminating illegal chemical and biological warfare programs, but actually just moved, renamed and expanded the same programs as public health emergency-medical countermeasures programs. *See* May 10, 2022 - Shell game. November 1997. Congress pretended to protect military servicemen and women from forced submission to biological and chemical weapons experiments. But really just transferred the program to FDA; Sept. 28, 2022 - DOD chemical and biological warfare program: herd-culling plus stockpile disposal in one tidy package.

[143] https://www.congress.gov/105/plaws/publ85/PLAW-105publ85.pdf
[144] https://www.law.cornell.edu/uscode/text/50/1520a

G. March 23, 2010 - Biologics Price Competition and Innovation Act, Title VII, Subtitle A of Patient Protection and Affordable Care Act,[145] PL 111-148, 124 Stat. 814-815.

Through the BPCIA, Congress added "protein (except any chemically synthesized polypeptide)" and added a new category of *biosimilars* to the list of biological products subject to regulation under 42 USC 262.

> ...Section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) is amended—
>
> ...by inserting "protein (except any chemically synthesized polypeptide)," after "allergenic product," and...by adding:
>
> "(2) The term 'biosimilar' or 'biosimilarity,' in reference to a biological product that is the subject of an application under subsection (k) [*Licensure of biological products as biosimilar or interchangeable*], means—
>
> > (A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and
> >
> > (B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.
>
> (3) The term 'interchangeable' or 'interchangeability'...means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.
>
> (4) The term 'reference product' means the single biological product licensed under subsection (a) [Biologics license] against which a biological product is evaluated in an application submitted under subsection (k).

As of 2010, biological products identified by Congress as subject to manufacturing regulation under 42 USC 262 included "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings" and "biosimilar" products.

[145] https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf

H. Dec. 20, 2019 - Further Consolidated Appropriations Act, 2020,[146] PL 116-94, 133 Stat. 3127

Congress removed "(except any chemically synthesized polypeptide)" — which had been added, with "protein" in 2010 — from the biological products definition.

> Section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)) is amended by striking "(except any chemically synthesized polypeptide)."

As of December 2019, biological products listed by Congress as subject to manufacturing regulation under 42 USC 262 included
"a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings" and "biosimilar" products.

I. FDA "What is a biological product?[147] (undated)

> Biological products are regulated by the Food and Drug Administration (FDA) and are used to diagnose, prevent, treat, and cure diseases and medical conditions. Biological products are a diverse category of products and are generally large, complex molecules.
>
> These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs.
>
> There are many types of biological products approved for use in the United States, including therapeutic proteins (such as filgrastim), monoclonal antibodies (such as adalimumab), and vaccines (such as those for influenza and tetanus).
>
> The nature of biological products, including the inherent variations that can result from the manufacturing process, can present challenges in characterizing and manufacturing these products that often do not exist in the development of small molecule drugs. Slight differences between manufactured lots of the same biological product (i.e., acceptable within-product variations) are normal and expected within the manufacturing process...

[146] https://www.congress.gov/116/plaws/publ94/PLAW-116publ94.pdf
[147] https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf

III. Statutory and regulatory definitions of "vaccine"

A. No definition of vaccine in federal biological product manufacturing regulatory law.

Congress established the federal biological products licensing and regulation program in 1944.

Vaccines were added to the list of regulated, licensed biological products by Congressional statute in 1970, and regulatory, licensing functions were transferred from NIH to FDA in 1972.

Congress did not define the term vaccine.

FDA regulations covering biological product manufacturing, including vaccines, were consolidated and re-published in 1973, and have been amended extensively since.

FDA did not define the term vaccine.

In 1976, Congress authorized and funded a nationwide vaccination campaign including liability exemption for manufacturers, for swine flu, (National Swine Flu Immunization Act,[148] PL 94-380, 90 Stat. 1113) without defining the term vaccine.

In 1986, Congress authorized and funded a nationwide child vaccination program, including liability exemption for manufacturers and establishment of the Vaccine Injury Compensation Program, (National Childhood Vaccine Injury Act,[149] PL 99-660, 100 Stat 3755, codified at 42 USC 300aa-1 to 34[150]), without defining the term vaccine.

'Vaccine' has not been defined by Congress through amendments to the Food Drug and Cosmetics Act (FDCA), or to the Public Health Service Act (PHSA), and the term has not been defined by the FDA through regulations published in the Federal Register.

B. Definition of vaccine in tax code

In 1987, Congress provided a statutory definition of vaccine through the Internal Revenue Code, 26 USC 4132.[151]

The "Certain vaccines" provision authorized collection of excise tax by the Treasury Secretary, from manufacturers, per dose of vaccine sold. The list of taxable vaccines has been expanded since 1987.

> 26 USC 4132a(2) Vaccine.
>
> The term “vaccine” means any substance designed to be administered to a human being for the prevention of 1 or more diseases.
>
> 26 USC 4132a(1) Taxable vaccine
>
> The term “taxable vaccine” means any of the following vaccines which are manufactured or produced

[148] https://www.congress.gov/94/statute/STATUTE-90/STATUTE-90-Pg1113.pdf
[149] https://www.congress.gov/99/statute/STATUTE-100/STATUTE-100-Pg3743.pdf
[150] https://www.law.cornell.edu/uscode/text/42/chapter-6A/subchapter-XIX
[151] https://www.law.cornell.edu/uscode/text/26/4132

in the United States or entered into the United States for consumption, use, or warehousing:

(A) Any vaccine containing diphtheria toxoid.
(B) Any vaccine containing tetanus toxoid.
(C) Any vaccine containing pertussis bacteria, extracted or partial cell bacteria, or specific pertussis antigens.
(D) Any vaccine against measles.
(E) Any vaccine against mumps.
(F) Any vaccine against rubella.
(G) Any vaccine containing polio virus.
(H) Any HIB vaccine.
(I) Any vaccine against hepatitis A.
(J) Any vaccine against hepatitis B.
(K) Any vaccine against chicken pox.
(L) Any vaccine against rotavirus gastroenteritis.
(M) Any conjugate vaccine against streptococcus pneumoniae.
(N) Any trivalent vaccine against influenza or any other vaccine against seasonal influenza.
(O) Any meningococcal vaccine.
(P) Any vaccine against the human papillomavirus.

C. Other government-issued vaccine definitions.

Federal public health officials have also published definitions of the term vaccine that have not been established by statute or regulation. Some are dictionary definitions or medical and scientific definitions, including the revised definition promulgated by CDC in September 2021, replacing "a product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease," to "a preparation that is used to stimulate the body's immune response against diseases."[152]

CDC-Advisory Committee on Immunization Practices Glossary[153] (ACIP) currently defines vaccine:

> A suspension of live (usually attenuated) or inactivated microorganisms (e.g., bacteria or viruses) or fractions thereof administered to induce immunity and prevent infectious disease or its sequelae. Some vaccines contain highly defined antigens (e.g., the polysaccharide of *Haemophilus influenzae* type b or the surface antigen of hepatitis B); others have antigens that are complex or incompletely defined (e.g., *Bordetella pertussis* antigens or live, attenuated viruses).

CDC Vaccines and Immunizations Glossary[154] defines vaccine:

> A suspension of live (usually attenuated) or inactivated microorganisms (e.g., bacteria or viruses), fractions of the agent, or genetic material of the [sic] administered to induce immunity and prevent infectious diseases and their sequelae. Some vaccines contain highly defined antigens (e.g., the polysaccharide of Haemophilus influenzae type b or the surface antigen of hepatitis B); others have antigens that are complex or incompletely defined (e.g. *Bordetella pertussis* antigens or live attenuated viruses).

[152] https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm
[153] https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/glossary.html
[154] https://www.cdc.gov/vaccines/terms/glossary.html

IV. Brief Analysis

There are many terms for, and/or related to, biological products currently in use.

Statutes, regulations, FDA guidance documents, World Health Organization documents, Mutual Recognition Agreements, and other records include allergen; allergenic product; antitoxin; antigen; biopharmaceutical; biosimilar biological product; biotechnology product; biotechnology; blood, blood component, or derivative; cell therapies; emerging technology in the context of the pharmaceutical and related industries; first interchangeable biosimilar biological product; gene therapies; immunogen; intentionally altered genomic DNA; monoclonal antibody; plasma-derived pharmaceutical; plasma-derived product; plasmid; polypeptide; protein; recombinant protein; reference product; somatic cell therapy; synthetic biological product; therapeutic biotechnology-derived biological product; therapeutic recombinant DNA-derived product; therapeutic serum; vaccine; virus; toxin; and more.

Many of the documents acknowledge the extent to which biological product manufacturing cannot be standardized, such that product purity is an impossible regulatory standard for any biological product to achieve.

Manufacturing quality for a given package of biological material can, at best, contain a percentage of product assayed to be in conformity with contents as described on the label, at the moment of sample testing.

Even if products meet limited, fractional purity standards at the moment of sample testing, the contents of each package are subject to further changes over time due to metabolic processes and byproducts, sedimentation, mixing, temperature changes, degradation and other factors, because the contents are comprised of living, dynamic and therefore non-stable components.

After entering the body of each recipient, each biological product undergoes additional unpredictable, widely variant changes as the components interact with the living organism through billions of biological events.

Deregulation of biological product manufacturing, mid-1990s to present.

Published March 15, 2024

Don't-ask-don't-tell as applied to vaccines and other difficult-to-characterize, highly-susceptible-to-contamination medical-military poisons.

Catherine Austin Fitts, speaking Feb. 9, 2023[155] -

> "…The financial coup started in 1995. There was a budget deal that busted and I was told by a variety of people that quote, 'They have given up on the country and are moving all the money out starting in the fall...'
>
> But what is interesting is the month after the bust-up of the budget deal you had the FDA approve Oxycontin. And the HUD, and some of the other agencies, approved predatory lending practices for poor neighborhoods. And suddenly those neighborhoods were being targeted by three things: by Oxycontin and the pill mills; by unbelievable predatory lending which was driving people out; and finally by SWAT teams that were rounding up and stuffing people into slave labor camps is the only way I can describe it...
>
> And a series of things started. I call it the Great Poisoning, that we're bringing down life expectancy...
>
> We're going to intentionally bring down life expectancy, because if you cannot get the retirement system on a sound financial footing, and there's no political support for that, then your only other way of balancing the budget is to either bring down life expectancy, and or take the money and run, which is what I think has happened..."

As reported in the March 12 post, in November 1973, FDA issued a set of consolidated regulations[156] governing biological product manufacturing under Section 352 of the Public Health Service Act (42 USC 262), including definitions for key terms.

> 21 CFR 600.3(h) *Biological product* means any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man:
>
> 21 CFR 600.3(h)(1) A *virus* is interpreted to be a product containing the minute living cause of an infectious disease and includes but is not limited to filterable viruses, bacteria, rickettsia, fungi, and protozoa.
>
> 21 CFR 600.3(h)(2) A *therapeutic* serum is a product obtained from blood by removing the clot or clot components and the blood cells.
>
> 21 CFR 600.3(h)(3) A *toxin* is a product containing a soluble substance poisonous to laboratory animals or to man in doses of 1 milliliter or less (or equivalent in weight) of the product, and having the property, following the injection of non-fatal doses into an animal, of causing to be produced therein another

[155] Feb. 5, 2024 - Feb. 9, 2023 Children's Health Defense Q&A, transcript.
[156] https://bailiwicknewsarchives.files.wordpress.com/2024/03/1973.11.20-38-fr-32048-fda-biological-product-regulation-baseline-21-cfr-600-to-680-42-usc-262.pdf

soluble substance which specifically neutralizes the poisonous substance and which is demonstrable in the serum of the animal thus immunized.

21 CFR 600.3(h)(4) An *antitoxin* is a product containing the soluble substance in serum or other body fluid of an immunized animal which specifically neutralizes the toxin against which the animal is immune.

21 CFR 600.2(h)(5) A product is *analogous*:

(i) *To a virus* if prepared from or with a virus or agent actually or potentially infectious, without regard to the degree of virulence or toxicogenicity of the specific strain used.

(ii) *To a therapeutic serum*, if composed of whole blood or plasma or containing some organic constituent or product other than a hormone or an amino acid, derived from whole blood, plasma, or serum.

(iii) *To a toxin or antitoxin*, if intended, irrespective of its source of origin, to be applicable to the prevention, treatment, or cure of disease or injuries of man through a specific immune process…

21 CFR 600.3(p) The word "*safety*" means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time.

21 CFR 600.3(q) The word "*sterility*" is interpreted to mean freedom from viable contaminating microorganisms, as determined by the tests prescribed in Section 610.12 of this chapter.

21 CFR 600.3(r) "*Purity*" means relative freedom from extraneous matter in the finished product, whether or not harmful to the recipient or deleterious to the product. "Purity" includes but is not limited to relative freedom from residual moisture or other volatile substances and pyrogenic substances…

<u>As noted in the March 12, 2024 post, FDA has never defined the term *vaccine* through rule-making.</u>

After reading through rule-making documents and thinking about things more the last few days, I now think that *vaccines* as a biological product class are non-specifically, pseudo-defined defined in 21 CFR 600.3(h).

I think *vaccines* are products "*analogous to*" viruses, therapeutic serums, toxins and antitoxins, for which FDA has promulgated definitions, and *vaccines* are probably also covered by a new category of *protein* added to the list in February 2020.

To wit, in February 2020, at the initiation of fake clinical trials for the biological products unleashed on the world as Emergency Use Authorization "Covid-19 vaccines," then-FDA Commissioner Stephen Hahn issued a Final Rule (85 FR 10057[157]) revising the definition at 21 CFR 600.3(h), *biological product*, to align it with statutory changes made by Congress to 42 USC 262 between 1973 and 2019.

[157] https://bailiwicknewsarchives.files.wordpress.com/2024/03/2020.02.21-85-fr-10057-fda-final-rule-definition-protein-40-amino-acid-21-cfr-600.3h6-biological-product.pdf

The introductory section now reads:

> 21 CFR 600.3(h) - *Biological product* means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.
>
> And the *protein* category of biological product has been added to the list of defined biological products: 21 CFR 600.3(h)(6) - A *protein* is any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. When two or more amino acid chains in an amino acid polymer are associated with each other in a manner that occurs in nature, the size of the amino acid polymer for purposes of this paragraph (h)(6) will be based on the total number of amino acids in those chains, and will not be limited to the number of amino acids in a contiguous sequence.

Don't-ask-don't-tell was a Clinton-era military policy.

"Don't ask, don't tell" (DADT) was the official United States policy on military service of non-heterosexual people. Instituted during the Clinton administration, the policy was issued under Department of Defense Directive 1304.26 on December 21, 1993, and was in effect from February 28, 1994, until September 20, 2011…The act prohibited any non-heterosexual person from disclosing their sexual orientation or from speaking about any same-sex relationships, including marriages or other familial attributes, while serving in the United States armed forces…The "don't ask" section of the DADT policy specified that superiors should not initiate an investigation of a service member's orientation without witnessing disallowed behaviors… (Wikipedia[158])

*

The mechanisms for legalized non-regulation of biological products are very similar in structure to "Don't ask, don't tell."

Briefly, since the mid-1990s, citing authority derived from Congressional acts and Presidential executive orders, the Food and Drug Administration has been quietly eliminating its own regulatory functions through Federal Register rule-making notices and Guidance for Industry publications.

FDA has essentially told biological product manufacturers:

"We're not going to ask you what's in the products that you send out of your factories, and you shouldn't tell us what's in the products that you send out of your factories."

The ostensible reason was to relieve paperwork burdens and costs on pharmaceutical manufacturers. The changes are scientifically pseudo-justified with assertions that manufacturers have developed such excellent internal quality-control processes and technologies, that FDA validation of manufacturer claims about product purity, sterility and safety are no longer needed.

This is nonsense, as are many other FDA claims to be found in Federal Register notices and guidance documents.

[158] https://en.wikipedia.org/wiki/Don%27t_ask,_don%27t_tell

Biological products, including but not limited to vaccines, are inherently heterogeneous, impure, non-sterile, immuno-toxic, and unstable.

FDA lawyers, pharmacologists, toxicologists, factory inspectors and product reviewers know those truths. They have known those truths for many, many decades.

The real reason for the rule changes was to enable biological product factories to be more fully converted to non-regulated, black-box poison factories and to increase the toxicity of the poisons distributed from their loading bays.

As I continue working my way through the documents to understand what happened in more detail and write about it more fully, some relevant records are listed below for readers who are also interested in piecing the story together.

Vaccines have always been heterogeneous mixtures of toxins used to intentionally sicken people and animals.

Public health and regulatory systems have consistently hidden those truths behind false claims about the effects of vaccines, and behind legalized non-regulation of biological product manufacturing.

Published March 20, 2024

The US Food and Drug Administration and other drug manufacturing regulators claim that drug manufacturing regulation is about assessing product purity, sterility, potency, safety and efficacy to protect humans and animals from impure, adulterated, contaminated, impotent, harmful, and/or ineffective products.

Biological products can be defined as a subset of the larger category of drugs. Biological products are drugs manufactured through biological processes that take place within living organisms. Drugs that aren't biological products are manufactured through chemical processes. Vaccines are included in the biological products class of drugs.

A defining characteristic of biological products, in legal terms, is their rule-governed exemption from regulatory oversight that applies to and is enforceable for drugs manufactured using chemical processes.

One of several defining characteristics of biological products as murder weapons, is their ability to biologically incorporate into the target's body, such that weapons become indistinguishable from victims. Empty vials, syringes and other residual evidence disappears into garbage dumps and medical waste incinerators.

Eleanor McBean published a book in 1957 called *Poisoned Needle*.[159]

She carefully documented the history of vaccination lies prior to and since Edward Jenner's cow-pox and smallpox lies. She collected dozens of doctors' observations throughout the 1700s, 1800s and early 1900s, supporting the conclusion that vaccines have always been nothing more than toxic slurries introduced into healthy people and animals for the purpose of making them weaker and sicker and dead, while enabling the poisoners to lie to themselves and to their victims about what they're doing, how and why.

One example from *Poisoned Needle*:

> Dr. J. W. Hodge had considerable experience with vaccination before he denounced it and wrote a book on his collected data. In his [1902] book *The Vaccination Superstition* (p. 41) he states:
>
> "After a thorough investigation of the most authentic records and facts in harmony with the physician's daily observations and experiences, the conclusion is drawn that instead of protecting its subjects from contagion of smallpox, vaccination actually renders them more susceptible to it.
>
> Vaccination is the implantation of disease — that is its admitted purpose. Health is the ideal state to be sought, not disease . . . Every pathogenic disturbance in the infected organism wastes and lowers the vital powers, and thus diminishes its natural resisting capacity.
>
> This fact is well known and so universally conceded that it seems superfluous to cite authorities. Nevertheless, I shall mention one. *The International Textbook of Surgery - Vol. 1*. p. 263, is authority for the

[159] https://archive.org/details/the_poisoned_needle_mcbean

following statement: 'Persons weakened by disease or worn out by excessive labor yield more readily to infection than healthy individuals.'

If this is true, it explains why, in various epidemics, smallpox always attacks the vaccinated first, and why these diseases continue to infest the civilized world while its allied (unvaccinated) 'filth diseases' have disappeared before the advance of civilization, through the good offices of sanitation, hygiene and improved nutrition."

For the last few years, I've been documenting the development of American public health emergency anti-law[160] as a distinct layer of statutes, regulations, executive orders and court cases that overrides and suspends good laws criminalizing (among other crimes[161]) intentional use of poisons, including vaccines, to injure and kill people.

Public health emergency law as a tool to enable deniable, spatially-distant, time-shifted homicide became more visible because public health emergency law was used to start the Covid-19 killing programs and is still being used to maintain the Covid-19 killing programs.

Public health emergency statutes, regulations, executive orders and court cases govern, among other things, non-regulation of poisons (i.e. emergency use authorization/EUA countermeasures[162]) during declared emergencies.

In December 2023, I located a *Federal Register* Notice of Final Rule through which then-FDA Commissioner Scott Gottlieb shut the doors of all biological product manufacturing facilities to FDA inspections, effective May 2, 2019, eight months before public announcement of Covid-19, and more than a year and a half before the Covid-19 mass vaccination campaign got underway in December 2020.

This fact helps to answer the question: How could hundreds of millions of doses be manufactured, shipped and ready for use a few weeks after the FDA's December 2020 "emergency use authorization" decisions? Manufacturing began well before Covid was announced, inside factories not subject to inspection. That's how.

Reading Gottlieb's rule-change a few months ago, I realized that non-regulation of biological product manufacturing under routine, non-emergency conditions, had been in effect — or, rather, non-effect — since long before Covid, and will still be in effect/non-effect even if emergency declarations about Covid and other fake communicable disease and public health threats are revoked someday.

So for the last couple of months, I've been thinking about and collecting more legal evidence that biological product anti-law under non-emergency conditions *also* suspends or overrides good laws criminalizing (among other crimes) intentional use of poisons to injure and kill people, just as effectively as public health emergency anti-laws do.

The legal history of routine non-regulation of all biological products can be assembled in the same way the legal history of emergency-predicated non-regulation of EUA countermeasures has been assembled.

Such a collection would document how, over time, built-in exemptions from otherwise applicable, enforceable manufacturing rules, along with rule changes, and explicit notices from FDA to manufacturers (called Guidance for Industry) that FDA would not, will not and does not enforce rules, have rendered biological product non-

[160] https://bailiwicknews.substack.com/p/american-domestic-bioterrorism-program
[161] https://bailiwicknews.substack.com/p/constitutional-challenges-to-kill
[162] https://bailiwicknews.substack.com/p/on-the-significance-of-21-usc-360bbb

regulation more non-regulatory as each year has passed.

However, sifting through hundreds of rule changes to track each rule as it's become increasingly inapplicable and unenforceable, is an exercise in grasping at smoke. So I'm not planning to pursue it further, unless an attorney contacts me with a credible proposal for a case that would be strengthened by detailed accounts of FDA *Federal Register* rule-making activities over the past half-century or so.

As an example, in November 1973, just after regulation of biological products transferred from NIH Division of Biologics Standards to the FDA Bureau of Biologics, FDA published a revised, consolidated set of biological product manufacturing regulations at 21 CFR 600 to 21 CFR 680.[163]

At 21 CFR 610.11, the 1973 FDA rules established that the only "general safety" test (GST) required to claim a biological product was safe, was to inject a sample into two mice and two guinea pigs. If the two mice and two guinea pigs didn't get "significant symptoms" or die within seven days, "the product meets the requirements for general safety."

FDA authorized "exceptions to this test...when more than one lot is processed each day" and "variations of this test...whenever required." Manufacturers were directed to apply to the Bureau of Biologics (now the Center for Biologics Evaluation and Research) for exemptions.

After a series of revisions, FDA eliminated general safety test requirements for biological products, effective Aug. 3, 2015 (80 FR 37971).

FDA has made dozens of similar rule changes, weakening and eliminating rules about samples, protocols and lot-by-lot release; establishment and product licensing applications; post-approval manufacturing process changes; mixing, diluting and repackaging and more, including the elimination of facility inspections Gottlieb put in place effective May 2, 2019.

It's important to understand that the acts FDA officials have committed, to eliminate applicability and enforceability of drug manufacturing regulations for biological product manufacturing, have not been acts to eliminate actual regulation of medicines.

They have been acts to eliminate what has, from the start, been pretend-regulation to enable unimpeded manufacture, distribution and use of intentional poisons, so that their true character as poisons could be hidden from and invisible to the public.

A few weeks ago, I located Mutual Recognition Agreements. MRAs are international trade treaties. When signed and ratified by national governments, MRAs authorize national regulators — including drug regulators — to be "relieved of" their regulatory obligations and instead, recognize and rely on the regulatory decisions of other countries' regulators, especially the US Food and Drug Administration.

The two systems interlock.

Under the legal terms of MRA treaties, US-FDA can be legally construed as the sole regulator for worldwide drug manufacturing and distribution systems.

[163] https://bailiwicknewsarchives.files.wordpress.com/2024/03/1973.11.20-38-fr-32048-fda-biological-product-regulation-baseline-21-cfr-600-to-680-42-usc-262.pdf

Under the legal terms of the US-FDA drug regulation system, all biological product manufacturing can be legally conducted with no substantive disclosure, monitoring or enforcement of rules controlling purity, sterility, safety, potency, efficacy, raw materials, manufacturing processes, or chemical and biological composition of finished, packaged, distributed products.

Also note, the legal structure of Mutual Recognition Agreements plus FDA-non-regulation-of-biological-products, operates separate from and in addition to the UN-World Health Organization, International Health Regulations system.

National governments interested in shielding their populations from intentional poisoning must withdraw from the United Nations and WHO treaties; must withdraw from the IHR treaty; and also must withdraw from each Mutual Recognition Agreement treaty that subordinates their own federal drug regulation to other countries' regulators, including the US-FDA non-regulation, poison-facilitation system.

It's plausible that some simpler biological products (insulin, for example) may have historically been manufactured, and may still today be manufactured, to meet measurable, achievable standards of safety and batch-to-batch consistency, because doing that would help US-FDA and pharmaceutical companies maintain public confidence and reduce the likelihood that the public would begin to see and understand the biological-product-based intentional poisoning program.

It's also plausible that biological products labeled as vaccines have had, for many decades and still today, a high degree of batch-to-batch variation ranging from low to high toxicity, because that also would be a sensible way for US-FDA and pharmaceutical companies to maintain high levels of public ignorance, complacency and compliance with vaccination programs.

Vaccine and related biological product manufacturing as US government-licensed poison manufacturing.

Evidence from November 1986 'mandate for safer childhood vaccines' codified at 42 USC 300aa-27, and July 2018 stipulation by HHS.

Published March 21, 2024

Summary of legal history findings to date

The development since 1944, of American statutes and regulations governing US-Food and Drug Administration product licensing functions and non-functions, along with international Mutual Recognition Agreements and public health emergency/emergency use authorization/medical countermeasures law, support the conclusion that *all* biological products allegedly regulated by the FDA for compliance with manufacturing quality standards, distributed and used on the American population — and through MRAs, exported to countries around the world for use on populations worldwide — are in fact, unregulated.

Laws have been written to enable operators of biological product manufacturing facilities to legally make and distribute poisons. Legalized poisons are produced by US military-public health contractors working under black box conditions inside pharmaceutical factories in the US and in countries occupied by US financial, public health and military forces.

FDA, DoD and military-pharmaceutical manufacturing contractors don't take every opportunity to adulterate every production run. They have vested interests in keeping the public in the dark about their legal access to production lines, and the availability of some harmless and/or beneficial products makes it more difficult for people to understand that the chemical and biological weapons emerging from the same factories are weapons.

The toxicity of vaccines and vaccine-related biological products has been incrementally increased over time.

Injuries and deaths caused by vaccines are falsely attributed to communicable disease, inherited genetic disorders and environmental exposures by the same public health, military and pharmaceutical manufacturing executives jointly running the intentional poisoning programs.

One of the most striking features of this almost-unimaginably vast military/public-health/pharmaceutical deception program is how the things that don't happen matter as much as — and often more than — the things that do happen.

The records that can't be located are as revealing as, and often more revealing than, the records that can be found.

One vivid example: blank pages enclosed as package inserts with Covid-19 vaccines.

Another example: if there had ever been any legal requirement for FDA to prevent Covid-19 vaccines from harming clinical trial subjects, and from later harming recipients in what many still irrationally insist is a consumer product market, FDA officials would have denied all of the Covid-19 vaccine manufacturers' licensing applications submitted starting in February and March 2020.

FDA would have denied the applications based on evidence accrued since genetic engineering research began, about harms caused to animal and human recipients of cell- and gene-based compounds, lipid nanoparticles,

and other components listed on and/or redacted from application documents.

FDA did not deny manufacturers legal access to human targets.

Instead, FDA authorized legal access to several thousand targets in spring, summer and fall 2020, and then authorized legal access to everyone else in the world in December 2020.

Following FDA's failure to deny manufacturers' authorization to conduct what have since been revealed as fake clinical trials,[164] if FDA had held a legal obligation to protect the public from biological product poisons, FDA officials would have immediately halted the alleged clinical trials in mid-2020 upon the first reported adverse effects and deaths.

Failing that, a drug manufacturing regulator with a legal obligation to protect people from harm would have immediately recalled all Covid-19 vaccines as soon as general public recipients in December 2020 and early 2021 started having anaphylactic reactions, developing heart damage and turbo-cancers and dropping dead; as soon as women started shedding decidual casts and miscarrying babies in the womb; and as soon as all the other injuries, diseases and deaths became clearly observable worldwide. (*See,* for example, Pfizer 5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports received through Feb. 28, 2021, Table 1 at p. 7[165])

FDA did not halt the pretend clinical trials, and has not recalled the vaccines, ordered the manufacturers to cease production, or ordered pharmacists, nurses and doctors to stop using them.

National Childhood Vaccine Injury Act

The "mandate for safer vaccines" section of the 1986 National Vaccine Act and the Vaccine Injury Compensation Program offers another good example of events that should have taken place but didn't, and records (recording those events) that should have been produced but weren't.

In November 1986, Congress and President Reagan passed the State Comprehensive Mental Health Services Plan Act.[166]

The National Childhood Vaccine Injury Act section of the act (Title III) amended the 1944 Public Health Service Act to establish and fund a National Vaccine Program; grant vaccine manufacturers legal immunity for injuries and deaths caused by their products; and establish and fund a National Vaccine Injury Compensation Program, all of which was codified at 42 USC 300aa et seq.[167]

At 42 USC 300aa-27,[168] Congress established a "mandate for safer vaccines."

> (a) General rule. In the administration of this part and other pertinent laws under the jurisdiction of the [HHS] Secretary, the Secretary shall—
>
> > (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

[164] https://sashalatypova.substack.com/p/eua-countermeasures-are-neither-investigational
[165] https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf
[166] https://www.congress.gov/99/statute/STATUTE-100/STATUTE-100-Pg3743.pdf
[167] https://www.law.cornell.edu/uscode/text/42/chapter-6A/subchapter-XIX
[168] https://www.law.cornell.edu/uscode/text/42/300aa-27

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) Task force

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

(2) The Director of the National Institutes of Health shall serve as chairman of the task force.

(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

(c) Report. Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

*

The 1986 National Childhood Vaccine Injury Act gave manufacturers immunity from liability for injuries and deaths caused by vaccines listed on the government-recommended childhood immunization schedule.

One of the justifications used to exempt manufacturers from liability was that the US government, through the Department of Health and Human Services, would monitor the childhood vaccine program, collect safety data, report the data to Congress to provide oversight, and take harmful vaccines off the market.

Safety monitoring and reporting as called for in the 1986 law did not occur.

In August 2017, the Informed Consent Action Network[169] (ICAN) filed a FOIA request with HHS, requesting copies of the biennial reports that should have been prepared and submitted to House and Senate committees between 1987 and 2018.

In June 2018, HHS responded to ICAN's request:

"The [Department]'s searches for records did not locate any records responsive to your request. The [HHS] Immediate Office of the Secretary (IOS) conducted a thorough search of its document tracking systems. The Department also conducted a comprehensive review of all relevant indexes of HHS Secretarial Correspondence maintained at Federal Records Centers that remain in the custody of HHS. These searches did not locate records responsive to your request, or indications that records responsive to your request and in the custody of HHS are located at Federal Records Centers."

[169] https://icandecide.org/get-informed/?t=25

Informed Consent Action Network v. US-HHS, (1:18-cv-03215-JMF), resulted in a July 9, 2018 stipulation[170] signed by Attorney Robert F. Kennedy Jr.

The stipulation quoted the June 2018 acknowledgement, by HHS, that HHS had no record of any safety monitoring activity or public, Congressional reporting of the childhood vaccination program, under the 1986 law, between 1986 and 2018.

Later two reports were located, filed on May 4, 1988[171] and July 21, 1989[172] (partial, no appendices). The 1988 and 1989 reports addressed vaccine promotion, vaccine supply, vaccine research activity (see, for example, pp. 67-78 of 1988 report), and set-up of reporting and data analysis programs.

Since 1989: nothing.

HHS has never systematically collected or reported information from parents, pediatricians, toxicologists, manufacturers, or anyone else about harms caused by childhood vaccines administered in single doses, combined doses (i.e. measles-mumps-rubella), or cumulative doses (the childhood schedule), and HHS has never collected or reported information about the harmful effects of biological components, chemical adjuvants, preservatives or any other ingredients.

*

What would a true vaccine monitoring, reporting and product safety program have looked like?

It would have included detailed records of:

- Date, time and location of vaccine administration, including the name of the nurse or other health care worker who administered the vaccine, and the doctor who ordered the vaccine.
- Parent and doctor observations of symptoms of injury in the baby and child post-vaccination: what the symptoms were, when they occurred in relation to the vaccine, how long they lasted, how severe they were, whether they were transient or chronic, and whether the parent was subsequently advised to refrain from further vaccination of the child.
- Serial number of the vaccine vial, identifying the manufacturing facility by name and address, lot number, batch number, date of manufacture, and names of production line workers who prepared the batch, separated out the lot, and filled the vial.
- Dates, times and shipping methods through which the vaccine vial was shipped from the factory and received by the doctors' office, hospital or pharmacy.
- Storage and handling of the vaccine vial by the employees at the doctors' office, hospital or pharmacy.
- Each chemical and biological component listed or not listed on the vaccine label, including chemical and molecular structure, raw materials, cell lines, active ingredients, adjuvants, preservatives and all other components.
- Each manufacturing protocol used at each step in the production process, fully describing the chemical and biological reactions, procedures and methods used to make each component of the vaccine, including the final, finished product.

[170] https://www.icandecide.org/wp-content/uploads/2019/09/Stipulated-Order-copy.pdf
[171] https://www.documentcloud.org/documents/5835885-Report-1.html
[172] https://www.documentcloud.org/documents/5835886-Report-2.html

- Names of the suppliers of each chemical and biological ingredient; date and time at which each ingredient was delivered to the vaccine factory; name of the employee who received the delivery.
- FDA inspections of the manufacturing facility during the period when the vaccine was manufactured, including date and time of inspections and names of the inspectors.
- Samples and protocols from the lot, submitted by the manufacturers to the FDA Bureau of Biologics, including date, time, shipping method and name of the person who submitted the samples and protocols.
- Samples and protocols from the lot, received by the FDA Bureau of Biologics, including date, time, shipping method and the name of the person who received the samples and protocols.
- Results of sample and protocol testing, by FDA inspectors, validating that the sample contained the compounds listed on the label; did not contain any compounds (adulterations or contaminants) not listed on the label; and that the protocol the manufacturer reported using, in fact yielded a chemically and biologically identical final product when applied by an FDA inspector to the same ingredients in the same sequence using the same methods.
- FDA written certification of each lot for release, distribution and use, including names of FDA inspectors, signatures and dates of lot-release.

*

The July 2018 ICAN-HHS stipulation supports the conclusion that none of those regulatory functions have been performed, no records of vaccine manufacturing regulation have been produced by FDA or regulated manufacturers, and no records have been collected, assessed or used by HHS.

No vaccine manufacturing safety regulation has been conducted by FDA, NIH, CDC or any other HHS department, at any time since Congress passed the 1986 "mandate for safer vaccines."

Or, if such evidence has been collected, it's been collected under classified military data collection systems, to confirm and refine national vaccination programs as an effective chemical and biological weapons production and distribution system capable of deniably inducing rapid death (i.e. Sudden Infant Death Syndrome) and chronic diseases including asthma, allergies, neurological disorders, gastrointestinal disorders, autoimmune disorders, heart disease, diabetes, obesity, cancer and other immune-mediated diseases.

Pray the Rosary.

Stop taking vaccines.

On why FDA revised written non-rules for non-regulation of biological products to make them more unintelligible, inapplicable and unenforceable since the 1990s. Part 6 of series.

Published April 3, 2024

March 24, 2024 - Katherine Watt email to Sasha Latypova

I've been thinking about the FDA regulation and guidance changes that sped up during the 1990s. Since the FDA's function regarding biological products, especially vaccines, was non-regulatory from the beginning because the contents have always been toxic mixtures intended to harm recipients, I wondered why they would need or want to get rid of or change the way the earlier rules were/are inapplicable and unenforceable.

Part of the reason has to do with pretend-oversight events by Congress, such as after thalidomide in the late 1950s, after some Government Accountability Office (GAO) and news reports about vaccines in the early 1970s, and then after the military anthrax vaccine events in the early 1990s. After each such event, a new shuffling of departments and/or set of non-rule rules came into play.

I think another reason is that the non-regulation rules had to be aligned with technical improvements in the ability to sequence biological and genetic samples.

If it's correct that the 1990s were the beginning of more widespread laboratory access to equipment and computer software capable of processing samples and producing a more accurate, detailed gene map of what was in the samples, and the graduates of more biology and chemistry programs would have known how to use that equipment and interpret that data as they started filling the lab positions at FDA, then there would have been a need to make sure that the equipment either never got installed at FDA, or got installed in alignment with proper indoctrination of the incoming FDA lab technicians/inspectors alongside the elimination of the procedures for manufacturers to submit samples and protocols to be tested by the FDA technicians.

Probably that also aligned with the increased ability of the poisoners to insert specific types of damaging gene fragments, with a greater knowledge about what those sequences would do in vivo.

In other words, the poisons pre-1990s were somewhat more crude, and since 1990s are somewhat more refined. Still dirty bombs,[173] but dirty bombs whose components can increasingly be identified, as the separation chemistry techniques and software and sequence-matching databases get better.

Kevin McKernan's work is an example of what an FDA technician could have done, if the manufacturers had had to submit samples, and if FDA had had to run the samples and produce accurate, public reports about the results.

Does this line up with what you know about the development of chromatography and related techniques, equipment, software and databases since the 1990s?

*

[173] https://bailiwicknews.substack.com/p/mrna-lnp-compounds-are-cellular-genetic

March 24, 2024 - Sasha Latypova email to Katherine Watt

> Yes, in general this would be the evolution. Kevin McKernan's lab is a good example. He is set up to perform only one aspect of impurity testing: plasmid DNA removal.
>
> There are many more things that would need to be tested properly to identify RNA stability, LNP stability, other impurities, etc.
>
> The evolution of tools to characterize what is being produced by bio-chemistry methods is very important.
>
> I didn't work in the area of biologics, so I am not too familiar with these methods and the current state of technology.
>
> From what I read in Pfizer's leaked manufacturing documents, however, a very large portion of the characterization techniques were either missing or de-novo invented by Pfizer, and thus were black box, unvalidated, non-standard techniques that would normally require a separate approval. So, this area of manufacture is basically still an unknown.
>
> They can't demonstrate that they make what they claim. It is, of course, on purpose.
>
> This also explains why FDA removed all the requirements for testing samples by the inspectors in 2019, because they knew there is no way to do this, and the inspectors themselves would have raised concerns.

*

From another email exchange, with a reader who holds the view that the killers possess the knowledge and manufacturing methods to develop "high quality heterogeneous products that specifically target multiple physiological processes and cause variable expected (on target) and unexpected disease (off target) outcomes."

Sasha Latypova:

> There is no "gene targeting" whatsoever. They cannot manufacture what they claim they do. As I said in an interview with Malik,[174] their CRISPR and other "gene targeting" claims amount to claiming that they can bake a loaf of bread with exact number of holes of exact size in exact locations. They cannot do that.
>
> They can't even make the loaves weigh the same every time. The manufacturing quality control is non-existent. They don't even have methods to evaluate LNP size, and can't figure out what those might be.

Katherine Watt:

I think researchers who have studied Gardisil, Covid-19 and other vaccines have correctly identified some of the mechanisms of injury caused by some of the possible contents of the studied products, keeping in mind that the main sources for information about what may be in the products, are manufacturers, who provide only false and incomplete/redacted information to regulators and regulators, who provide only false and incomplete/redacted information to the public and to academic researchers.

[174] https://docmalik.substack.com/p/152-sasha-latypova-on-the-covid-19

My understanding of all vaccines — based on my understanding of drug manufacturing, communicable disease control, and public health emergency law — is that since the beginning of their modern use, as far back as the mid-1800s, then increasing use starting in the first decade of the 20th century, vaccines have been mixtures comprised primarily of fragments of foreign (xeno) proteins whose basic function is to interfere with and damage normal cells and normal cell growth, division, repair and destruction processes.

The exact composition of each batch, lot and vial contents is not predictable, because the manufacturing processes themselves don't lend themselves to standardization. Biological products result from biological processes, which are complex and highly variable. As sequencing equipment and techniques became more sensitive and widely available in the 1990s, the protein fragments have become increasingly identifiable, but the only way to identify all of the fragments in each vial, would be to test all of the contents, leaving none for use.

Also, identification of all the fragments would lead to public knowledge of their inherent and intentional toxicity; this is why the regulatory systems had to develop more complex written forms and justifications for non-regulation over the last several decades.

The chemical components (i.e. adjuvants and preservatives) have their own toxicity profiles, and are more subject to standardization.

On a population-wide scale, therefore, people who want to induce infertility, cancer, heart disease, autoimmune disorders, and all the other observed disorders that have increased throughout the 20th century and exploded since 2021, have not needed or wanted, and still do not need or want, predictability of effect for a given vial or dose (or series of doses), as used on a specific individual.

They need and want widespread, non-critical trust in the class of products known as vaccines combined with mass, ongoing, serial use of the products, which are widely varying, protein-fragment-rich and toxic-chemical-rich mixtures whose compositions are highly unpredictable and which are not subject to testing to identify their contents before use.

The less predictable the effects on a per-dose, per-target basis under social conditions of high, non-critical trust in vaccines as a product class, the better for the killers, because the chain of causation is more difficult to discern.

The only change the killers have needed or wanted to introduce over time to increase infertility, cancers, and other causes of premature death, has been to increase the concentration and variety of the toxic protein fragments and toxic chemical compounds, while maintaining and increasing non-critical public trust in the product class and increasing the number of doses on the child and adult immunization schedules.

They maintain the high levels of non-critical public trust in the vaccine product class, in two main ways.

First, they attribute all observed adverse effects to non-vaccine causes and attempt to discredit and suppress all information that correctly identifies vaccines as intentional toxins, preventing sound investigation into vaccines as the primary causes.

Second, they suggest that if, hypothetically, some vaccines have some adverse effects, those effects are due to specific, predictable, identifiable components with specific, predictable, identifiable effects, thus reinforcing the false notion that vaccines generally are a class of products whose contents and effects are specific, predictable and identifiable, thus maintaining and/or increasing non-critical public trust in the product class.

This is why I'm working to disrupt public trust in the entire class of products known as vaccines, not only Covid-19 vaccines.

One way to confirm or refute the claim that all vaccines are heterogeneous mixtures of intentional toxins, would be to subject vials of all vaccines promoted by the CDC through the child and adult immunization schedules, to complete, accurate genetic sequencing and chemical analyses, at research laboratories equipped with the appropriate sequencing and analytical tools and databases.

That's why complete, accurate, publicly-reported genetic sequencing and chemical analysis of vaccines isn't done and why FDA changes biological product manufacturing rules over time, to more fully legalize the non-conduct of such investigations.

Bits and pieces about 10 USC 1107a(a) consent waivers, EUA products, BLA products, legalized FDA non-regulation of pharmaceutical manufacturing, and related things.

Published May 7, 2024

Correspondence with Bill Marshall of Judicial Watch this morning. FOIA (Freedom of Information Act) officers with US Department of Defense responded to another request Marshall filed on Feb. 1, 2023, seeking:

> Signed, dated documents recording date on which Presidents Trump and/or Biden waived informed consent for military personnel under 10 USC 1107a(a) to receive injections for the stated or intended purpose of preventing infection by the SARS-CoV-2 virus and/or prevention of COVID-19 disease.

*

10 USC 1107a(a) is a law authorizing the US president to waive the fake informed consent provision of the Emergency Use Authorization law — "option to accept or refuse," 21 USC 360bbb-3(e)(1)(A)(ii) — "if the President determines, in writing, that complying with such requirement is not in the interests of national security."

Congress passed it as another move in the multi-decade tug-of-war between Presidents, Defense Secretaries and FDA lawyers who like to force-poison military personnel using vaccines and other inherently toxic biochemical agents, and the handful of Congress members and federal judges who sometimes feel a little uneasy about providing legislative and judicial cover for those poisoning programs and try to pin the culpability tail on the executive donkey.

See, for example, President Bill Clinton's Executive Order 13139[175] (Sept. 30, 1999) *Administration of Investigational New Drugs to Members of the Armed Forces;* DoD Directive 6200.2[176] (Aug. 1, 2000), *Use of Investigational New Drugs for Force Health Protection*; NDAA FY2004 (PL 108-136, Nov. 24, 2003) at 117 Stat. 1690, *Emergency use products, Waiver by the President; Doe v. Rumsfeld I-III* (2003-2005)*;* and FDA Office of Counterterrorism Policy and Planning, *Guidance: Emergency Use Authorization of Medical Product*s (July 2007):[177] "…informed consent under part 50 of FDA regulations (21 CFR part 50) is not required for administration of an EUA product [and] Congress authorized the President to waive, under certain circumstances, the option for members of the armed services to accept or refuse administration of an EUA product (10 U.S.C. 1107a)."

See also, Dec. 1, 2023 - On 'mandates,' and the irrelevance of informed consent principles in the EUA countermeasures use context.

> "…Part of this is the substitution of "option to accept or refuse" for "informed consent" in a context in which informed consent is an incoherent principle, because no true information about the contents or effects of the product exists to be provided to targets; because the authorized consequences of refusal include firing and expulsion from school; and because targets are military targets whose consent is irrelevant, not clinical trial subjects (because no clinical trials are happening) and not patients (because no doctor-patient, diagnosis-treatment relationship exists)."

*

[175] https://www.govinfo.gov/content/pkg/WCPD-1999-10-04/pdf/WCPD-1999-10-04-Pg1875.pdf
[176] https://mrdc.health.mil/assets/docs/orp/irbo/11_DOD_6200.2_Use_of_INDs_for_FHP.PDF
[177] https://www.fdanews.com/ext/resources/files/archives/e/Emergency-Use-Authorization.pdf

On May 7, 2024, a DoD FOIA officer responded to Marshall's FOIA request:

> …No records were located responsive to your request.
>
> Additionally, please note that the Office of the Under Secretary for Personnel and Readiness noted that on August 23, 2021, US-FDA approved the biologics license application [BLA] for the Pfizer vaccine, which had previously been released under an emergency use authorization (EUA).
>
> According to the Secretary of Defense memo, "Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members," it states that "...Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the FDA...".

10 USC 1107a(a) requires a Presidential waiver only for products authorized for emergency use and no such waiver would have been necessary to mandate vaccination with a fully licensed vaccine.

*

Marshall asked for feedback.

My reply:

…DoD is probably correct that neither Trump nor Biden issued waivers under 10 USC 1107a(a). The fake BLA process was probably conducted mostly to provide cover so that Trump and Biden wouldn't need to issue the waivers. The dates of mandates, dates of injection, and vaxx lot identification (to identify EUA lots and BLA lots) are complicated.

The DOD Memorandum ordering vaccination was issued August 24, 2021. Some military personnel were injected before that date, and some after. Some believed that there was a physical difference between the EUA lots and the BLA lots, and some believed that there was a legal difference between the EUA lots and the BLA lots.

In truth, neither the EUA product nor the BLA product went through any real FDA manufacturing regulation process — both the EUA process and the BLA process were faked, by FDA, in collaboration with DoD and the manufacturers.

The fake-regulation is legal, under biological product licensing law and under public health emergency law. All biological product licensing and manufacturing in the US, as allegedly supervised by FDA, is faked, and the fake regulation is legal, and has been since before FDA took over biological product regulation from NIH in 1972. The rule-making paper trail is more readily available for the period since 1973.

I have not written much about the BLA process or its application to the Covid vaccines, because after I understood that the EUA was a completely separate track…(*See* Jan. 31, 2023 - August 2020 - Elizabeth Sadove presentation to FDA-CDC: Regulatory Updates on Use of Medical Countermeasures; Feb. 9, 2023 - On the significance of 21 USC 360bbb-3(k): "use" of EUA products "shall not constitute clinical investigation.")...I saw the BLA process as solely a distraction/misdirection campaign, and because I lack the detailed experience with regulatory paperwork and terminology to be able to untangle it properly for general readers.

Sasha has done some reporting on this.

As of June 2023, she regarded the BLA process as a real regulatory process, but not properly used — manipulated for improper, deceptive, "bait-and-switch" purposes: June 20, 2023 - Declaration of Peter "Pretzel" Marks[178]

By November 2023, she and I were discussing the fact that the BLA process is also fake, and one of the ways in which it was faked for the Covid-19 vaccines was by citing the alleged "clinical trials" conducted during the EUA process, as the basis for the BLA decision, when in truth, valid clinical trials were never and are never possible under the EUA legal framework, because by statute, use of EUA products "shall not constitute clinical investigation."

That's the legal mechanism that exempts use of EUA products from informed consent, Institutional Review Boards, prescriptions, labeling requirements, non-adulteration rules and all other protections for consumers of drugs, devices and biological products. See Latypova, Nov. 4, 2023 - Do C-19 Vax Manufacturers Violate cGxP?[179] and Nov. 8, 2023 - FDA "Approval" for Covid-19 Vaccines Was Fake - based non-investigational use of a non-experimental unapproved substance (a poison) [180]

The DoD FOIA response would be a good hook for more reporters to do more writing about the FDA's fake regulation of EUA products (as a subcategory of biological products) and fake regulation of the whole class of biological products, to help more people understand the massive fraud under which they consume manufactured products that are presented as FDA-regulated.

I've been working on a series about it for several months (since I realized in December 2023 that *all* biological products are legally regulation-exempt) and the intricacy of the lie structure built since 1973 is kicking my ass.

[178] https://sashalatypova.substack.com/p/declaration-of-peter-pretzel-marks
[179] https://sashalatypova.substack.com/p/do-fentanyl-dealers-violate-cgxp
[180] https://sashalatypova.substack.com/p/fda-approval-for-covid-19-vaccines

There is no legal limit to the amount of so-called contamination that can legally be included in vaccines or any other biological products.

Published May 21, 2024

On Kevin McKernan's latest re contaminants found[181] (by McKernan's lab and other labs) in vaccines:

> KW: There is no legal limit to the amount of so-called contamination that can legally be included in Covid-19 vaccines or any other vaccines or biological products. The FDA has no regulatory obligation to enforce compliance with any safety, efficacy or purity standards, and there are no defined safety, efficacy or purity standards to which FDA could enforce compliance, even if FDA inspectors were legally obligated to enforce compliance, which FDA is not obligated to do.
>
> The entire FDA regulatory system pertaining to biological products, including vaccines, is fake: it's intended only to deceive the public into believing that unregulated poisons are regulated medicinal products.

Reply to a comment[182] at one of Sage Hana's recent posts,[183] about mRNA technology having been around since the 1970s, but not used "because of the regulations."

> KW: From my findings about the non-regulation/pretend-regulation and non-definition of all biological products including vaccines, going back to 1902 and earlier, but better documented since the 1944 Public Health Service Act, 42 USC 262, and even better documented since the transfer of fake-regulatory functions from NIH to FDA in 1972, I think the statement that they've had the tech for about 50 years is also a mischaracterization.
>
> There is no "tech" in the sense of a predictable method to produce measurable, physically/chemically/pharmacologically identifiable, standardized, pure biological products.
>
> All vaccines are heterogenous mixtures of immunotoxic nucleic acids, metals, lipids and other junk, and they're all inherently unstable and inherently destructive to the recipient organism.
>
> The innovation of the post-2020 vaccines, I think, is slightly more effective lipid packaging to get the encased unstable junk into cells better and faster, to better bypass the functional parts of the immune system that can flag and destroy non-self genetic material (xenogeneic/different species, allogeneic/same species, different individual).
>
> Maybe they've known about the better lipid packaging since the 1970s, but also were playing the long con and then decided circa 2019 to put the pedal to the floor.
>
> The statutes and regulations were never in the way of putting toxic junk into babies and children and adults. They were always written to make and keep clear the legal path for the junk to get injected, and to make it look to the public like there was a real regulatory process to monitor and control manufacturing and use for safety, efficacy and purity. Which there was not.

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[181] https://substack.com/@bailiwicknews/note/c-56854218
[182] https://sagehana.substack.com/p/the-job-is-to-include-things-like/comment/56810869
[183] https://sagehana.substack.com/p/the-job-is-to-include-things-like

As I've written previously, I have a firehose of information and supporting evidence that I would like to share, because the information may be useful to one or more readers, but my available time, energy and ability to concentrate to digest the material and write it in more-accessible form comes nowhere near close to enough.

For readers interested in putting together more of the data points themselves, a key false concept and FDA term to study is "well-characterized therapeutic recombinant DNA-derived" biotechnology products.

Briefly, in the mid-1990s, analytical equipment, techniques and skilled labor capable of more fully characterizing nucleic acids, genetic material, chemicals, metals and other biologically-active compounds became more readily available.

By that time, people working in the US Government, especially in the Public Health Service (PHS), Department of Health and Human Services (HHS), National Institutes of Health (NIH), Food and Drug Administration (FDA), National Institute for Allergies and Infectious Diseases (NIAID), Centers for Disease Control and Prevention (CDC) and related military divisions, had already been working since 1955 (mass vaccination of children with polio-predicated immunotoxins) to systematically poison American babies and children using heterogeneous slurries of bacteria-, animal- and human-derived genetic material, toxic chemicals and toxic metals.

They had been increasing the toxic loads deliberately put into American babies and children by leaps and bounds since the 1986 adoption of the aptly-named National Childhood Vaccine Injury Act (Pub.L. 99-660) through the childhood immunization schedule inflicted by pediatric vaccine nurses.

And the health of American children was clearly deteriorating, as chronic disease rates shot up for autism, asthma, diabetes, cancer, depression and many other disorders.

The NIH/FDA regulatory record for biological products is non-existent, because the object of the vaccination program was and still is to systematically poison people and induce chronic disease for two purposes.

Long-term, over several decades, the perpetrators want to lower vitality, fertility and life expectancy among the population and thereby bring down budget expenditures for education, health care and pensions.

Short-to-medium term, the perpetrators want to increase profits, kickbacks and money-laundering for pharmaceutical corporation shareholders and Congress members, by supplying additional poisons to sick people, to manage the symptoms of induced chronic diseases.

To meet those dual goals, the most important thing was to build and maintain unquestioning public trust in the product class of vaccines.

The best way to build and maintain that trust — to shield the intentional poisoning from public view — was to pretend to operate a regulatory system that sets standards for product safety, efficacy and purity; monitors vaccine production to assess compliance by testing samples; and removes unsafe, ineffective and contaminated vaccines from the supply chain.

NIH-FDA set up and operated the required fake regulatory system from 1944 to the mid-1990s. Without going into detail, it hinges on provisions including 21 CFR 610.2, promulgated by Federal Register notice Nov. 20, 1973:

> 21 CFR 610.2. Requests for samples and protocols; official release.
>
> Samples of any lot of any licensed product, together with the protocols showing results of applicable tests, **may** at any time be required to be sent to the Director, [FDA] Bureau of Biologics [now CBER].
>
> Upon notification by the Director, Bureau of Biologics, a manufacturer shall not distribute a lot of a product until the lot is released by the Director, Bureau of Biologics; Provided, That the Director shall not issue such notification except when deemed necessary for the safety, purity or potency of the product. 38 FR 32048.

This is called "lot-release" or "lot-by-lot release."

It was a non-regulatory regulation when published in 1973.

Why non-regulatory or performative only?

1. Because of the conditional terms. Director "may" require samples and protocols, but "shall not except when deemed necessary."
2. Because the regulatory definitions of safety and potency were relative, not objective (all medical interventions involve personalized calculations about the starting condition of the patient, the risks of causing harm, and the potential benefits of the intervention);
3. Because the regulatory definition of purity was also given in relative, not objective terms; biological products are intrinsically impure, unstable, heterogeneous and non-standardizable, and FDA regulators and vaccine manufacturers knew this, have known this since the early 1900s and still know it.
4. Because the patient, in the case of vaccines, is a healthy baby or child, and the probability that introducing mixtures foreign genetic material, chemicals and metals into a healthy child's body will cause more harm than good, by inducing chronic disease and death, approaches 100% as more toxins are introduced, sooner during pregnancy or after birth, additively, and cumulatively.

That's the nutshell version of the non-regulation regulation "lot-release" system that was in play between 1973 and 1996.

In 1996, under the deregulation framework launched by President Ronald Reagan and continued by President Bill Clinton, the FDA eliminated lot-release for "well-characterized therapeutic recombinant DNA-derived" biotechnology products, stripping itself of the manufacturing quality control lot-release tool it had pretended to have and had pretended to use since 1973.

Lot-release was only one of many regulations eliminated or rendered more inapplicable to and unenforced for biological products since the mid-1990s.

*

If you work for an organization (Public Health Service-HHS-FDA-CDC-NIH-NIAID) that's systematically poisoning people with intrinsically heterogeneous, unstable, immunotoxic products, and you understand that parents will eventually start to notice the sickliness of their children and themselves, the last thing you want is a regulatory process — supported by analytical equipment and techniques — through which toxins might be identified and disclosed to the public, justifying removal of those toxic products from the supply chain.

But you also don't want to reduce public trust in the poison-products known as vaccines. That's the point the systematic poisoners had reached by the mid-1990s.

The solution, to buy themselves what turned out to be another 30 years, was to further eliminate the pretend-regulatory functions they had pretend-fulfilled, by simply claiming that the manufacturers would self-regulate using the analytical equipment, methods and skilled labor that became available by the mid-1990s.

Throughout the process, FDA would make true statements such as:

> Biologics have traditionally been complex mixtures of substances produced primarily from living organisms, and have been difficult to characterize by precise tests. They include vaccines, products made from human or animal blood, and other products made from a variety of materials. 60 FR 63048

And then establish non-regulatory policy based on the false, opposite premise:

> …technical advances over the last 15 years have greatly increased the ability of manufacturers to control and analyze the manufacture of many biotechnology- derived biological products. 61 FR 24227

In other words, FDA offers the public a series of lies — that biological products are homogeneous, stable and non-toxic; that biological products can be "well-characterized" as such; and that biological products are produced and distributed in safe and pure form by manufacturers, who police their own compliance with regulatory standards so thoroughly that FDA need not test samples or enforce compliance.

The lies are offered as a substitute for the truth: biological products are heterogeneous, unstable and toxic; every vial tested provides evidence of those truths; and FDA and manufacturers coordinate with each other to ensure that vials are not properly tested and that information about the intrinsic heterogeneity, instability and toxicity of vaccines doesn't reach the public in credible, actionable form.

There is no legal limit to the amount of so-called contamination that can legally be included in Covid-19 vaccines or any other vaccines or biological products.

Some relevant documents below for readers who want to track this a bit more around the mid-1990s, and also bring it up to date with Antonietta Gatti and Stefano Montanari's 2017 study identifying contaminants "not declared among the components," in 43 of 44 vaccine samples tested; HHS' 2018 stipulation that HHS has conducted no valid, public vaccine manufacturing or vaccine safety monitoring since 1986 adoption of the National Childhood Vaccine Injury Act; Joy Garner's 2019-2020 study comparing chronic disease burdens of vaccinated and unvaccinated cohorts, cited in her 2021-2022 federal litigation;[184] Mike Yeadon and Wolfgang Wodarg's December 2020 petition to European Medicines Agency; Sasha Latypova and Craig Paardekooper's initial study from October 2021 on Covid vaccine batch variability, foundation for HowBadIsMyBatch website;[185] Max Schmeling, Vibeke Manniche and Peter Riis Hansen's March 2023 study of batch variability;

[184] https://informedconsentdefense.org/

[185] https://www.howbadismybatch.com/states.html

and Kevin McKernan's April 2023 study of DNA contamination.

Note: Readers who read very closely will notice that in some documents, FDA states that vaccines are in the class of "well-characterized" biological products exempt from manufacturing regulation, and in other documents, FDA states that vaccines are excluded from the class of "well-characterized" biological products. World Health Organization does the same thing.

Following the paper trail long enough, and looking at the documents alongside what you can see happening and not happening in your own body, your own family and friends, in the regulatory agencies and in the courts, supports the conclusion that vaccines are not subject to valid regulation.

FDA and WHO use a wide variety of ill-defined terms, which cannot be clearly defined because biological products are inherently heterogeneous, unstable and toxic, and an intricate web of cross-references, exemptions, exclusions, suspensions, conditionals and waivers, because those linguistic and legal tools are very effective for deceiving the public.

FDA and WHO have forged those linguistic and legal tools for themselves, to obscure the criminal nature of the systematic, deliberate worldwide poisoning campaign they have conducted for about 100 years in collaboration with pharmaceutical companies and non-governmental organizations such as Bill and Melinda Gates Foundation and GAVI.

- 1995.11 Clinton Gore FDA National Performance Review Reinventing the Regulation of Drugs Made from Biotechnology[186]
- 1995.12.08 60 FR 63048 HHS FDA Notice Interim Definition, elimination lot by lot release biologics 610.2 42 USC 262
- 1996.01.29 61 FR 2733 HHS FDA Proposed Rule exempt well characterized elimination lot by lot release testing 610.2 42 USC 262
- 1996.05.14 61 FR 24227 HHS FDA Final Rule Eliminate ELA and lot release test biotech synthetic biological products 610.2 42 USC 262
- 2013.11.13 HHS FDA slide deck Biosimilar Biological Products small molecule biological product comparison chart[187]
- 2017.01.23 paper Gatti Montanari New quality-control investigations on vaccines micro nanocontamination[188]
- 2018.07.09 HHS ICAN Stipulation No monitoring of vaccines adverse effects signed by RFK Jr[189]
- 2020.11.19 paper Joy Garner Statistical Evaluation Health Outcomes Unvaccinated[190]
- 2020.12.01 petition Wodarg Yeadon EMA Covid vaccines syncytin[191]
- 2021.10.31 report Latypova Paardekooper 100% Covid-19 Vaccine Deaths caused by 5% batches[192]

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[186] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/1995.11-clinton-gore-fda-national-performance-review-reinventing-the-regulation-of-drugs-made-from-biotechnology.pdf

[187] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/2013.11.13-hhs-fda-slide-deck-biosimilar-biological-products-small-molecule-biological-product-comparison-chart.pdf

[188] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/2017.01.23-paper-gatti-montanari-new-quality-control-investigations-on-vaccines-micro-nanocontamination.pdf

[189] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/2018.07.09-hhs-ican-stipulation-no-monitoring-of-vaccines-adverse-effects-signed-by-rfk-jr.pdf

[190] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/2020.11.19-paper-joy-garner-statistical-evaluation-health-outcomes-unvaccinated.pdf

[191] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/2020.12.01-petition-wodarg-yeadon-ema-covid-vaccines-syncitin.pdf

[192] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/2021.10.31-report-latypova-paardekooper-100-covid-19-vaccine-deaths-caused-by-5-batches.pdf

- 2022.11.15 paper Joy Garner IJVTPR Re vaccines and health outcomes[193]
- 2023.03.26 paper Schmeling Manniche Hansen Investigation Batch-dependent safety BioNTech Pfizer[194]
- 2023.04.05 paper Palmer Gilthorpe paper on DNA contamination[195]
- 2023.04.11 paper McKernan Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose[196]
- undated HHS FDA Biologics Definitions reference biosimilar interchangeable What is a biological product[197]

[193] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/2022.11.15-paper-joy-garner-ijvtpr-re-vaccines-and-health-outcomes.pdf
[194] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/2023.03.26-paper-schmeling-manniche-hansen-investigation-batche28090dependent-safety-biontech-pfizer.pdf
[195] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/2023.04.05-paper-palmer-gilthorpe-paper-on-dna-contamination.pdf
[196] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/2023.04.11-paper-mckernan-sequencing-of-bivalent-moderna-and-pfizer-mrna-vaccines-reveals-nanogram-to-microgram-quantities-of-expression-vector-dsdna-per-dose.pdf
[197] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/undated-hhs-fda-biologics-definitions-reference-biosimilar-interchangeable-what-is-a-biological-product.pdf

On FDA buildings as virtual mailboxes to project the public illusion of biological product manufacturing regulation. Part 9 of series.

Published May 25, 2024

A Bailiwick reader is doing a deep research dive into pre-1972 statutory and regulatory history of some Public Health Service-Health and Human Services divisions, including National Institutes of Health (NIH) and Food and Drug Administration (FDA).

For context, 1972 is the year that ostensible biologics regulation — which is actually non-regulation — transferred from the NIH Division of Biologics Standards to the FDA Bureau of Biologics.

November 1973 is when FDA published a consolidated set of biological product manufacturing non-regulations in the Federal Register.

Administrative rule-making by FDA since 1973 is relatively easy to locate. Administrative rule-making by NIH prior to 1973 is more difficult to locate.

One of the questions the reader is trying to answer has to do with whether biological regulation authority was ever statutorily established by Congress, for NIH and its precursor organizations, going back to the late 1800s.

Modern-day NIH and FDA officials present historical accounts of how the biological product and vaccine manufacturing regulatory systems began and developed. But from her research so far, the reader has concluded that their origin-story claims are not supported by the text of the statutes they cite.

During an email exchange recently, she raised the question "Why are they lying" about their statutory and/or administrative origins?

I sent her a reply with my hypothesis about why NIH and FDA lie about their origins and evolution.

> …The "why they are lying" question is one that I've been mulling for a few months.
>
> My hypothesis is that they have maintained a bunch of empty office buildings that serve only as mailing addresses (virtual mailboxes[198]), without having any actual technical staff, laboratory equipment, or application and sample processing procedures.
>
> They do that so that they can have fake forms for vaccine manufacturers to fill out. These included both the establishment license application, ELA, and product license application, PLA, from 1973 to the mid-1990s.
> The ELA+PLA application process became, in the mid-1990s, the biologics license application, or BLA, by eliminating even the ostensible/fake requirement for establishment inspections and licensing, and by breaking up the "responsible head" at the factories, into multiple responsible people, so that no one would be responsible.
>
> The factory employees, who are also just a handful of paper pushers with no scientific knowledge or responsibility, in a building whose equipment just makes immunotoxic junk and puts it in vials and slaps labels on it, filled out the application forms and mailed them to the FDA addresses (Bureau of Biologics

[198] https://en.wikipedia.org/wiki/Virtual_mailbox

in 1973, all its NIH predecessors and FDA successors, Center for Biologics Evaluation and Research-CBER now).

The application forms arrived at that address where another one or two paper pushers put them in a filing cabinet and then shredded them a few years later.

Since the advent of electronic filing systems, the application and licensing forms have been filed, transferred and stored electronically, and deleted at regular intervals.

There are no technicians in the buildings, there's no equipment, no sample testing occurs.

It's all a front: statutes, regulations, procedures, application forms, buildings, addresses, offices, labs, approved applications and licenses sent by FDA back to the factories, everything.

A handful of people at pharma companies know it.

A handful of people at FDA know it.

And everyone else just assumes that a different, specialized department with specialized staff, equipment and procedures, is handling it somewhere in the factory, and somewhere within FDA.

*

Nov. 1995 - Clinton-Gore National Performance Review, Reinventing the Regulation of Drugs Made from Biotechnology:[199]

Revision of the Requirements for a Responsible Head for Biological Establishments

Background: Manufacturers of biological products are required to name a "Responsible Head" who is to exercise control of the manufacturing establishment in all matters relating to compliance with the regulations and who is to represent the manufacturer in all dealings with FDA. This individual must have an understanding of the scientific principles and techniques related to the manufacture of biological products…

Today, however, manufacturers of biological products tend to be larger firms with more manufacturing locations and more complex corporate structures. Most companies do not have one person with the knowledge to represent a company in all matters, but instead have several people with expertise in regulatory affairs, manufacturing, and medical issues…

FDA proposes to revise its requirements for a "Responsible Head" to allow more flexibility to assign control and oversight responsibility within a company…

Firms will be able to divide management responsibility among appropriate regulatory, medical, or manufacturing staff…

[199] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/1995.11-clinton-gore-fda-national-performance-review-reinventing-the-regulation-of-drugs-made-from-biotechnology.pdf

Documents

- 1973.11.20 38 FR 32048 FDA Biological product regulation baseline 21 CFR 600 to 680 42 USC 262
- 1995.11 Clinton Gore FDA National Performance Review Reinventing the Regulation of Drugs Made from Biotechnology
- 1996.05.14 61 FR 24227 HHS FDA Final Rule Eliminate ELA and lot release test biotech synthetic biological products 610.2 42 USC 262
- 1997.01.29 62 FR 4221 HHS FDA Proposed Rule Responsible head biologic 21 CFR 600.10
- 1997.10.15 62 FR 53536 HHS FDA Final Rule Responsible head biologic 21 CFR 600.10
- 1999.10.20 64 FR 56441 HHS-FDA Final Rule eliminate ELA, replace PLA with BLA 21 CFR 601

Sen. Rand Paul, FDA Modernization Act 2.0, and animal testing of new drugs.

Published June 4, 2024

...Reader commented at Sasha Latypova's post[200]:

> "…If, as we know due to your and Katherine Watt's research that pharma is just a front for DoD EUA countermeasures bioweapon deployment, and if Jerry Hayseed from Upper Buttcrack, Missouri (read: ME!) knows this, HOW IS IT [Rand] Paul isn't addressing this?… …And Dr. Naomi Wolf and Dr. Peter McCullough why aren't THEY talking about it?!""

My reply, expanded:

Yes, if you know about it, Rand Paul, Naomi Wolf, Peter McCullough and everyone else not talking about it, also know about it.

Those who don't talk about it, keep silent about it because they serve on the team assigned the job of misdirecting the public away from the DoD-FDA-Pharma complex and the intentionality of the worldwide sterilization and killing program.

Specific to Rand Paul, he sponsored FDA Modernization Act 2.0, passed in Dec. 2022 as part of the Consolidated Appropriations Act (PL 117-328).

Animal testing amendments were covered at Sec. 3209, 136 Stat 5821) and codified as revisions to 21 USC 355(i) and 42 U.S.C. 262(k)(2)(A)(i)(I), amending apparent requirements (which actually were never required or enforced) for new drugs under FDCA and for biosimilars under PHSA.

> SEC. 3209. Animal Testing Alternatives.
>
> (a) In General.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—
>
> (1) in subsection (i)—
>
> (A) in paragraph (1)(A), by striking ''preclinical tests (including tests on animals)'' and inserting ''nonclinical tests''; and
>
> (B) in paragraph (2)(B), by striking ''animal'' and inserting ''nonclinical tests'';
>
> and
>
> (2) by inserting after subsection (y) the following:
>
> ''(z) Nonclinical test defined.—For purposes of this section, the term 'nonclinical test' means a test conducted in vitro, in silico, or in chemico, or a nonhuman in vivo test, that occurs before or during the clinical trial phase of the investigation of the safety and effectiveness of a drug. Such test may include the following:
>
> (1) Cell-based assays.
> (2) Organ chips and microphysiological systems.
> (3) Computer modeling.
> (4) Other nonhuman or human biology-based test methods, such as bioprinting.
> (5) Animal tests

[200] https://sashalatypova.substack.com/p/grand-princess-quarantine-orders

(b) Biosimilar Biological Product Applications —Item (bb) of section 351(k)(2)(A)(i)(I) of the Public Health Service Act (42 U.S.C. 262(k)(2)(A)(i)(I)) is amended to read as follows:

"(bb) an assessment of toxicity (which may rely on, or consist of, a study or studies described in item (aa) or (cc))...".

In other words, previously-apparently required preclinical animal studies (which were never scientifically valid and were not conducted or enforced for biological products) were replaced with options for "nonclinical tests in vitro, in silico, or in chemico, or a nonhuman in vivo test, that occurs before or during the clinical trial phase of the investigation of the safety and effectiveness of a drug, including (1) Cell-based assays; (2) Organ chips and microphysiological systems; (3) Computer modeling; (4) Other nonhuman or human biology-based test methods, such as bioprinting; or (5) Animal tests."

For context, Congress and President Clinton passed the first FDA Modernization Act, PL 105-15, in November 1997, alongside the NDAA for FY1998, setting the legal framework for intentionally toxic, regulation-exempt EUA countermeasures to be deceptively presented to the public as regulated medicinal products, and coercively used. *See* May 10, 2022 - Shell game. November 1997. Congress pretended to protect military servicemen and women from forced submission to biological and chemical weapons experiments. But really just transferred the program to FDA.

The December 2022 law, FDA Modernization Act 2.0, sponsored by Sen. Rand Paul and Sen. Cory Booker, addressing what pharmaceutical companies theoretically must do to demonstrate safety of new drugs, eliminated animal testing requirements.

Press Releases issued by Sen. Rand Paul:

- Sept. 29, 2022 - Senate passes Paul-Booker bipartisan FDA Modernization Act 2.0, end animal testing mandates…[201] "Last October, Dr. Rand Paul and Sen. Cory Booker introduced the…FDA Modernization Act [2.0], and in the spirit of the bill, Dr. Paul hosted a Puppy Press Conference.[202]
- Jan. 6, 2023 - Dr. Paul's Bipartisan FDA Modernization Act 2.0 to end animal testing mandates included in 2022 year end legislation[203]
- Nov. 20, 2023 - Dr. Rand Paul Urges FDA to Update Animal Testing Guidance in Accordance with the FDA Modernization Act 2.0[204]

News report on the FDA Modernization Act 2.0:

> Jan. 12, 2023 - The FDA no longer requires all drugs to be tested on animals before human trials[205] (Joe Hernandez, KUOW)
>
> "…Signed by President Biden in December as part of a larger spending package, the law doesn't ban the testing of new drugs on animals outright.
>
> Instead it simply lifts the requirement that pharmaceutical companies use animals to test new drugs

[201] https://www.paul.senate.gov/news-senate-passes-paul-booker-bipartisan-fda-modernization-act-20-end-animal-testing-mandates/
[202] https://rumble.com/vnfvtf-fda-modernization-act-press-conference-october-7-2021.html
[203] https://www.paul.senate.gov/dr-pauls-bipartisan-fda-modernization-act-2-0-to-end-animal-testing-mandates-included-in-2022-year-end-legislation/
[204] https://www.paul.senate.gov/dr-rand-paul-urges-fda-to-update-animal-testing-guidance-in-accordance-with-the-fda-modernization-act-2-0/
[205] https://www.kuow.org/stories/the-fda-no-longer-requires-all-drugs-to-be-tested-on-animals-before-human-trials

> before human trials. Companies can still test drugs on animals if they choose to...
>
> There are a slew of other methods that drugmakers employ to assess new medications and treatments, such as computer modeling and "organs on a chip," thumb-sized microchips that can mimic how organs' function are affected by pharmaceuticals…
>
> This year's federal budget also includes $5 million for a new FDA program aimed at reducing animal testing by helping to develop and encourage industry to adopt new product testing methods…"

Keep in mind that FDA is not legally obligated to hold pharmaceutical companies to any safety, efficacy or purity standards for biological products.

Regulations, guidance documents, false nonclinical and clinical trial records, product licensing records, and press conferences are put forward only to deceive the public into thinking that there is a manufacturing regulatory system whose goal is to keep toxic products out of human bodies.

The truth is the opposite: the FDA-Pharma-DoD system's goal is to get toxic products into human bodies.

National and worldwide vaccination programs and US-FDA vaccine non-regulation as among the longest of long cons.

Learn to distrust pharma, FDA, Congress, vaccination, vaccine-regulation, and 'vaccine confidence' promotional campaigns.

Published June 10, 2024

For more than 100 years, confidence men (con men) have been inducing marks to accept real chronic disease and sudden death, caused by vaccination, in exchange for false protection against communicable disease, by deceiving marks into believing the lie that communicable diseases pose mortal threats to people and societies ('public health,') and by deceiving marks into believing the lie that vaccines are developed, manufactured and FDA-regulated to be safe, pure, and effective at preventing infection and transmission of communicable diseases.

> Scam[206] (Wikipedia)
>
> A scam, or a confidence trick, is an attempt to defraud a person or group after first gaining their trust.
>
> Confidence tricks exploit victims using a combination of the victim's credulity, naïveté, compassion, vanity, confidence, irresponsibility, and greed.
>
> Researchers have defined confidence tricks as "a distinctive species of fraudulent conduct ... intending to further voluntary exchanges that are not mutually beneficial," as they "benefit con operators ('con men') at the expense of their victims (the 'marks')...
>
> Other terms for scam (aside from confidence trick) include con, con game, confidence game, confidence scheme, ripoff, stratagem, finesse, grift, hustle, bunko (or bunco), swindle, flimflam, gaffle, and bamboozle.
>
> The perpetrator is often referred to as a scammer, confidence man (or con man), con artist, grifter, hustler, or swindler.
> The intended victims are known as marks, suckers, stooges, mugs, rubes, or gulls (from the word *gullible*).
>
> When accomplices are employed, they are known as shills…

Over the last few years, detractors trying to undermine her credibility have falsely characterized Sasha Latypova as being a "pharma shill," ostensibly because she has decades of professional experience in pharmaceutical product development and regulatory compliance procedures for drug-products and devices that are *not* classified as biological products, vaccines and/or EUA medical countermeasures.

Her decades of professional experience in pharmaceutical regulation procedures gave her the knowledge and skills to quickly see and understand that fake Covid-19 product regulatory procedures — for products that *are* classified as biological products, vaccines and/or EUA medical countermeasures — although presented to the public as true, were in fact false.

Her decades of professional experience also gave her the knowledge and skills to read and correctly interpret

[206] https://en.wikipedia.org/wiki/Scam

pre-positioned public health emergency law; understand what it means for plaintiffs and lawyers suing pharmaceutical companies for injuries caused by Covid vaccines, remdesivir, ventilators and other EUA countermeasures; and explain what she learned to other people in her writing, interviews and public speeches.

People may have levied the "pharma shill" accusation against me. I don't know because I don't closely follow the work of people who demonstrate a pattern of lying and mischaracterizations, after I've concluded that they're prone to lying and mischaracterizations. If they've tried to paint me as a pharma shill, it's probably been a little more difficult, because I have no background in the pharmaceutical industry.

Sasha and I have not urged and still don't urge those who read, hear or view our findings to trust pharmaceutical companies involved in the Covid vaccine and EUA countermeasures confidence game (and emerging and forthcoming sequels), including Pfizer, Moderna and many other large and small companies. We urge people to distrust pharmaceutical companies.

We also urge people to distrust the US Food and Drug Administration (FDA).

Our work exposes the essential complicity of the US-FDA and other fake drug regulation agencies around the world, in the vaccination and pandemic-preparedness-and-response long con, alongside the pharmaceutical companies, under statutory legal authority and funding programs enacted by US Congress members and US Presidents, under operational direction of the US Department of Defense, US Department of Health and Human Services, US Department of Homeland Security, US Department of Agriculture, US State Department, US Treasury Department, US Justice Department, US Commerce Department and other federal agencies in collaboration with the Federal Reserve, Bank for International Settlements and United Nations World Health Organization.

Our work exposes how pre-positioned legal structures preclude judicial relief for individuals injured and killed by acts of product manufacturing committed by pharmaceutical company executives and employees; acts of fake FDA product regulation committed by fake FDA manufacturing regulators; and acts of product use committed by medical-mercenary killers, until Congress repeals the crime-enabling, criminal-act-inducing laws and states nullify them and repeal state-level public health emergency, emergency management and communicable disease control laws.

Three examples of the pre-positioned federal legal and financial inducement structures:

- Public Health Service Act (PHSA) PREP Act liability immunity provisions and Food Drug and Cosmetics Act (FDCA) EUA countermeasure provisions provide manufacturers, regulators and distributors of drugs, devices and biological products, and nurses, doctors and pharmacists, as administrators of drugs, devices and biological products, with legal license to intentionally poison people with drugs and biological products, and intentionally misuse devices, to injure and kill people, with impunity.
- DoD contracts are financial inducements to commit crimes, for manufacturers, regulators and distributors working under declared 'public health emergency' conditions.
- CMS reimbursement policies are financial inducements to commit crimes, for nurses, doctors and pharmacists working in hospitals, nursing homes, and clinics under declared 'public health emergency' conditions.

We have urged — and still urge — those who read or view our work to distrust pharmaceutical companies and to also distrust the FDA, whose fake manufacturing compliance reviews and fake regulatory authorizations and approval documents enable deceitful public officials worldwide to more effectively lie to the public about the safety, efficacy and purity of intentionally-toxic products bearing name-brand pharmaceutical company labels.

Have zero confidence in pharmaceutical companies.

Have zero confidence in FDA officers.

Have zero confidence in NIH, CDC, CMS and NIAID officers.

Distrust Congress until Congress repeals the American federal enabling laws.

Distrust Defense Secretary Lloyd Austin, and his subordinates and successors in the military chain of command.

Distrust HHS Secretary Xavier Becerra and his subordinates and successors in the Public Health Service of the military chain of command.

Distrust OPPR Director Paul Friedrichs and his subordinates and successors in the White House Office of Pandemic Preparedness and Response Policy.

Distrust USDA Secretary Tom Vilsack and his subordinates and successors in the US Department of Agriculture.

Distrust DHS Alejandro Majorkas and his subordinates and successors in the Department of Homeland Security and Federal Emergency Management Agency.

Distrust Attorney General Merrick Garland and his subordinates and successors in the Department of Justice.

Distrust State Secretary Antony Blinken and his subordinates and successors in the State Department, including Samantha Power, Administrator of the US Agency for International Development.

Distrust Treasury Secretary Janet Yellen and her subordinates and successors in the Treasury Department.

Distrust Commerce Secretary Gina Raimondo and her subordinates and successors in the Commerce Department.

Distrust Director-General Tedros Adhanom-Ghebreyesus and his subordinates and successors in the UN-World Health Organization and World Health Assembly military chain of command.

Distrust anyone who suggests that it's a good idea to trust any of those people and federal agencies.

Pretense of biological product manufacturing de-regulation layered on pretense of biological product manufacturing regulation.

Published June 17, 2024

Sasha Latypova: June 15, 2024 - Reminder: there are no requirements for FDA inspections of biologics facilities. This affects ALL biologics, not just EUA Countermeasures which do not have to comply with cGMP laws anyway.[207]

> "…Gottlieb's [2019] inspection rule change affects ALL biologics manufacturing, not just EUA Countermeasures. This includes all vaccines, human and animal, and all other biologics products…Now all these medications can be shipped adulterated for years, and there is no regulatory mechanism of catching the problem other than random luck. In case of non-EUA products, the manufacturers face liability for harming consumers, however, identifying adulteration of these products requires complex lab set up and expertise, not something easily accessible to a harmed consumer…"

Comment[208] on Sasha's post from ExcessDeathsAU[209]:

> …As this occurred in 2019, I wonder if it was part of the Trump administration's ostensible 'cutting red tape and building American industry' agenda as well as receipts payable for all the pharma donations.

KW reply, expanded:

The 2019 FDA rule-change was just a continuation of deregulation launched in the 1980s by Reagan and continued in the 1990s by Clinton — including three executive orders, EO 12291 (Reagan, 1981); EO 12498 (Reagan, 1985) and EO 12866 (Clinton, 1993).

Reagan and Clinton executive orders were followed by EO 13563, Improving Regulation and Regulatory Review (Obama, Jan. 18, 2011), EO 13771, Reducing Regulation and Controlling Regulatory Costs (Trump, Jan. 30, 2017) and EO 13777, Enforcing the Regulatory Reform Agenda (Trump, Feb. 24, 2017).

All administrations — Republican and Democrat — keep the deregulation scam moving.

Gottlieb cited EO 12866, EO 13771 and EO 13777, and related Congressional acts, in the 2019 rule change eliminating cGMP inspections for ALL biological product manufacturing, April 2, 2019 - 84 FR 12505 FDA Final Rule, effective May 2, 2019:

> "This action is part of FDA's implementation of Executive Orders (E.O.s) 13771 and 13777. Under these E.O.s, FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification…We have examined the impacts of the final rule under E.O. 12866, E.O. 13563, E.O. 13771, the Regulatory Flexibility Act [of 1980, Pub.L. 96-354] (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4)…"

For FDA and pharma, they're deregulating a system that wasn't regulating even before the deregulation: it's pretense of deregulation layered on pretense of regulation....

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[207] https://sashalatypova.substack.com/p/scott-gottlieb-removed-requirements
[208] https://sashalatypova.substack.com/p/scott-gottlieb-removed-requirements/comment/59136073
[209] https://vicparkpetition.substack.com/

Note on *biological product* classification

Published June 19, 2024

As I learn more, I think the primary legal classification that matters, legally, is the classification as "biological product." It's the classification that renders intentional poisons as legally non-regulated products, thus facilitating development, manufacture, fake-FDA-review, distribution, use, and non-liability.

All the other subcategory terms — vaccine, gene therapy, etc. — are, as far as I can tell, legally irrelevant and also almost all chemically and physically undefined and undefinable.

They're used mostly to create confusion and debate downstream of the 'biological product' classification, which is the classification that renders members of the class unregulated and legally unregulatable (because physically/chemically undefined and undefinable), and renders all FDA acts and non-acts as part of the regulatory simulation.

120+ years of legalized, US-government-led pharmaceutical fraud. Part 12 of series.

Published July 5, 2024

Since December 2023, I've researched and written a series of reports (listed below) tracking the development of federal Congressional laws and federal agency non-regulations that have non-regulated the licensing and manufacture of biological products and vaccines from 1944 to the present.

The series so far focuses on the period since 1972, when the fake biological product regulation program was fake-transferred from NIH to FDA.

The record of laws passed by Congress, signed by US Presidents, implemented through the US Code of Federal Regulations, with rule changes published in the *Federal Register*, and upheld by federal and state courts, confirm that biological product and vaccine licensing, cGMP-compliance monitoring and related programs allegedly operated by the US Food and Drug Administration have been nothing more than pretextual, deceptive acts carried out to elicit and maintain broad public compliance with vaccination programs, because vaccines are actually intentionally harmful biological weapons developed, manufactured, promoted and distributed jointly by the federal Public Health Service and pharmaceutical companies, and vaccinators don't want targets to know it.

Public Health Service[210] (Wikipedia), "one of the United States eight uniformed services:[211]

> Nine of the twelve operating agencies within the Department of Health and Human Services (HHS) are designated as part of the Public Health Service [including]
>
> - National Institutes of Health [NIH];
> - Food and Drug Administration [FDA];
> - Centers for Disease Control and Prevention [CDC];
> - Health Resources and Services Administration [HRSA];
> - Agency for Toxic Substances and Disease Registry…
> - Agency for Healthcare Research and Quality [AHRQ]; and
> - Administration for Strategic Preparedness and Response [ASPR]

The people who develop, manufacture, promote, distribute and use these weapons to intentionally hurt and kill people don't want the targets to understand what's been done to us, our parents and grandparents, our children and our grandchildren, because people who understand biological product and vaccine non-regulation become people who stop believing false vaccine histories, stop trusting vaccine promoters, and stop taking vaccines.

Elements of the program include the reclassification of the US military's Chemical and Biological Warfare program, since 1969, as public health emergency and pandemic preparedness and response programs, emergency use authorization medical countermeasures programs, "select agents and toxins" programs, and biodefense programs, jointly operated by the Department of Defense, Department of Health and Human Services/Public Health Service and Department of Homeland Security and coordinated through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), Biomedical Advanced Research and Development Authority (BARDA), Defense Advanced Research Projects Agency (DARPA) and related federal interagency committees.

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[210] https://en.wikipedia.org/wiki/United_States_Public_Health_Service

[211] https://en.wikipedia.org/wiki/Uniformed_services_of_the_United_States

Vaccination programs are not conducted to promote public health or welfare, strengthen human immune systems, or to protect people from communicable diseases.

Vaccination programs are conducted to cause population-wide harms, damage human immune systems and induce chronic disease and premature death.

*

I've been working with a Bailiwick reader — Lydia Hazel — for several months to get a better understanding of the pre-1972 history of biological product and vaccine non-regulation.

Hazel has been compiling the statutory, regulatory, institutional and budget history from the 1798 establishment of the Marine Hospital Service (precursor to the Public Health Service) through the 1902 Biologics Control Act and 1944 Public Health Service Act, to the 1972 alleged transfer and delegation of alleged biological product regulation authorities from Public Health Service, Secretary of Health, Education and Welfare (HEW, now HHS), National Institute of Health-Division of Biologics Standards, to the Food and Drug Administration-Bureau of Biologics.

This week I've been working on Hazel's latest draft of the timeline. As anticipated, she's found the same patterns of concealed non-regulation and similar key words in the 1798-1972 period, as compared to the non-regulation patterns and key words found in the 1972 to 2024 regulatory history...The meat of the report — the statute, regulation and court case timeline — will try to lay out the "how."

As in:

How (legal mechanics) Congress, presidents, federal agencies and courts between 1900 and 1972, and from 1972-2024, set up and simultaneously hid/hide from public view, the legal conditions so that no biological product rules, procedures or tests governing product identity, safety and efficacy have ever existed or were ever applied…

Because each new apparent product review or rule-making event has referred to alleged prior product assessments, standards and rules that had never existed or been applied, as the basis for extending existing licenses (pretending that such rules had existed and had been applied), and/or has referred to future assessments and reviews that the vaccinators claimed would occur, and future standards and rules they claimed would be drafted and applied, which never materialize into adopted or enforced identification and assessment procedures, standards, rules or tests.

"Jam to-morrow, jam yesterday, but never jam to-day."[212]

For 120 years.

The wall-to-wall statutory, regulatory, prosecutorial and judicial, *legalized* pharmaceutical fraud that facilitates the ongoing use of unregulated Covid and forthcoming "bird flu" and other new vaccines since 2020 (which are equally corrupt for EUA and BLA products) is simply an extension of the wall-to-wall *legalized* pharmaceutical fraud that has facilitated the use of every preceding, non-regulated, fake-licensed, old vaccine since 1902.

[212] https://en.wikipedia.org/wiki/Jam_tomorrow

Prior to Covid, the perps may have had some close calls in terms of possible public exposure of federally-directed pharmaceutical fraud.

One close call was the 1955 mass polio vaccination of children and expectant mothers, and resulting injuries and deaths attributed to the vaccines.

Evidence and analysis connecting injury and death with vaccination was quickly suppressed by Public Health Service authorities and academic, medical and industrial co-conspirators.

In 1972, vaccinators were faced simultaneously with mainstream media reports about ineffective influenza vaccines, and the opening of the signing period for the UN Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction.

In 1972, to make the legalized federal pharmaceutical regulation fraud harder to see — so as to continue the American worldwide deployment of biological weapons promoted as vaccines — then-Assistant HEW Secretary for Health and Scientific Affairs Merlin K. DuVal, under the direction of Elliot Richardson (then-Secretary of then-Health, Education and Welfare Department, whose career highlights also included Undersecretary of State, Secretary of Defense, Attorney General and Secretary of Commerce) "concurrently re-delegated" the non-regulation of biological products from the NIH Division of Biologics Standards to the FDA Bureau of Biologics.

Then FDA-Commissioner Charles Edward and then-NIH Director Robert Q. Marston signed and published a memorandum of understanding, and FDA and NIH officials announced a set of biological product advisory panel reviews, plus a forthcoming set of "standards" that would accept, as evidence of product identity, safety and efficacy, "alternatives" to controlled studies.

The work of the advisory panels was tightly controlled to preordain outcomes that would not interfere with continued manufacturing, distribution and use of vaccine-weapons, including strict limits on who had standing to present data and data analysis. *See* 37 FR 4004 (Feb. 25, 1972); 37 FR 12865 (June 29, 1972); 37 FR 15993 (Aug. 9, 1972); 37 FR 16679 (Aug. 18, 1972); 38 FR 4319 (Feb. 13, 1973)

In 1986, Congress passed the National Childhood Vaccine Injury Act to provide full indemnification for manufacturers of by-then routine childhood vaccines, and the non-crime, legalized pharmaceutical fraud enterprise rolled on from there into the deregulation programs of the 1990s; into the post-9/11 homeland security and bioterrorism preparedness policies and programs; into Covid.

There are still no established, enforced standards for biological product or vaccine identity, safety or efficacy, and there never will be, because biological products are inherently unstable, heterogeneous and toxic.

The systematic worldwide mass poisoning non-crime crime of vaccination rests on the federal legalization of pharmaceutical regulation fraud, and public lack of knowledge about it.

On "unavoidable, adverse side effects" as deceptive language used to conceal the intentionality of vaccine toxicity.

Published July 11, 2024

After Sasha Latypova's recent post -- July 6, 2024 - General Perna and Colonel Hepburn speak about Operation Warp Speed[213] - A reader in the comment section discussed FDA's role in promoting public submission to vaccination and Brook Jackson's federal *qui tam*[214] case filed in January 2021 under the False Claims Act.

Jackson's case was dismissed in March 2023 and re-filed (Second Amended Complaint). She is currently awaiting the federal court's decision on a second round of motions to dismiss.

Some Bailiwick reporting on Jackson's case:

- Feb. 3, 2023 - Recap of Jackson v. Pfizer, whistleblower Brook Jackson's False Claims Act case. (Katherine Watt) "…On Oct. 4, 2022, US Government [DOJ] stepped into the case again — this time taking Pfizer's side in the dispute, concurring with Pfizer that there was never any fraud to prosecute, because Pfizer was never obligated to conduct valid clinical trials in order to receive payment for the manufactured bioweapons that they [US government officials and contractors] refer to as vaccines…"
- June 6, 2023 - Repost: Federal judge in Brook Jackson's case covered up DoD's Dec. 2020 knowledge of Pfizer's clinical trial fraud, to fabricate a false timeline, to better immunize DoD from prosecution. (Katherine Watt) "…Bottom line: Judge Truncale [by order March 31, 2023] has now added his own criminal federal judicial review to the sequence that includes: Criminal 'vaccine' development and production contracts, which are actually contracts for the development and production of injectable bioweapons; criminal 'vaccine' clinical trial safety records, which are actually records of bioweapon potency results for mRNA and DNA classes of injectable bioweapons; criminal 'vaccine' regulatory review, authorization, manufacturing compliance and safety monitoring records, which are actually theatrical props intended to block public knowledge that the products mislabeled as 'vaccines,' transported across state lines, and injected into military targets, are intentionally-lethal bioweapons…"

Sasha Latypova's March 2024 reporting on Jackson's case:

- March 17, 2024 - Department of Justice: fraud and resulting death/injury from covid shots are part of the US public health policy[215] - [US-DOJ March 12, 2024 Motion to Intervene and to Dismiss[216]:] (Sasha Latypova) "…The anticipated discovery and litigation obligations associated with the continued litigation of this case will impose a significant burden on FDA, HHS, and DOJ. The United States should not be required to expend resources on a case that is inconsistent with its public health policy." [Latypova:] I suggest you all re-read this a few times to truly grasp the depth of depravity outlined in the argument by the DOJ. They are stating that they know that pharmaceutical fraud has been committed, and that deaths and injuries resulted from it. They are also stating that mass death and injury are in fact fully known to the pharmaceutical regulators, and that no corrective action is required because this is consistent with the United States of America's public health policy…"

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213 https://sashalatypova.substack.com/p/gen-perna-and-col-hepburn-heritage
214 https://www.law.cornell.edu/wex/qui_tam_action
215 https://sashalatypova.substack.com/p/department-of-justice-admits-pharmaceutical
216 https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/07/2024.03.12-jackson-v.-pfizer-doj-notice-of-intervene-support-mtd-jackson-v.-pfizer-doc-137.pdf

I have followed the progress of Jackson's case since writing about it in Spring 2023, but have not written more about her case publicly, for several reasons including time limitations. Case documents are below for interested readers.

*

I posted several replies in the comment thread[217] below Latypova's Perna-Hepburn post, revised/expanded:

There is no legal requirement that any vaccine manufacturer or regulator assess vaccines for safety or efficacy, and FDA has never established any safety or efficacy standards for vaccines.

Neither has the US Pharmacopeia-National Formulary.[218]

FDA has also never defined, by regulation, what a vaccine is, or how to physically or chemically identify a vaccine…

I don't think Jackson's *qui tam* case is going to have the result you're hoping for.

I think her lawyers have teed the case up for the federal judge to dismiss it for the second time, and thereby reinforce the use of US DoD military weapon manufacturing contractors (in her case, Pfizer/BioNTech) operating under derivative sovereign immunity and related indemnification, to make and distribute intentionally harmful weapons labeled as vaccines and countermeasures without legal interference.

SCOTUS is on board with the vaccine-mediated cull; they've already addressed it through *Bruesewitz v. Wyeth*[219] (2011).

What they called "unavoidably unsafe" products and "unavoidable, adverse side effects" was simply a deceptive way of describing intentionally harmful products produced by contractors and US government working together to achieve a goal they share: sickening and killing a lot of people, starting with babies, children and expectant mothers, and then adding general working age and retired adults.

Another key phrase from *Bruesewitz,* citing *Hurley v. Lederle* (1988)*,* identifies the FDA as a "passive agency," which is code for non-regulatory, having no legal authority or historical record of setting or enforcing standards for vaccine design, identity, safety, or efficacy.

See Bruesewitz v. Wyeth, Sotomayor dissent at p. 21, FN 19. *See also*, Scalia opinion at p. 13:

> "Design defects…do not merit a single mention in the [1986 National Childhood Vaccine Injury Act] or the FDA's regulations. Indeed, the FDA has never even spelled out in regulations the criteria it uses to decide whether a vaccine is safe and effective for its intended use."

FDA has never established criteria for safety or efficacy, which is why FDA has never spelled out its non-existent criteria in regulations.

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[217] https://substack.com/profile/8540123-katherine-watt/note/c-61318913
[218] https://en.wikipedia.org/wiki/United_States_Pharmacopeia
[219] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/06/2011.02.22-bruesewitz-v.-wyeth-scotus-vaccination-unavoidably-unsafe-product.pdf

Pharmas got a few decades of product sales for products they claimed would manage symptoms of chronic diseases induced by vaccines.

For the government, it's always been about reducing life expectancy and population.

The so-called medical freedom lawyers are in on the scam too.

They don't want to see vaccination programs brought to a close, because they want continued access to attorney fee payouts through the VICP program. So their goal is just to get Covid vaccines and other countermeasures (currently funneled into the dead-end CICP program) folded into the VICP program, keep the vaccination/kill programs running to keep generating a large pool of potential claimants, and skim off profit from the claims filed by a small fraction of the maimed and a small fraction of the survivors of the dead.

Another reader commented:

> "I thought Robert Barnes was a top-notch lawyer. How did he mess this up?"

My reply[220]:

Barnes and [Warner] Mendenhall wasted the opportunities presented by Jackson's case, by deliberately refusing to incorporate the knowledge of kill box law and the intentionality of vaccine toxicity gained through the earlier phases of Jackson's case (especially Pfizer's April 2022 Motion to Dismiss, and DOJ Oct. 2022 Statement of Interest supporting dismissal) into appeals and amended complaints filed after the federal judge dismissed the case the first time in March 2023.

[220] https://substack.com/profile/8540123-katherine-watt/note/c-61648516

On FDA 'Guidance for Industry' documents as regulatory fraud coordination tools for US government and pharmaceutical co-conspirators.

Published July 26, 2024

Important new post from Sasha Latypova: July 26, 2024 - New FDA guidance for pharma on "countering misinformation" online. FDA authorizes pharmas to lie when needed, promising non-enforcement of pharmaceutical marketing regs. I interpret this as we are winning the information war.[221]

> …The FDA is guiding the manufacturers to lie and "debunk" these detected harms by waving hands around "but it was a very high dose"!
>
> From my experience, in normal, non fraudulent pharmaceutical R&D setting you have 2 choices after your animals died or had fetal damage at a "high dose":
>
> 1) redo the study with a dose that is more representative of the human exposure at therapeutic levels;
>
> 2) kill the drug program.
>
> In both cases, the entire class of medicine becomes suspect for fetal abnormalities, and all subsequent programs are under greater scrutiny for this issue. At a minimum, concentration-response justifications must be provided for the selected doses in animals and humans.
>
> They were nowhere to be found in the 2000+ pages of garbage "nonclinical package" from Pfizer and Moderna
> I wasted a few weeks of my life on!
>
> That's because it is not possible to dose mRNA in a controlled manner (this explains why Pfizer is 30 mg and Moderna is 100mg per dose in humans for the same thing - dosages are meaningless with mRNA products)...

*

I posted a comment:

My understanding is that all FDA "Guidance for Industry" documents, going back to the mid-1980s, when they started issuing them [called "Points to Consider" at that time] are instructions to pharmaceuticals, from FDA, about how the pharmaceuticals should ignore FDA regulations (because the regulations are non-regulations), and how they should engage in performative acts designed to look similar to compliance, and how FDA will (on its own side) pretend to establish and enforce regulatory standards, but actually not enforce them.

The language tricks typically involve the term "discretion," leaving whether or not to enforce an alleged standard to FDA discretion (and they choose not to), or involve juxtapositions of "shall" and "may" language, such as regulations that state FDA "shall" issue a license for a product, and "may" inspect the premises where those are produced.

[221] https://sashalatypova.substack.com/p/fda-publishes-guidance-for-pharma

FDA, in its discretion, does not inspect and does not establish or enforce standards.
Similar examples to this new one about misinformation, include

January 2017 Guidance for Industry 187, Regulation of Intentionally Altered Genomic DNA in Animals[222]

> "FDA has not and does not intend to enforce INAD and NADA requirements for: (1) animals of nonfood-producing species whose genomes have been intentionally altered that are regulated by other government agencies or entities, such as insects whose genomes have been intentionally altered that are under APHIS oversight; and (2) animals of nonfood-producing species whose genomes have been intentionally altered that are raised and used in contained and controlled conditions such as laboratory animals with intentionally altered genomes used in research institutions."

and

January 2018 Guidance for Industry - Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application[223]

> "FDA does not intend to take action for violations of section 351 of the PHS Act or sections 502(f)(1) or 582 of the FD&C Act if a state-licensed pharmacy, a federal facility, or an outsourcing facility mixes, dilutes, or repackages a biological product in accordance with the conditions described below, and any applicable requirements. In addition, FDA does not intend to take action for violations of section 501(a)(2)(B) of the FD&C Act when a state-licensed pharmacy or a Federal facility mixes, dilutes, or repackages a biological product in accordance with the conditions described below, and any applicable requirements..."

[222] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/07/2017.01-fda-guidance-187-regulation-intentionally-altered-genomic-dna-in-animals.pdf
[223] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/07/2018.01-fda-guidance-mixing-diluting-repackaging-biological-products-outside-scope-approved-bla.pdf

Aug. 22, 2024 - FDA's document-only, 2010 definition of 'viral vaccines;' FDA's 2007 recommendation that developers not assess whether vaccination causes autoimmune disease.

Published Aug. 22, 2024

Aug. 22, 2024 Note 1

I do not believe that FDA "guidance for industry" documents are intended by FDA or construed by pharmaceutical manufacturers, as enforceable rules.

I believe they are written and published as part of the regulatory charade, and are one method through which FDA, DoD and pharmas coordinate the militarized fraud they are jointly perpetrating on the public.

I'm posting this 2010 FDA document-only definition of "viral vaccines" (FDA has not defined *vaccine,* or *viral vaccine*, in CFR regulations) because such definitions, when viewed alongside the complete absence of physical standards and methods/techniques/equipment capable of determining product purity, safety and efficacy, which have not been established by FDA or by FDA's allegedly private-sector partner, the US Pharmacopeia/National Formulary — see, for example, USP June 2020 *Standards for Quality Vaccines–General Vaccine Development and Manufacturing*,[224] indicating the non-existence of measurable standards and measurement techniques by the phrase "Not intended to convey requirements enforceable by regulatory agencies;" -- may help more people understand that vaccines, from the batch and lot level at the factories, through the vial and dose level when administered to a person, are intrinsically heterogeneous, unstable and toxic.

There is no safe dose of vaccine material.

There never will be.

And these facts have been known for many, many decades by FDA officials, pharmaceutical company officials, military officers and US Pharmacopeia/National Formulary officials.

FDA (February 2010) - *Guidance for Industry - Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications*[225]

> "For the purpose of this document, viral vaccines are a heterogeneous class of preventive, and in some cases, therapeutic medicinal products that when administered are intended to elicit immune responses that could prevent and/or lessen the severity of one or more infectious diseases. These products include live attenuated preparations of viruses, inactivated (killed) whole or subunit virions, purified recombinant proteins, synthetic antigens, or live viral vectors expressing specific heterologous vaccine antigens…"

[224] https://www.usp.org/sites/default/files/usp/document/our-impact/covid-19/standards-for-quality-vaccines-general-development-and-manufacturing.pdf

[225] http://fda.gov/media/78428/download

Aug. 22, 2024 Note 2

Repeating points from previous note — FDA guidance for industry documents are to be understood as fraud coordination tools through which FDA and pharmas jointly withhold and cover-up from the public, knowledge that all vaccine material is intrinsically heterogeneous, unstable and toxic.

Here's another example of how the fraud coordination works, from a 2007 FDA publication.

FDA (November 2007) - *Guidance for Industry - Considerations for Plasmid DNA Vaccines for Infectious Disease Indications*[226]

> "Published preclinical studies indicate that DNA vaccination can activate autoreactive B cells to secrete IgG anti-DNA autoantibodies. However, the magnitude and duration of this response appears to be insufficient to cause disease in normal animals or accelerate disease in autoimmune-prone mice. These preclinical studies suggest that systemic autoimmunity is unlikely to result from DNA vaccination. Similarly, the absence of an immune response against cells expressing the vaccine-encoded antigen (including muscle cells and dendritic cells) suggests that an autoimmune response directed against tissues in which such cells reside is unlikely.
>
> Yet the possibility persists that DNA vaccines might idiosyncratically cause or worsen organ-specific autoimmunity by encoding antigens (including cryptic antigens) that cross-react with self. Thus, we no longer recommend that preclinical studies be performed to specifically assess whether vaccination causes autoimmune disease, but recommend that the general welfare of animals in preclinical immunogenicity and toxicity studies continue to be carefully monitored…"

[226] https://www.fda.gov/files/vaccines, blood & biologics/published/Guidance-for-Industry--Considerations-for-Plasmid-DNA-Vaccines-for-Infectious-Disease-Indications.pdf

On 'critical quality attributes' or CQAs

Published Aug. 28, 2024

In recent months, as I've learned more about the non-regulatory, fraudulent character of FDA's purported oversight of biological product manufacturing, I've tried to convey a few key points.

Vaccine manufacturers, FDA and the FDA's regulatory partner — the US Pharmacopeia-National Formulary[227] — have never established any objective, measurable, verifiable physical, chemical or biological standards for gene-containing, cell-based products including but not limited to products labeled as vaccines.

Pharmaceutical manufacturers, FDA and USP-NF have never identified or developed techniques or equipment that can validly measure physical, chemical and biological characteristics of vaccines and related biological products.

And FDA has never enforced, on vaccine manufacturers, compliance with any objective, measurable, verifiable physical, chemical or biological standards for vaccines and related biological products, because such standards have never been established and do not exist.

I have argued that these failures are attributable to the inherent heterogeneity, instability and toxicity of biological material contained in vaccine packages.

In each vial and each dose, there is a wide variety of genetic material, along with other, non-biological substances such as metals.[228]

At every step along the path, from the raw materials and cell lines propagated in the factories, to the moment of injection and after the contents enter the living human or animal body, genetic material is prone to decay, fragmentation, sedimentation, protein-folding, and other transformations.

It is not in stasis; it is dynamic; it is unstable.

And the genetic material, because it is foreign to the person receiving it and living creatures are designed to respond defensively to invasions of foreign matter, is harmful to the recipients.

It is toxic — to a greater or lesser degree depending on infinite variables — to every person who receives any vaccine, each time such invasion occurs.

There is no way for anyone to know even the identity of the biological material in the vials, and thus also no way for anyone to know the purity, potency, safety or efficacy of genetic material whose identity is unknown.

All vaccines, up to and now including mRNA/LNP vaccines, have always contained genetic, cell-based material foreign to the recipient.

All vaccines, up to and now including mRNA/LNP vaccines, have always caused harm to the recipients.

*

[227] https://en.wikipedia.org/wiki/United_States_Pharmacopeia

[228] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/05/2017.01.23-paper-gatti-montanari-new-quality-control-investigations-on-vaccines-micro-nanocontamination.pdf

In the last couple of days, I've come across reinforcement of these points from several sources.

Without providing in-depth analysis, I'm offering some quotes and links for readers who want to study and think about these things more, to further develop confidence in decisions to stop taking all vaccines and stop all vaccination of babies and children.

The sources cited below support the conclusion that the inherent heterogeneity, instability and toxicity of vaccines has been known to manufacturers, fake-regulators and vaccination proponents for a very long time.

For more than 100 years, and still today, US and international government and non-governmental agents have advocated and coerced public submission to vaccination as an intentional program to deceive, harm and kill people.

*

Critical Quality Attributes

An important phrase to learn is "critical quality attributes."

I first heard it in June 2024 during a conversation with a pharmacist about the relationship between FDA and the US Pharmacopeia-National Formulary, and about USP-NF employees' efforts, in recent years, to grapple with mRNA/LNP vaccines and other novel genetic, cell-based products.

FDA has defined CQAs as

> "a physical, chemical, biological, or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality." (November 2009, FDA Guidance for Industry Q8 (R2) Pharmaceutical Development[229])

CQAs are related to all the things that Sasha Latypova has investigated and written about, concerning Chemistry, Manufacturing and Controls (CMCs), the complete non-applicability and non-enforcement of CMCs to Covid vaccines, including her December 2022 memo to Senator Ron Johnson.[230]

Again, without trying to contextualize the information, apart from a few brief comments, below are the sources I've come across in the last few days.

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1910 - *Vaccine Virus*,[231] paper by Milton J. Rosenau,[232] [second Director of Public Health and Marine Hospital Service Laboratory of Hygiene, 1899-1909], published by JAMA

> "Vaccine virus is the specific principle in the material obtained from the skin eruption of calves having a disease known as vaccinia [cowpox]…
>
> Both the pulp and the lymph are mixtures containing epithelial cells, serum, blood, leucocytes, products

[229] https://www.fda.gov/media/71535/download
[230] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2023/02/2022.12.18-latypova-memo-re-cgmp-intentional-noncompliance-12-p.pdf
[231] https://jamanetwork.com/journals/jama/article-abstract/431147
[232] https://www.ncpedia.org/biography/rosenau-milton-joseph

of inflammation, debris, bacteria, etc., in varying proportions.

The specific principle of vaccinia [cowpox] is unknown…

It is impossible to obtain vaccine virus free from the bacteria of the skin…

The fact that a serum or vaccine is granted a license does not mean that it is a valuable curative or prophylactic; in fact, it may have little or no therapeutic value…"

Why vaccine virus should be in the Pharmacopeia…

"The objection, that vaccine virus is an indefinite substance, the 'active principle' of which is not known, is no longer valid, for the Pharmacopeia contains many such substances, including the ferments, against which similar objection holds.

The objection that vaccine virus cannot be "assayed" [quantitatively and qualitatively analyzed[233] to determine the presence, amount or functional activity of a substance] by the average druggist also lacks force when we recall that the potency and purity of vaccine virus in interstate traffic is cared for by the federal government under the law of July 1, 1902, which relieves the pharmacist of this responsibility…"

KW comment:

Rosenau asserted that the presence of other undefined substances in the Pharmacopeia, meant that pharmacists should have no problem handling and dispensing the undefined substances contained in vaccine packages.

Rosenau further asserted that, although the unknown and unknowable contents of vaccine packages couldn't be objectively analyzed by anyone, including dispensing pharmacists, pharmacists should not be concerned about it: the federal government had legally relieved them of responsibility for the contents of vaccines.

*

2010 - Sequence-Based Classification of Select Agents, A Brighter Line: Committee on Scientific Milestones for the Development of a Gene Sequence-Based Classification System for the Oversight of Select Agents[234] (NASEM)

"…Natural variation and intentional genetic modification blur the boundaries around any discrete list based on taxonomic names…

The committee was specifically charged with identifying: the scientific advances that would be necessary to permit serious consideration of developing and implementing an oversight system for Select Agents that is based on predicted features and properties encoded by nucleic acids rather than a relatively static list of specific agents and taxonomic definitions.

It is implicit in the charge that a "predictive oversight" system is not now feasible. It is also implicit that "gene sequence-based classification," is synonymous with "predict[ing] features and properties encoded by nucleic acids."

However, it soon became clear that the committee was confronted by two quite different tasks, one of

[233] https://en.wikipedia.org/wiki/Assay

[234] https://nap.nationalacademies.org/catalog/12970/sequence-based-classification-of-select-agents-a-brighter-line

which is feasible and one is not. It is possible to *classify* a new sequence as belonging within a group of known sequences; it is *not* feasible to *predict* the function(s) that sequence encodes. Thus, it is essential to distinguish sequence-based *classification* from sequence-based *prediction* of biological function.

A sequence-based prediction *system for oversight of Select Agents is not possible now and will not be possible in the usefully near future.*

- Select Agent is not a biological term; rather it is a regulatory designation. Some properties historically considered in assigning an organism to the Select Agent list are not biological properties, and therefore, can never be determined from the organism's genome sequence.

- High-level biological phenotypes—such as pathogenicity, transmissibility, and environmental stability—cannot plausibly be predicted with the degree of certainty required for regulatory purposes, either now or in the foreseeable future.

- Reliable prediction of the hazardous properties of pathogens from their genome sequence alone will require an extraordinarily detailed understanding of host, pathogen, and environment interactions integrated at the systems, organism, population, and ecosystem levels. It is a prediction problem of the greatest complexity.

- Biology is not binary. Microorganisms are not either "potential weapons of mass destruction" or "of no concern." No single characteristic makes a microorganism a pathogen, and no clear-cut boundaries that separate a pathogen from a non-pathogen. Pathogenic microorganisms are not defined by taxonomy; it is common for a given microbial species to have both pathogenic and non-pathogenic representatives. An agent has multiple biological attributes, and the degree to which these are expressed fall along a spectrum for each biological characteristic; (1) consequently, agents present varying degrees of risk.

- For the foreseeable future, the only reliable predictor of the hazard posed by a biological agent will be actual experience with that agent…

…The scientific community does not have sufficient knowledge to create a novel, viable life form, even a virus, from the bottom up. Designing an infectious viral genome *de novo* by sequence requires the accurate prediction of protein structure and function, the design of protein-protein interactions and protein machines, all of which must produce progeny virions efficiently in an order of magnitude more complex host cell.

If we cannot predict protein structure and function on the basis of sequences with any accuracy, how can we design and synthesize novel viruses that will replicate, regardless of their disease potential?

KW comments:

There is no 'bright line'[235] or even the possibility of a bright line, distinguishing cell-based biological weapons — 'select agents and toxins,' in HHS regulatory language' (42 USC 262a[236]; 42 CFR 73[237]) from vaccines and other biological, genetic, cell-based products.

And because it is not feasible to predict biological functions of encoded sequences, for the purposes of classifying a sequence as a select agent or biological weapon, it is also not feasible to predict biological functions of encoded sequences in terms of their therapeutic value as treatments or prophylactics.

In other words, there is no scientifically-feasible foundation upon which vaccine manufacturers, regulators, advocates or users can make any valid, verifiable, credible, trustworthy claims about the identity, purity, potency, safety or efficacy of vaccines and other genetic products.

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2017 - Navigating the Manufacturing Process and Ensuring the Quality of Regenerative Medicine Therapies: Proceedings of a Workshop[238] (National Academies of Sciences, Engineering and Medicine)

> …Although regenerative medicine has great potential for producing both health and economic benefits, this relatively new field faces unique regulatory and manufacturing challenges. The reliance of regenerative medicine products on living cells and tissues, which are inherently dynamic, adds a fundamental complexity to the manufacturing and scale-up process that is not present in the manufacture of most non-biologic therapies.
>
> Since the variety of cells and tissues used in regenerative medicine is vast and the characteristics of cells can differ between in vitro and in vivo environments, defining and assessing the quality of products is challenging.
>
> In addition, it can be difficult to accurately measure or test for critical quality attributes (CQAs) (i.e., physical, chemical, biological, or microbiological characteristics that should be within an appropriate limit, range, or distribution in order to ensure the desired product quality (2) of cells because these attributes can change over time as they are affected by the cell maturation process and exposure to environmental stimuli.…
>
> [O]n June 26, 2017, the Forum on Regenerative Medicine hosted a public workshop in Washington, DC…to examine and discuss the challenges, opportunities, and best practices associated with defining and measuring the quality of cell and tissue products and raw materials in the research and manufac turing of regenerative medicine therapies. (4)
>
> The goal of the workshop was to learn from existing examples of the manufacturing of early-generation regenerative medicine products and to address how progress could be made in identifying and measuring CQAs.
>
> While there are increasingly more regenerative medicine products in the clinical pipeline and on the market, there is not yet consistency in the approaches to cell sourcing, product characterization,

[235] https://www.merriam-webster.com/dictionary/bright-line
[236] https://www.law.cornell.edu/uscode/text/42/262a
[237] https://www.ecfr.gov/current/title-42/chapter-I/subchapter-F/part-73?toc=1
[238] https://www.ncbi.nlm.nih.gov/books/NBK475688/pdf/Bookshelf_NBK475688.pdf

manufacturing processes, or logistics and delivery models…

Inherent Challenges to Preparing and Regulating Biologics

Many of the approaches and practices that the day's presentations and discussions would highlight are rooted deeply in the history of biologics development, said Jay Siegel, a forum co-chair and the chief biotechnology officer and head of scientific strategy and policy at Johnson & Johnson.

Vaccine production is centuries old, he noted, with the use of antisera products to treat infections going back to the 1890s. Monoclonal antibodies and cell and gene therapies are examples of more recent biologic products used to treat disease.

Although each of these biologics has its unique manufacturing obstacles, he said, they share common challenges, such as difficulty in characterizing the final product and the variations that inherently occur when living cells and tissues from several different sources are used.

Unlike the case with non-biologic drugs, there is no method to sterilize a cell-based biologic in its final packaging, Siegel said, and the cell-based biologics can be reactive, immunogenic, and relatively unstable.

There is no scientific definition of vaccine in US biological product law.

Published Dec. 13, 2024

Reader question: Is there a formal definition of vaccine in law?

There is no scientific definition of vaccine in statute or regulation.

That's why I urged Kirk Moore to ask DOJ to provide proof that what they supplied to his office was a vaccine. (*See* Aug. 8, 2023 - USA v. Dr. Kirk Moore et al.)

DOJ can't provide that proof, because the proof doesn't exist.

Congress added the term 'vaccine' to the biological products law in 1970 for the first time but did not define the term or direct the executive agencies to adopt or promulgate scientific definitions in regulations. (*See* March 12, 2024 - Statutory and regulatory definitions for drugs, biological products, and biosimilars; Aug. 26, 2024 - Intentional elusivity of definitions for virus and vaccine.)

There is a financial definition of 'vaccine' and a definition based on the design intention, adopted by Congress in 1987.

> 1987/12/22 - Congress and President Reagan passed Omnibus Budget Reconciliation Act of 1987, PL 100-203, 101 Stat. 1330,[239] including Sec. 9201, Manufacturers Excise Tax on Certain Vaccines, to establish an excise tax on vaccines ordered and purchased by US government and manufactured by private companies, to fund the Vaccine Injury Compensation Trust Fund established in 1986.
>
> This act is the only act through which Congress has ever defined the term 'vaccine,' defining 'vaccine' as "any vaccine (A) which is listed in the table contained in [26 USC 4131[240](b)(1)], and (B) which is manufactured or produced in the United States or which entered into the United States for consumption, use or warehousing."

Congress in 1987 defined *vaccine* in the form that now appears at 26 USC 4132a(2) — "any substance designed to be administered to a human being for the prevention of 1 or more diseases" — but has never defined the term "vaccine" in physical, chemical or pharmacological terms, and neither has the HHS-FDA.

See Dean v. HHS, No. 16–1245V, 2018 WL 3104388, at * 9 (Fed. Cl. Spec. Mstr. May 29, 2018), cited in 86 FR 6249[241], *HHS Final Rule, National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table*, "(defining ''vaccine'' as ''any substance designed to be administered to a human being for the prevention of 1 or more diseases'') (quoting 26 U.S.C. 4132(a)(2))."

[239] https://www.congress.gov/100/statute/STATUTE-101/STATUTE-101-Pg1330.pdf
[240] https://www.law.cornell.edu/uscode/text/26/4131
[241] https://www.govinfo.gov/content/pkg/FR-2021-01-21/pdf/2021-01211.pdf

The lack of scientific definition for vaccine was reinforced/corroborated in 2011 by the US Supreme Court in Bruesewitz v. Wyeth,[242] when the majority opinion stated at p. 13:

> "Design defects…do not merit a single mention in the [1986 National Childhood Vaccine Injury Act] or the FDA's regulations. Indeed, the FDA has never even spelled out in regulations the criteria it uses to decide whether a vaccine is safe and effective for its intended use."

Justice Scalia did not write, but it is also true, that FDA has never spelled out in regulations the criteria it uses to identify a product as a vaccine.

In other words, FDA has never spelled out in regulations the criteria it uses to determine if a product is or is not a vaccine.

This is because there are no available methods to do so, because vaccines are not stable, purified products.

They are mixtures that are constantly changing composition from initial production up through the point of injection and within the living organism into which they're injected.

[242] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/06/2011.02.22-bruesewitz-v.-wyeth-scotus-vaccination-unavoidably-unsafe-product.pdf

Pay-to-play and play-to-get-paid

Published Jan. 16, 2025

Expanding on Jan. 13, 2025, On using proposed mRNA bans, and opposition thereto from vaccination proponents, to deepen public understanding of vaccine non-regulation history and amplify vaccine hostility.[243]

My view is that vaccines have all always been DNA/RNA platforms — developed, distributed and used under many different terms — going back to the very beginning of legalized, militarized, systematic mass poisoning under the medicalized cover of vaccination campaigns.

Military/WRAIR-PBF [244] /US-AMRIID/DARPA, HHS/PHS/NIH/FDA and drug companies change the terms, to hide the consistent underlying facts about biological materials taken from many different living creatures, including human embryos, mixed together with each other and with synthetic chemicals, which are then inserted into a recipient living organism for which they are foreign materials and therefore toxic.

I think the actual process for vaccines, going back to the polio-labeled vaccines in 1954, is that military-public health DoD-WRAIR-PHS-NIH officers (Joseph Smadel and others) coordinated with Jonas Salk, John Enders and others to write fake production protocols based on the fake science of the Charles Armstrong, Leslie Webster and John Enders papers.

Those production protocols were distributed, with cell lines, tissue cultures and other starter materials, from US military laboratories (WRAIR Department of Biologics Research then, currently named Pilot Bioproduction Facility) to the selected six polio-labeled vaccine manufacturers (drug, pesticide and chemical companies) who were to supply product for the "field trials" organized by the National Foundation for Infantile Paralysis (now called March of Dimes.)

The manufacturers assembled and bottled unstable, unidentifiable junk, slapped labels on the bottles and shipped them to Salk and the field trial locations.

After the NFIP/Salk trials — data manipulated, subjects dropped from results, etc. — the same production protocols were provided to the manufacturers by federal military-public health officers, with instructions to resubmit those protocols back to Public Health Service, National Institute of Health, Division of Biologics Standards (DBS) regulators as part of packages meant to provide the illusion of manufacturing standards and controls to the public.

Then in December 1956, the fake production standards and fake manufacturing compliance controls for polio-labeled vaccines were put into the Code of Federal Regulations at 21 CFR 73.100 to 105.

The same illusion has been carried out for all subsequent vaccines, including Covid-labeled vaccines.

Federal agents instruct the drug, pesticide and chemical companies what to pretend to do, supply them with raw and finished materials, and instruct them how to pretend that they've complied with the pretend standards, by submitting fake documents such as nonclinical, preclinical and clinical trial records and applications for product approval and establishment licenses.

The drug companies do it; they play their parts.

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[243] https://bailiwicknews.substack.com/p/on-using-proposed-mrna-bans-and-opposition

[244] https://wrair.health.mil/Collaborate/Pilot-Bioproduction-Facility/

Federal agents then pretend to receive and review the submitted data as if it's substantive and valid rather than performative and false, and pretend to ensure compliance by issuing marketing approvals and establishment licenses.

*

The new FDA Bureau of Biologics set up in 1972 was comprised of the people who had previously worked in NIH-DBS, and it was directed by Harry M. Meyer, the former second-in-command at DBS.

By 1972 when the transfer happened, DBS had driven out almost all of the microbiologists who understood or objected to the scam. They had quietly gone to academia or out of scientific profession entirely.

One exception was J. Anthony Morris, who held on until 1976 and was fired just after the rollout of the swine flu vaccines. (*See* Nicholas Wade 1972 series in *Science*.)

The only remaining FDA Bureau of Biologics employees were willing participants in the deception and poisoning project, didn't understand what they were doing, or, as the virtual-mailbox hypothesis holds, there just weren't any real employees in BoB at all.

It was a dead-drop for false research records and application forms.

And still is.

The loopholes had already always been in place, going back to the 1902 virus-toxin law to make loopholes ahead of the 1906 food and drug law, and developed further in the 1944 PHSA law to maintain loopholes from the 1938 FDCA.

Since 1972, the loophole system complexity has increased, but not the basic structure.

I think of it as a combined pay-to-play and play-to-get-paid system.

Through the consortia, interested companies and universities pay to get a shot at the government contracts.

Once they have the contracts, they have to play along with the pretense of scientific validity and regulatory review, in order to get paid.

For all vaccines (pre- and post-2020) I think there's no way (equipment or method) to identify all of the natural/biological components (proteins, enzymes, cell wall fragments, and on and on) and no way to know the original living source of those substances, but they probably include combinations of human, cow, mouse, rabbit, chicken, pig, monkey, plant (i.e. peanut, wheat), bacterial and fungal cells, tissues and organs.

This relates to the debunking of contagion theory and genetics theory; the reality of changes over time (instability, dynamism) of living organisms and the molecular products they produce; and the inability of USP-NF to develop any workable reference materials or processing equipment or draft any workable assays or testing methods for vaccines.

For example, researchers like Antonietta Gatti and Stefano Montinari were only able to report that samples of vaccines contained organic matter, but could not specify its identity, source or quantity. The only "contaminants" they could identify, measure and report on were inorganic compounds: salts and metals.

From 2017 Gatti-Montinari paper, New quality-control investigations on vaccines: micro- and nanocontamination (*International Journal of Vaccines & Vaccination*)

> "So, organic entities are visible and easy to distinguish from inorganic ones. The method cannot distinguish between proteins and organic adjuvants (e.g. squalene, glutamate, proteins, etc.) or viruses, bacteria, bacteria's DNA, endo-toxins and bacteria's waste, but their comparatively low atomic density allows us to identify these entities as organic matter."

Public legislative hearings — at which state or county legislators present blinded samples of any vaccines (pre- or post-2020) to vaccination supporters, and ask those witnesses to state whether they have the scientific knowledge, techniques or equipment to correctly and fully identify and quantify the inorganic *and organic* contents and then match the results for a blinded vial to the product name, indication (purpose, i.e. preventing transmission of a named disease) and manufacturer on the original (removed for blinding) label — would be an effective method to demonstrate the scientific, medical, legal, political and moral bankruptcy of vaccination.

There are no available scientific equipment and testing procedures that would enable anyone to identify the contents of blinded vials or match blinded vials to label claims, because vaccine product contents are not fully identifiable or characterizable and are not stable.

The best anyone can do is use primers or reference sequences to identify some short fragment sequences that existed at the moment of testing; speculate about the longer sequences they might have come from; speculate about what might still be in any other vials filled from the same lot and batch, but might not be there, because other vials had different starting mixtures and have undergone different decomposition processes; and speculate about which living creatures might have been the source of the fragments, without any guarantee of accuracy, because many short sequences are shared across species, kingdom, phyla, etc.

Scientists can collect products (cells, tissues and organs) produced by living biological organisms out of the organisms' bodies, culture them, mix them, put them in different nutrient mixes, coat them in temporary, partial stabilizers (i.e. lipids), bottle the mixtures, refrigerate or freeze them for temporary, partial stability and ship them.

Physicians, nurses and pharmacists can pull the bottles from refrigeration, return them to room temperature, inject them — untraceably, because of shared sequences and fragility — into subjects at body temperature, and allow the metabolic processes in the recipient organism to take up, act upon, decompose and excrete the complex molecules until the last remnants leave the body.

That's vaccination: injecting people and animals with toxic biological slurries.

Laws and regulations and guidance-for-industry documents are intentionally written to hide/cover up historic and ongoing, systematic criminal malfeasance in vaccine development, manufacturing, distribution, promotion and use.

They are staging instructions for laboratory acts in government, academic and corporate laboratories and dialog scripts (for written exchanges and for public oral statements) transmitted by theatrical performance directors to theatrical performers.

Stefan Lanka, Northern Tracey, Jamie Andrews, Sasha Latypova and others are demonstrating the invalidity of foundational scientific methods underlying contagion theory and genetic theory, because of the inherent time-dependent, not-controlled-by-humans changes in form for products of biological processes in living organisms.

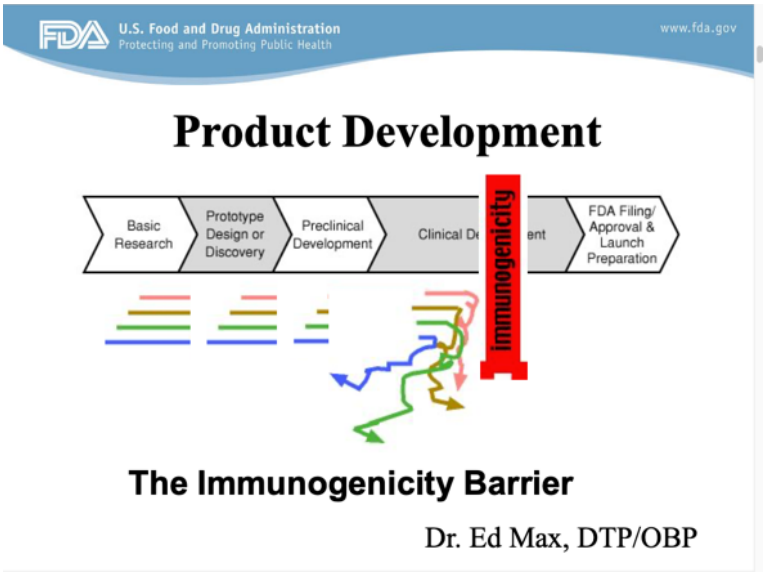
Cells and tissues can only be artificially sustained outside a living body temporarily with nutrient feeding, and their decay can only be temporarily suspended by encapsulation, refrigeration and freezing; when restored to room or body temperature, infinitely-variable transformation and decay processes continue.

The invalidity of those scientific methods was known to the military-public health scientist-actors, theatrical scientific-medical script publishers and lawyers at the time that they published scientific papers; wrote, exchanged and pretended to use vaccine production protocols; and wrote deceit-enabling laws and regulations.

There was evil intent — intent to deceive and intent to poison — from the start.

Immunogenicity is toxicity.

The intentional induction of a living organisms' capacity to identify, isolate and expel poison and the intentional insertion of poison into a living organism are two aspects of the same single, evil act: the act of vaccination.



From 2014 FDA slide deck: The immunogenicity of therapeutic proteins- what you don't know can hurt YOU and the patient, João A. Pedras-Vasconcelos, PhD CMC and Immunogenicity Reviewer, Division of Therapeutic Proteins OBP/CDER/FDA

Labeling deceits and omissions and fake informed consent for vaccines and other legalized biological and chemical weapons.

Analysis of South Carolina's S.54: Medical Informed Consent Act

Published Jan. 29, 2025

Notes:

Labeling deceit and labeling omissions are about labeling biological products, including vaccines, with ill-defined words and arbitrary units of measure and units of potency to deceive users into holding false beliefs: that package contents are identifiable, measurable, stable, non-toxic and therapeutic.

Labeling deceit and omissions represent only a small fraction of the many layers of legalized deceit and omissions that have comprised biological product manufacturing, communicable disease control, and vaccination law at any given time since 1902 and up to the present moment.

Pulling on any thread of deceit, in any layer at any time, leads to other layers of deceit. It's not possible to fully describe any layer, in any single report. I encourage readers who want to better understand other layers of deceit surrounding any word, phrase, unit of measure, or unit of potency described below or in other Bailiwick reporting, to pull the threads.

Deepen vaccine hostility.

Help more people stop taking vaccines and stop vaccinating babies and children.

Pray the Rosary.

*

A Medical Informed Consent Act bill (S. 54)[245] was introduced in the South Carolina state Senate on Jan. 14, 2025, proposing amendments to South Carolina's current Emergency Health Powers law (Title 44, Chapter 4, enacted in 2002[246]) and related provisions in other sections of South Carolina state law.

I looked at the draft Medical Informed Consent Act, focusing on proposed changes to SC Code 44-4-520, *Vaccinations and Treatment*.

Based on my knowledge of how federal law addresses biological product and vaccine package labeling and informed consent to enable and hide intentional poisoning programs by disguising poisoning campaigns as regulated pharmaceutical product manufacturing, distribution and use, I think people who are knowledgeable about how to neutralize this state law proposal, neutralized it before introduction.

It would still be good if it passed, if only because other amendments proposed by S.54 would require notification to product recipients that they and their survivors can't prosecute or sue anybody if they're injured or killed, by defining the term *Indemnified product*.

Indemnified product means any product including, but not limited to, a covered countermeasure, for which the manufacturers and distributors are shielded from direct civil or criminal liability to consumers for personal injuries

[245] https://www.scstatehouse.gov/sess126_2025-2026/bills/54.htm

[246] https://www.scstatehouse.gov/code/t44c004.php#44-4

and damages resulting from the use of the product as determined by state or federal law.

That's notification by South Carolina lawmakers, to South Carolina people, that US-HHS, US-DoD, US-FDA, US-NIH, US-CDC, US-ASPR, US-BARDA, US-DARPA, (and all other federal government officers); Pfizer, BioNTech, Moderna, National Resilience, Rentschler (and all other vaccine manufacturers); and South Carolina pharmacists, nurses and doctors are all jointly licensed to maim and kill using all vaccines (which are all *indemnified products*) and countermeasures, under biological product laws that legalize manufacture of biological and chemical weapons, deceptive labeling of packages, and use of the products to torture, maim and murder recipients.

When people understand that FDA licenses, authorizations and approvals for manufacture and use of *indemnified products* are licenses to kill, those people stop taking vaccines and stop vaccinating babies and children.

Analysis

The current South Carolina law relating to Vaccinations and treatment (S.C. Code 44-4-520, adopted in 2002), does not include a section defining *informed consent*.

S.C. Code 44-4-520 currently reads:

> Vaccinations and treatment.
>
> (A) During a state of public health emergency, DHEC may exercise the following emergency powers, in addition to its existing powers, over persons as necessary to address the public health emergency:
>
> (1) to vaccinate persons as protection against infectious disease and to prevent the spread of contagious or possibly contagious disease;
>
> (2) to treat persons exposed to or infected with disease; and
>
> (3) to prevent the spread of contagious or possibly contagious disease, DHEC may isolate or quarantine, pursuant to the applicable sections of this act, persons who are unable or unwilling for any reason (including, but not limited to, health, religion, or conscience) to undergo vaccination or treatment pursuant to this section.
>
> (B) Vaccinations or treatment, or both, must be provided only to those individuals who agree to the vaccinations or treatment, or both.
>
> (C)(1) Vaccination may be performed by any qualified person authorized by DHEC.
>
> (2) To be administered pursuant to this section, a vaccine must not be such as is reasonably likely to lead to serious harm to the affected individual.
>
> (D)(1) Treatment must be administered by any qualified person authorized to do so by DHEC.
>
> (2) Treatment must not be such as is reasonably likely to lead to serious harm to the affected individual.
>
> HISTORY: 2002 Act No. 339, Section 24, eff July 2, 2002.

With S.54, South Carolina lawmakers are proposing to add *informed consent* provisions to S.C. Code 44-4-520.

> Section 44-4-520. Vaccinations and Treatment
>
> (A) For purposes of this section, "informed consent" means a written document that is signed and dated by an individual; or, if the individual is a minor, by a parent or legal guardian; or, if the individual is incapacitated or without sufficient mental capacity, by a designated health care agent pursuant to a health care power of attorney, that at a minimum includes:
>
> (1) an explanation of the vaccine or treatment that is written in language that is understandable to the average lay person;
>
> (2) a description of the potential risks and benefits resulting from vaccine or treatment, along with a realistic description of the most likely outcome;
>
> (3) a statement acknowledging risks associated with the vaccine or treatment if the vaccine or treatment is an *indemnified product* as defined in Section 44-1-55(A)(7) [another amendment proposed by S.54 but not yet in South Carolina state law]; and
>
> (4) language that clearly indicates that the individual agrees to the administration of the vaccine or treatment, that the individual has had time to thoughtfully and voluntarily accept or decline the vaccine or treatment free from coercion.

The proposed S.54 amendments would also add a new provision to Section 44-4-520 on "safety and efficacy" review and "adverse event monitoring."

> ...(F) The safety and efficacy of vaccines, tests, and treatments performed and administered as provided in this section must be reviewed and adverse events monitored by the department. References to evidence-based data determined to validate vaccines, tests, and treatments including, but not limited to, VAERS data must be prominently posted on the department's public website.

*

The proposed South Carolina state law language about informed consent for vaccination and treatment mirrors federal law for all biological products since 1902 and for EUA countermeasures since 2003.

Federal biological product and EUA laws are written to exempt manufacturers and regulators from having to label products with information about the specific identity and quantity (mass, volume, concentration) of biological material inside packages of biological products.

For biological products (all vaccines) and for EUA products, proper name, manufacturer name and address, and general descriptions are the only enforceable and enforced legal requirements.

South Carolina lawmakers will, if S.54 passes, embed this limited general information format, mirroring federal law in state law, by limiting the required information to "an explanation of the vaccine or treatment that is written in language that is understandable to the average lay person."

This is related to what Sasha Latypova and I have pointed out: it's not possible for anyone to give informed consent without having specific information about what, exactly, is in the individual package presented to a specific recipient at a specific time and place.

Biological product labeling laws are written to require general, but not specific information, because the specific contents of any given package of biological material at any given moment in time, cannot be specifically known, identified or fully characterized at all.

Scientific identification and measurement methods are capable of only partial characterization of biological organisms and living systems not because of limits to scientific knowledge or technology that may someday be overcome, but because of the inherent variety and instability of biological organisms themselves. Assessment methods destroy the samples to obtain the limited information that can be gleaned. Each aliquot differs from each other aliquot, even those drawn from the same batch. And each aliquot differs from itself at earlier or later moments in its existence.

It's also related to what Sasha Latypova and Mike Yeadon have both pointed out: there is no way to establish any "dose" by mass or volume of injected biological material, because all injected biological material interacts in a unique way and for an unpredictable, indeterminate amount of time with the biological processes of each specific recipient.

Living organisms are in a state of constant change. They're born and they grow. They take in nutrients, use energy, change form, excrete waste. They communicate and cooperate with other living organisms. They decay, fragment and die.

At any given moment all along the biological product propagation and manufacturing chain, all of those processes are underway in vaccine batches and bottles.

The biological events unfold at active, rapid speeds when the living organisms are at room temperature or body temperature within a laboratory processing container.

The events occur at slower rates when the living organisms are suspended, encapsulated, refrigerated or frozen.

The events resume — rapidly again — when the living organisms are defrosted, diluted, warmed, mixed and injected into another, larger living organism.

Since there's no way for any public health-military officer, manufacturer, regulator or vaccinator to know the specific identity of what's in any package at any given time, because biological products are unstable mixtures of living and non-living matter, and no way to predict how each specific living body will respond to the material after injection, there's no way for any of them to tell the recipient what the product is or what effect it will have.

Poisoners among US public health, military, scientific, medical, legal and financial officers have known these facts from the beginning of the modern vaccination era.

That's why they have written and executed laws to exclude identity information from product labels for all viruses, serums, toxins, antitoxins and vaccines since the virus-toxin law enacted by Congress in 1902 [see below, section titled Leapfrogging Mutual Exemptions] and also from all labels and "fact sheets" for EUA products since the emergency countermeasures law enacted by Congress in 2003.

*

Oct. 22, 2020 FDA VRBPAC meeting: Marion Gruber, Director, FDA Center for Biologics Evaluation and Research CBER Office of Vaccines Research and Review (OVRR), transcript[247] at p. 37:

> In order to issue an EUA, the FDA must determine, among other things, that the product may be effective and that the known and potential benefits of the investigational product outweigh its known and potential risks.
>
> Use of an investigational COVID-19 vaccine under an EUA is not subject to informed consent requirements.
>
> However, vaccine recipients need to be provided a fact sheet, and that describes the investigational nature of the product, the known and potential benefits and risks of the product, available alternatives, and there is the option to refuse vaccination.

Gruber was correctly reporting on the legal requirements: regulators and manufacturers are legally-authorized to omit specific identity information from EUA product fact sheets, which are substitute or false informed consent documents containing only general information, descriptions, or explanations.

Congress enacted the omission provision in 2003 (PL 108-136, NDAA FY2004 at 117 Stat. 1686) and the provisions entered into the Food Drug and Cosmetic Act (US Code Title 21 at 21 USC 360bbb-3(e)

Congress enacted substitute or fake informed consent provisions to continue to hide labeling omissions; to continue to hide the non-existence of legal requirements, since 1902, that biological product manufacturers and regulators identify and publish (on labels and other printed material) the specific contents of vaccine and other biological product packages.

> 21 U.S. Code §360bbb–3(e)(1)(A)(ii), Authorization for medical products for use in emergencies, Conditions of authorization, Unapproved product
>
> (A) Required conditions
>
> With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:
>
> (ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—
>
> (I) that the Secretary has authorized the emergency use of the product;
>
> (II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
>
> (III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

[247] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2025/01/2020.10.22-fda-vrbpac-meeting-transcript-cber-ovrr-gruber-fact-sheet-no-informed-consent.pdf

Emergency Use Authorization letters for COVID-19 vaccines corroborate the legalized omission of specific identity information from product labels.

See, for example, Dec. 11, 2020 letter, Denise Hinton, FDA to Elisa Harkins, Pfizer, published at 86 FR 5204:

> "Product Description
>
> The Pfizer-BioNTech COVID-19 Vaccine is supplied as frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. After dilution, each vial contains 5 doses of 0.3 mL per dose. The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative.
>
> Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.
>
> Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutlyl)azanedyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradyecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.35 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection) contributes an additional 2.16 mg sodium chloride per dose.
>
> The dosing regimen is two doses of 0.3 mL each, 3 weeks apart."

The December 2020 Product Description by FDA and Pfizer-BioNTech uses the indefinite article "a nucleoside-modified messenger RNA..." and provides no information about how to validate the claimed mass and concentration of an indeterminate product (30 mcg per 0.3 mL dose) or convert from the claimed mass and concentration of the indeterminate biological product to predictable effects.

Again, this is because mass and concentration of unstable, dynamic mixtures of living and dying organisms and fragments of their cells cannot be validated — there are no scientific techniques, equipment or methods that don't fully destroy each sample — and because effects cannot be predicted accurately and specifically: effects vary immeasurably through the interaction of the injected material with itself before injection and with the recipient's own living body after injection.

FDA, Pfizer and vaccinators provide no information about the specific molecular structure of the claimed RNA molecules, because RNA molecules are not stable and, if present at all, are present in a variety of ever-changing forms in the package, interacting with, transforming and being transformed by all the other listed contents, which also may or may not be in the bottle at any given moment while the contents are active, growing, living and decaying.

The Dec. 2020 Fact Sheet[248] given to recipients includes a list of names of substances, including unspecified "mRNA."

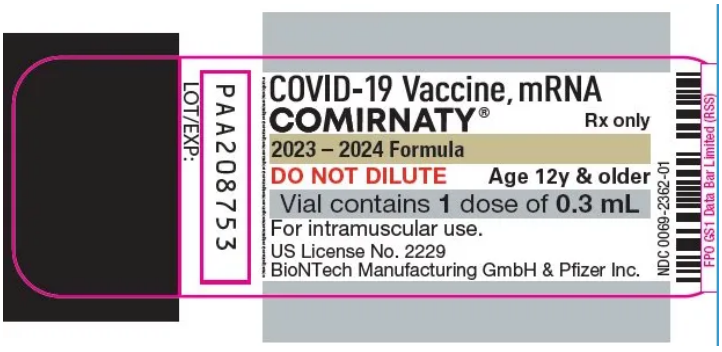
> What are the ingredients in the Pfizer-BioNTech COVID-19 Vaccine?
>
> The Pfizer-BioNTech COVID-19 Vaccine includes the following ingredients:
>
> mRNA, lipids, ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3- phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

*

Publicly-available manufacturing contracts, such as the Pfizer Statement of Work produced during Brook Jackson's False Claims Act case, and publicly-available regulatory application documents redact all information that would further reveal the unstable, mixed, unspecified, unidentifiable nature of vaccine contents.

- 2020.07.21 DOD ATI Pfizer Technical Direction Letter Statement of Work OTA-W15QKN-16-9-1002[249]
- 2021.08.19 FDA CBER CMC BLA Review Memo - COMIRNATY[250]
- 2021.08.20 FDA Analytical Method Review Memo - COMIRNATY[251]
- 2021.08.21 FDA Chemistry Manufacturing Controls CMC Review Memo - COMIRNATY Voluntary Action Indicated[252]
- 2022.02.15 HHS FDA Form 483 Rentschler Biopharma, Laupheim, Germany Failure cGMP drug substance simulated fill process[253]

Even after the fake FDA "approval" of the Pfizer-BioNTech Biologics License Application (BLA) in August 2021, for example, the Comirnaty label for the vial simply describes the contents as "one dose of 0.3 mL."



Screenshot from FDA Purple Book, Comirnaty entry, 2023-2024 Formula

[248] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2025/01/2020.12-fda-pfizer-eua-fact-sheet-pfizer.pdf
[249] https://bailiwicknewsarchives.files.wordpress.com/2022/10/2020.07.21-dod-ati-pfizer-technical-direction-letter-ota-w15qkn-16-9-1002-35-p.pdf
[250] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2025/01/2021.08.19-fda-cber-cmc-bla-review-memo-comirnaty.pdf
[251] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2025/01/2021.08.20-fda-analytical-method-review-memo-comirnaty.pdf
[252] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2025/01/2021.08.21-fda-chemistry-manufacturing-controls-cmc-review-memo-comirnaty-voluntary-action-indicated.pdf
[253] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2025/01/2022.02.15-hhs-fda-form-483-rentschler-biopharma-laupheim-germany-failure-cgmp-drug-substance-simulated-fill-process.pdf

Leapfrogging mutual exemptions

Tracking the two separate legal pathways for "biological products" and for "drugs" from the opening of the legal hole for biological products in 1902 through 1944.

BIOLOGICAL PRODUCTS - Viruses, serums, toxins, antitoxins and analogous products, including all vaccines.

1902 Virus, Serum and Toxin Act, PL 57-244

Congress required package labels for viruses, serums, toxins, antitoxins and analogous products - to contain:

> "the proper name of the article contained therein, the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results."

Congress required no information about product identity, mass, volume or other physical or chemical qualities or quantities.

That was the opening of the legal hole through which unidentified, unidentifiable, mixtures of unstable, foreign biological substances would be legally labeled as medicines and legally injected into people to poison, sicken and kill them for the following 120+ years.

DRUGS

1906 Pure Food and Drug Act, PL 59-384

Section 6 defined the term "drug" as "all medicines and preparations recognized in the United States Pharmacopeia-National Formulary [USP-NF] for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals."

Section 7 provided that, for drugs sold under USP-NF-recognized names, a drug would be deemed adulterated under either of two conditions:

- if it "differs from the standard of strength, quality, or purity, as determined by the test laid down" in the USP-NF "official at the time of investigation" with exemptions for drugs whose "standard of strength, quality or purity" was "plainly stated on the bottle, box, or other container" even if the standard differed from the standard determined by the USP-NF test, or

- if the product's "strength or purity fall below the professed standard or quality" stated on the package under which it was sold.

Section 8 defined misbranded as applying to all drugs "the package or label of which shall bear any statement...regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular."

The 1906 Pure Food and Drug Act also deemed drugs misbranded if demonstrated to be "an imitation of or offered for sale under the name of another article;" in packages that had had original contents removed and substituted with other contents; or if the package label failed to list the "quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances."

Unpacking the resulting status of biological products under the Pure Food and Drug Act:

Biological products were not sold under names recognized by the USP-NF, and — as biological products subject only to the 1902 law — were not required to be labeled with any specific, identifying information about ingredients or substances.

Since there were no specific "statements about the article, ingredients or substances" on biological products at all, there were no statements that could be assessed or deemed "false or misleading."

Adulteration and misbranding provisions were therefore not applicable to biological products.

DRUGS

1938 Federal Food, Drug and Cosmetic Act - (PL 75-717)

Congress in 1938 passed the Federal Food Drug and Cosmetic Act (FDCA), repealing and replacing the 1906 Pure Food and Drug Act, and carrying forward the comprehensive inapplicability of drug manufacturing, labeling and distribution regulations to biological product manufacturing, labeling and distribution activity, through Sec. 902(c):

"Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the virus, serum, and toxin Act of July 1, 1902."

For drugs already in use, the FDCA maintained most of the 1906 rules for drugs.

The 1938 FDCA deemed a drug sold under a USP-recognized name to be adulterated if

> "…its strength differs from, or its quality or purity falls below, the standard set forth in such compendium" to be determined by "tests or methods of assay set forth in such compendium…" 1938 FDCA Section 501

For drugs already in use, 1938 FDCA required labels to contain:

> "...the name and place of business of the manufacturer, packer, or distributor; and...an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count...adequate directions for use...adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application…" 1938 FDCA Section 502

For drugs already in use, 1938 FDCA deemed a drug to be misbranded if its labeling was: "...false or misleading in any particular..." 1938 FDCA Section 502

The 1938 FDCA also provided for several exemptions and waivers to be promulgated by the Secretary of Agriculture at his discretion, including conditions under which any otherwise applicable requirement "is not necessary for the protection of the public health."

For new drugs — drugs not already in use by 1938, that manufacturers wanted to begin selling — the 1938 FDCA required applicants to provide the Secretary of Agriculture with

> "…reports of investigations...to show whether or not such drug is safe for use...a full list of articles used as components of such drug...a full statement of the composition of such drug...a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packaging of

> such drug...samples of such drug and of the articles used as component thereof as the Secretary may require and...specimens of the labeling proposed to be used for such drug." 1938 FDCA Section 505(b)

New drug applications would become effective, allowing introduction of the drug into interstate commerce, automatically on the sixtieth day after filing, unless the Secretary issued an order refusing to permit the application to become effective.

For new drug applications, the 1938 FDCA authorized the Secretary to issue an order refusing to permit the application to become effective, upon finding

> "that the submitted test results were inadequate to demonstrate safety, or that the submitted tests results demonstrated the drug to be unsafe, or that "the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality and purity." 1938 FDCA Section 505(d)

BIOLOGICAL PRODUCTS

1944 Public Health Service Act (PL 78-410)

With the 1944 Public Health Service Act, Congress reinforced the separation of biological product regulation from drug regulation that had already been put in place in 1902 and 1906 and reinforced in 1938, PHSA 351(g): "Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug and Cosmetic Act."

Through the 1944 PHSA, Congress added to the list of biological products, which up until then included "virus, therapeutic serum, toxin, antitoxin or analogous product" the phrase "arsphenamine or its derivatives (or any other trivalent organic arsenic compound)." PHSA 351(a)

Through the 1944 PHSA, Congress left in place the very short list of required package markings, limited to: "the proper name of the article contained therein, the name, address and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results." (1944 PHSA Section 351(a)(2))

Through the 1944 PHSA, Congress left in place the legal hole through which poisons could be manufactured, labeled without specific identification or quantification of contents, distributed and used, disguised as standardized, regulated medicinal products.

At Section 351(d) Congress introduced the phrase "continued safety, purity, and potency" falsely described as "standards" biological product manufacturing processes must be "designed to insure" for licenses to be issued, even though no such standards had ever existed, and no manufacturing, testing or regulatory compliance procedures had ever been designed to insure them.

Such standards can never exist, and such manufacturing processes can never be designed or used, because biologically-active biological organisms cannot be stabilized, standardized, purified, or rendered safe to inject into another living creature, or rendered potent or effective for anything other than untraceable poisoning.

See Sept. 19, 2022 - In Nov. 2020, Pfizer told FDA reviewers, led by Marion Gruber, that safety studies were neither needed nor conducted. In making that argument, Pfizer cited WHO guidance written in 2002 by a team led by Marion Gruber; Feb. 9, 2023 - On the significance of 21 USC 360bbb-3(k): "use" of EUA products "shall not constitute clinical investigation."

Exemptions for biologics (all vaccines) under PHSA 351, from FDCA 505 'new drug' provisions requiring substantial evidence of effectiveness.

Published Feb. 8, 2025

Email to reader who is interested in untangling when and how some of the carve-outs exempting biological products — including all vaccines — from laws requiring 'substantial evidence' of effectiveness obtained through 'adequate and well-controlled' human studies for marketing and use of new drugs, came into being. Two other places to start (in addition to Tuskegee) are the 1937 Elixir tragedy (solvent used in antibiotic liquid caused 100+ deaths) and 1958/1959 thalidomide.

The Elixir incident is cited as a driver of the 1938 FDCA and the thalidomide incident is cited as a driver of the 1962 FDCA Kefauver-Harris amendments to FDCA 505 requiring non-biologic drug manufacturers to provide, in their marketing application materials, proof of safety and effectiveness of new non-biologic drugs.

Tuskegee is cited as the driver of the "informed consent" for human studies sections, which is related but more about the conduct of studies themselves, and less about product manufacturing and manufacturer submission of evidence in marketing application packages.

Because biologics and vaccine manufacturers have never had to collect or submit evidence from controlled human studies, rules about informed consent and conduct of human studies haven't ever applied to them….

In the original 1938 FDCA, the term *new drugs* is defined at FDCA 201 as

> "any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use..."

In 1962, Congress added effectiveness terms so that new drug was defined as

> "any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use..."

The 1962 amendments also added in "effective" language in several parts of FDCA 505.

For example, FDCA 505(e) is about conditions under which a regulator can withdraw or suspend approval for a non-biological new drug. Without such suspension or withdrawal action, the application is deemed approved and the drug can be marketed.

Prior to 1962, the FDCA 505(e) section ended at 505(e)(2).

In 1962, a third condition under which approval could be suspended was added at 505(e)(3):

> "on the basis of new information...that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have...in the labeling..."

The 1962 amendments added a definition for *substantial evidence*, at FDCA 505(d):

> "the term substantial evidence means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by

such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

To summarize, the finding of no substantial evidence of "effectiveness," as a basis for preventing new drugs from entering market or withdrawing new drugs from market, at least for drugs subject to FDCA (so not for PHSA biologics), was only added with the 1962 amendments, put in at 505(e)(3).

Setting aside, for now, the blanket or general legal exemptions that have existed from the beginning and still exist now for all PHSA 351 biologic products, from all provisions of FDCA 505 new drug rules, one specific carve-out the two-track system enabled, for PHSA biologic products, is that, because biologic product labels are not required to contain any information about the effect it is supposed to cause in the recipient, there is no statement of effect that could be assessed for whether the evidence that it will have such an effect is "adequate and well-controlled" or supports "fair and responsible conclusions" as to the validity of the claims.

Another legalized carveout for PHSA biologic products, appeared in implementing regulations (circa 1972) that said regulators could accept "partially controlled" "uncontrolled" and other implicitly insufficient, inadequate and not-well-controlled forms of evidence.

They also circumvented the FDCA effectiveness provisions usually by using some form of saying that human studies of biologicals, of the kind done for non-biologic drugs, are "not feasible" or "not ethical."

For example:

> "Where adequate and well-controlled studies are not feasible, and acceptable alternative scientific methods of demonstrating effectiveness are available, the latter will be sufficient."37 FR 16679, Aug. 18, 1972 FR.

Human safety and “efficacy” and effectiveness, could be derived, for “individual active components” of biological products, for “combinations of the individual active components” of biological products, and for “finished biological products” from:

- Controlled studies.
- Partially controlled or uncontrolled studies.
- Documented case reports.
- Pertinent marketing experiences that may influence a determination as to the safety of each individual active component.
- Pertinent marketing experiences that may influence a determination as to the safety of combinations of the individual active components.
- Pertinent marketing experiences that may influence a determination as to -the safety of the finished biological product.
- Pertinent marketing experiences that may influence a determination on the efficacy of each individual active component.
- Pertinent marketing experiences that may influence a determination as to the effectiveness of combinations of the individual active components.
- Pertinent marketing experiences that may influence a determination as to the effectiveness of the finished biological product.
- Pertinent medical and scientific literature.

There is useful discussion of the way that these terms created the gap for biologics to be used without controlled studies in the June 1980 GAO report: GAO Answers to Questions on Selected FDA Bureau of Biologics Regulation Activities[254]

It's tricky reading, but the meat is in the back and forth between GAO inspectors and HEW officials.

GAO noted that Congress had considered applying the evidence standard to biologics, but the provisions were repeatedly stripped out of bills in the early 1960s. GAO noted that FDA hadn't provided detailed criteria about what kind of studies meet the standard for "acceptable alternative scientific methods." GAO suggested Congress pass legislation requiring controlled studies. GAO suggested FDA label products to notify doctors and patients that no good evidence of effectiveness had been collected or existed. GAO suggested a lot of things.

HEW replied by saying, paraphrased:

> 1) the Congressional laws are already good enough, we don't need more laws, and
>
> 2) we [manufacturers and regulators] can't do controlled studies because biologics can't be standardized and we can't figure out which parts of biological materials are the "active components" or the ones having the effect, or if any effect is caused. And we can't figure out how to account for the wide variability in response in humans from person to person, and from time to time within the same person. We can't figure out dosing. We can't figure out clinical endpoints. We don't really know anything about biologics, what's in them, or what they do. But we think that partially-controlled, uncontrolled studies, with case reports, with post-marketing (aka "real world") reports and with "pertinent medical and scientific literature" (aka Enders and other scientific misconduct papers) are good enough to keep making and using biologics.

[254] https://bailiwicknewsarchives.wordpress.com/wp-content/uploads/2024/10/1980.06.06-gao-answers-to-questions-on-selected-fda-bureau-of-biologics-regulation-activities-hrd-80-55-ribicoff-kennedy-pagination-corrected.pdf