Fact Checking DHHS

FACT CHECKERS – PLEASE POST ALL APOLOGIES FOR MISLEADING THE AMERICAN PEOPLE ON FACEBOOK AND TWITTER – THEY WILL BE CENSORED SHORTLY THEREAFTER AND YOU CAN JOIN THE REST OF US IN SOCIAL MEDIA JAIL

COVID-19 Facts, The Ugly Truth: Vaccine Deaths & Denying Treatment That Works

Uttar Pradesh, the most heavily populated state in India, has mostly eradicated COVID-19 by prescribing Ivermectin prophylactically and as an early treatment to all of its citizens.

COVID caseload as of August 16, 2021;

ONLY 419 out of 200 million!!!!

https://covidcalltohumanity.org/2021/08/19/indias-uttar-pradesh-moving-towards-being-covid-free-ivermectin-central-to-virus-control/

Medicare Statistics

Percentage of Americans covered by Medicare in 2019:

18.1%

59.4 Million People

- 18% of 330 Million is: 59,400,000
- Total Medicare Budget: $899 Billion (2020)
- Largest data base available in the U.S. to study COVID-19 trends
- Includes all claims: vaccine dates, treatment dates, death dates, adverse events, hospitalizations, is not self-reporting like VAERS.

Why isn't the CDC, FDA, HHS using Medicare data to drive health decisions regarding the vaccine? Why did they disregard CMS data as an early warning signal mechanism?

Source: https://www.statista.com/topics/1167/medicare/

COVID Vaccine Deaths
CMS Data

Number of CMS beneficiaries who died within 14 days* of a COVID-19 vaccine:

Age Group	# of Persons who died within 14 days of a COVID-19 vaccine
<= 80 years old	19,400
Over 80 years old	28,065
Total	*48,465*

*within 14 days of 1st or 2nd dose, whichever difference was lower

Actual Data: Persons who died within 14 days after the COVID vaccine, age 80 years and younger

First record for 80 years and younger

	BENE_DEATH_DT	BENE_STATE	VACCINE_DATE	DAYS_DIED_AFTER_VAXX	AGE	BENE_ID
1	08MAR2021	ME	08MAR2021	0	68	31
2	24MAR2021	MA	24MAR2021	0	64	73
3	19JAN2021	CT	19JAN2021	0	65	145
4	15JAN2021	NJ	15JAN2021	0	74	188
5	15MAR2021	NJ	15MAR2021	0	77	399
6	27JAN2021	PA	27JAN2021	0	59	573
7	06FEB2021	DC	06FEB2021	0	74	761
8	06FEB2021	FL	06FEB2021	0	66	942
9	17FEB2021	IN	17FEB2021	0	59	999
10	18JAN2021	IL	18JAN2021	0	75	1081
11	21APR2021	KY	21APR2021	0	66	1094
12	05FEB2021	IL	05FEB2021	0	60	1140
13	20JAN2021	IL	20JAN2021	0	80	1142
14	29JAN2021	IL	29JAN2021	0	73	1150
15	02JUN2021	IA	02JUN2021	0	67	1152
16	25MAY2021	MI	25MAY2021	0	64	1224
17	29JAN2021	MI	29JAN2021	0	61	1230
18	25FEB2021	MI	25FEB2021	0	67	1239
19	12MAR2021	MI	12MAR2021	0	61	1294
20	11FEB2021	WI	11FEB2021	0	56	1312
21	04MAR2021	KY	04MAR2021	0	80	1377
22	25JAN2021	AL	25JAN2021	0	70	1512
23	16JAN2021	MS	16JAN2021	0	77	1516
24	04JAN2021	OK	04JAN2021	0	78	1707
25	28JAN2021	TX	28JAN2021	0	75	1729

Actual Data: Persons who died within 14 days after the COVID vaccine, age 80 years and younger

Last Record for 80 years and younger n=19,400

19378	17MAY2021	DE	03MAY2021	14	65	19152
19379	04AUG2021	TX	21JUL2021	14	65	19155
19380	12APR2021	OR	29MAR2021	14	65	19160
19381	09FEB2021	OK	26JAN2021	14	68	19170
19382	02MAR2021	NY	16FEB2021	14	65	19174
19383	19APR2021	WV	05APR2021	14	62	19205
19384	03JUN2021	MD	20MAY2021	14	60	19211
19385	01JUN2021	IL	18MAY2021	14	56	19224
19386	08APR2021	CT	25MAR2021	14	65	19225
19387	15JUN2021	NY	01JUN2021	14	65	19227
19388	19JAN2021	TX	05JAN2021	14	65	19238
19389	19FEB2021	CA	05FEB2021	14	65	19239
19390	02APR2021	PA	19MAR2021	14	64	19241
19391	04FEB2021	MN	21JAN2021	14	65	19257
19392	15MAR2021	ID	01MAR2021	14	65	19278
19393	30MAR2021	MI	16MAR2021	14	65	19291
19394	18AUG2021	TX	04AUG2021	14	65	19318
19395	16APR2021	FL	02APR2021	14	58	19327
19396	10JUN2021	AL	27MAY2021	14	65	19338
19397	22MAR2021	NM	08MAR2021	14	64	19357
19398	19APR2021	CA	05APR2021	14	70	19367
19399	17APR2021	AR	03APR2021	14	66	19371
19400	23APR2021	OR	09APR2021	14	66	19374

Remdesivir Deaths: The Real Numbers

Remdesivir (Veklury) deaths recorded in CMS database (2021):

- 7,960 beneficiaries prescribed Remdesivir for COVID-19
- 2,058 beneficiaries died

25.9% remdesivir patients died

46% of those died within 14 days of remdesivir treatment

How much does remdesivir cost?

Hospitals will pay $390 per vial of remdesivir, which equates to $2,340 (government) to $3,120 (private insurance) for a five-day course of the drug, using 6 vials

(source: https://www.kff.org/coronavirus-covid-19/issue-brief/how-could-the-price-of-remdesivir-impact-medicare-spending-for-covid-19-patients/)

Remdesivir Adverse Events

Clinical trials data reflects reality: 25% serious adverse events

From Remdesivir Clinical Trial Final Report:

“Serious adverse events were reported in 131 of the 532 patients who received remdesivir (24.6%).”

Is this safe and effective????

Source: https://www.nejm.org/doi/full/10.1056/nejmoa2007764

Ivermectin Safety Profile: Safer and Cheaper Than Remdesivir

Ivermectin Safety Profile as shown in the CMS data

Universe	# Beneficiaries Prescribed Ivermectin in 2021	# Beneficiaries who died	% Beneficiaries who died
All patients	142,778	5,093	3.5%
COVID patients	44,709	3,238	7.2%

Ivermectin average amount per patient: $24

Remdesivir average is $2,340 to $3,120 for one 5-day treatment

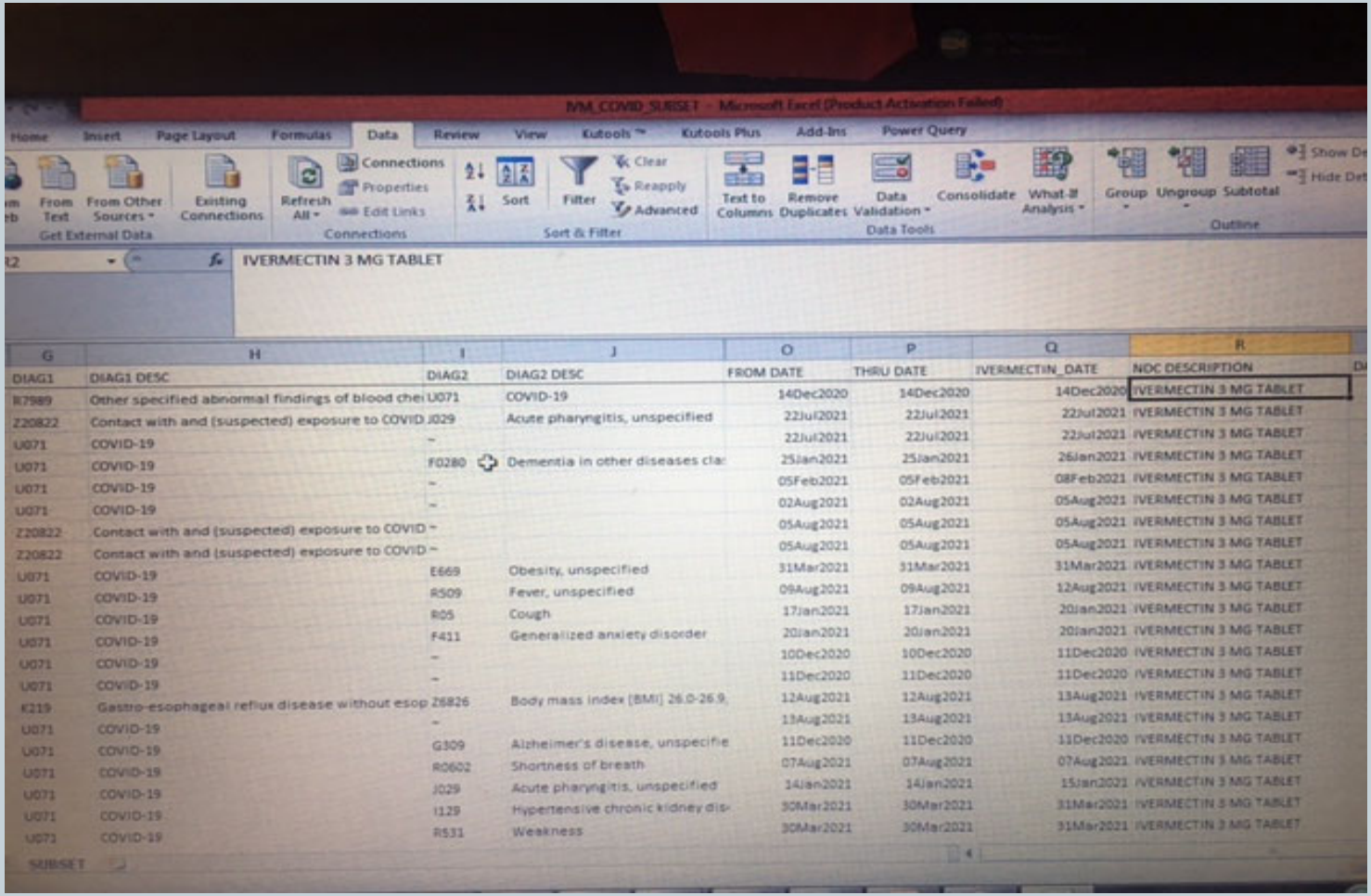
Ivermectin: Just for Horses?

Then why did CMS pay for Ivermectin for over 140,000 beneficiaries this year?

Year Prescribed	Number of Beneficiaries	Amount per Beneficiary
2018	51,106	$18
2019	51,583	$18
2020	72,775	$19
2021	142,778	$24

These numbers represent all Ivermectin 3mg prescribed to all patients, not just COVID patients

Actual Data: Ivermectin Prescribed for COVID-19



IVM_COVID_SUBSET - Microsoft Excel (Product Activation Failed)

Home | Insert | Page Layout | Formulas | Data | Review | View | Kutools | Kutools Plus | Add-Ins | Power Query

Get External Data: From Text | From Other Sources | Existing Connections
Connections: Refresh All | Connections | Properties | Edit Links
Sort & Filter: Sort | Filter | Clear | Reapply | Advanced
Data Tools: Text to Columns | Remove Duplicates | Data Validation | Consolidate | What-If Analysis
Outline: Group | Ungroup | Subtotal

IVERMECTIN 3 MG TABLET

G	H	I	J	O	P	Q	R
DIAG1	DIAG1 DESC	DIAG2	DIAG2 DESC	FROM DATE	THRU DATE	IVERMECTIN_DATE	NDC DESCRIPTION
R7989	Other specified abnormal findings of blood chei	U071	COVID-19	14Dec2020	14Dec2020	14Dec2020	IVERMECTIN 3 MG TABLET
Z20822	Contact with and (suspected) exposure to COVID	J029	Acute pharyngitis, unspecified	22Jul2021	22Jul2021	22Jul2021	IVERMECTIN 3 MG TABLET
U071	COVID-19	-		22Jul2021	22Jul2021	22Jul2021	IVERMECTIN 3 MG TABLET
U071	COVID-19	F0280	Dementia in other diseases cla	25Jan2021	25Jan2021	26Jan2021	IVERMECTIN 3 MG TABLET
U071	COVID-19	-		05Feb2021	05Feb2021	08Feb2021	IVERMECTIN 3 MG TABLET
U071	COVID-19	-		02Aug2021	02Aug2021	05Aug2021	IVERMECTIN 3 MG TABLET
Z20822	Contact with and (suspected) exposure to COVID	-		05Aug2021	05Aug2021	05Aug2021	IVERMECTIN 3 MG TABLET
Z20822	Contact with and (suspected) exposure to COVID	-		05Aug2021	05Aug2021	05Aug2021	IVERMECTIN 3 MG TABLET
U071	COVID-19	E669	Obesity, unspecified	31Mar2021	31Mar2021	31Mar2021	IVERMECTIN 3 MG TABLET
U071	COVID-19	R509	Fever, unspecified	09Aug2021	09Aug2021	12Aug2021	IVERMECTIN 3 MG TABLET
U071	COVID-19	R05	Cough	17Jan2021	17Jan2021	20Jan2021	IVERMECTIN 3 MG TABLET
U071	COVID-19	F411	Generalized anxiety disorder	20Jan2021	20Jan2021	20Jan2021	IVERMECTIN 3 MG TABLET
U071	COVID-19	-		10Dec2020	10Dec2020	11Dec2020	IVERMECTIN 3 MG TABLET
U071	COVID-19	-		11Dec2020	11Dec2020	11Dec2020	IVERMECTIN 3 MG TABLET
K219	Gastro-esophageal reflux disease without esop	Z6826	Body mass index [BMI] 26.0-26.9,	12Aug2021	12Aug2021	13Aug2021	IVERMECTIN 3 MG TABLET
U071	COVID-19	-		13Aug2021	13Aug2021	13Aug2021	IVERMECTIN 3 MG TABLET
U071	COVID-19	G309	Alzheimer's disease, unspecifie	11Dec2020	11Dec2020	11Dec2020	IVERMECTIN 3 MG TABLET
U071	COVID-19	R0602	Shortness of breath	07Aug2021	07Aug2021	07Aug2021	IVERMECTIN 3 MG TABLET
U071	COVID-19	J029	Acute pharyngitis, unspecified	14Jan2021	14Jan2021	15Jan2021	IVERMECTIN 3 MG TABLET
U071	COVID-19	I129	Hypertensive chronic kidney dis	30Mar2021	30Mar2021	31Mar2021	IVERMECTIN 3 MG TABLET
U071	COVID-19	R531	Weakness	30Mar2021	30Mar2021	31Mar2021	IVERMECTIN 3 MG TABLET

SUBSET

PS: Ivermectin IS for COVID

Table 2e. Characteristics of Antiviral Agents That Are Approved or Under Evaluation for the Treatment of COVID-19 – listed is Ivermectin on NIH website

https://www.covid19treatmentguidelines.nih.gov/tables/table-2e/

Ivermectin				
Adults: • The dose most commonly used in clinical trials is IVM 0.2–0.6 mg/kg PO given as a single dose or as a once-daily dose for up to 5 days.	• Generally well tolerated • Dizziness • Pruritis • GI effects (e.g., nausea, diarrhea) • Neurological AEs have been reported when IVM has been used to treat parasitic diseases, but it is not clear whether these AEs were caused by IVM or the underlying conditions.	• Monitor for potential AEs.	• Minor CYP3A4 substrate • P-gp substrate	• Generally given on an empty stomach with water; however, administering IVM with food increases its bioavailability.[2] • A list of clinical trials is available here: Ivermectin

Hydroxychloroquine Unsafe?

Then why did CMS pay for Hydroxychloroquine?

Year Prescribed	Number of Beneficiaries	Amount per Beneficiary
2018	434,226	$72
2019	455,901	$59
2020	595,638	$41
2021	511,698	$29

These numbers represent all Hydroxychloroquine prescribed to patients, not just COVID patients

Is FDA Watching for Vaccine Side Effects?

- In the next few slides, we will show you how the FDA said it is actively working with CMS real-time data to gather weekly reports on COVID-19 vaccine adverse events.
- Then we will show you some real numbers from CMS Medicare data.
- Then you will understand why these numbers have never been published.

The Center for Biologics Evaluation and Research (CBER) Plan to Monitor Vaccine Side Effects

"Near real-time surveillance" or rapid-cycle analyses (RCA)

- FDA plans on monitoring 10 -20 safety outcomes of interest to be determined based on:
  - Pre-market review of sponsor safety data submitted to FDA
  - In coordination with federal partners, international regulatory partners and organizations, academic experts, others
  - Literature and regulatory experience with similar vaccines, novel vaccine platforms, and using other relevant data
  - FDA plans on using CMS data for COVID-19 vaccine RCA – near real time with efforts

The FDA, with CBER, said they would monitor the following conditions post-vaccine

FDA Safety Surveillance of COVID-19 Vaccines :
DRAFT Working list of possible adverse event outcomes
Subject to change

- Guillain-Barré syndrome
- Acute disseminated encephalomyelitis
- Transverse myelitis
- Encephalitis/myelitis/encephalomyelitis/ meningoencephalitis/meningitis/ encepholapathy
- Convulsions/seizures
- Stroke
- Narcolepsy and cataplexy
- Anaphylaxis
- Acute myocardial infarction
- Myocarditis/pericarditis
- Autoimmune disease
- Deaths
- Pregnancy and birth outcomes
- Other acute demyelinating diseases
- Non-anaphylactic allergic reactions
- Thrombocytopenia
- Disseminated intravascular coagulation
- Venous thromboembolism
- Arthritis and arthralgia/joint pain
- Kawasaki disease
- Multisystem Inflammatory Syndrome in Children
- Vaccine enhanced disease

Adverse Events: Real CMS #s
Are they tracking these #s like they said they would?
THIS IS JUST ONE STATE: NEW YORK MEDICARE

Patients who did NOT have these serious conditions from 1/1/2020 to time of vaccination, who developed the condition OR DIED within 28 days of vaccination

TERM	# of Medicare Beneficiaries who Developed this Serious Adverse Event within 28 Days of Vaccine*
ANAPHYLAXIS	99
BELLS PALSY	154
CEREBROVASCULAR EVENT	1331
COVID-19	7612
DEATH	6586
EMBOLISM	2177
ENCEPHALITIS/MYELITIS/ENCHEPHALOMYELITIS/MENINGITIS/ENCEPHOLATPATHY	116
GUILLAIN-BARRE SYNDROME	25
INTRAVASCULAR COAGULATION	25
MYO-ENDO-PERI-CARDITIS	496
MYOCARDIAL INFARCTION	2883
NARCOLEPSY/CATAPLEXY	23
PLEGIA/PALSY/PARALYSIS	1316
SEIZURE/CONVULSION	1017
STROKE/CEREBRAL INFARCTION	2135
THROMBOCYTOPENIA	2353
THROMBOSIS	1942

*patients may have more than one adverse event, sum of this column does not equal the number of unique patients

What Pfizer Knew

- Next few slides show that Pfizer knew the COVID-19 cases were increasing post-vaccination.
- Pfizer also knew that Cominarty Lot numbers could not be tracked.

Vaccines and Related Biological Products Advisory Committee Meeting
September 17, 2021

FDA Briefing Document

Application for licensure of a booster dose for COMIRNATY (COVID-19 Vaccine, mRNA)

Although not independently verified by FDA, the post hoc analysis appears to indicate that the incidence of SARS-CoV-2 during the analysis period among 18,727 study participants originally randomized to BNT162b2 (mean of 9.8 months post-Dose 2 at the beginning of the analysis period) was 70.3 cases per 1,000 person-years, compared with an incidence of 51.6 cases per 1,000 person-years among 17,748 study participants originally randomized to placebo and crossed over to BNT162b2 (mean of 4.7 months post-Dose 2 at the beginning of the analysis period). An additional analysis appears to indicate that incidence of COVID-19 generally increased in each group of study participants with increasing time post-Dose 2 at the start of the analysis period. Only 3 severe COVID-19 cases were reported during the analysis period, all of which occurred among study participants originally randomized to BNT162b2.

https://www.fda.gov/media/152176,

Summary Basis for Regulatory Action

Date:	08/23/2021
From:	Ramachandra Naik, PhD, Review Committee Chair, DVRPA/OVRR
BLA STN:	125742/0
Applicant:	BioNTech Manufacturing GmbH (in partnership with Pfizer, Inc.)
Submission Receipt Date:	May 18, 2021
PDUFA Action Due Date:	January 16, 2022
Proper Name:	COVID-19 Vaccine, mRNA
Proprietary Name:	COMIRNATY
Indication:	Active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older

Recommended Action: The Review Committee recommends approval of this product.

Prescription Drug User Fee Act Date: Jan 16, 2022

https://www.fda.gov/media/151733/download

10. Other Relevant Regulatory Issues

a. Identification of BLA Lots

Upon CBER's request inquiring about what BLA-compliant EUA-labeled lots may be available for use upon licensure of COMIRNATY, the Applicant submitted information listing which lots they considered to be manufactured according to the BLA. To address the issue of these lots not bearing the vial label associated with BLA approval, CBER worked with the Applicant to develop a Dear HCP letter to be included with lots considered by CBER to be BLA-compliant. This letter explained that some lots labeled for EUA use were also considered BLA-compliant and refers HCP to a website for additional information. CBER requested and the Applicant agreed that only EUA-labeled lots that had also undergone CBER lot release according to the BLA would be considered BLA-compliant and listed at the website included in the Dear HCP letter.

https://www.fda.gov/media/151733/download

Shedding? Gene Therapy?

- Are the vaccinated spreading variants or otherwise posing a risk to others?
  - *A female is found to be pregnant while being exposed or having been exposed to study intervention due to environmental exposure. Below are examples of environmental exposure during pregnancy:*
    - *A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact.*
      - https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf

Shedding? Gene Therapy?

- Are the vaccinated spreading variants or otherwise posing a risk to others?
  - Pfizer seems to have acknowledged its vaccine is a gene therapy and [again] that it poses a risk of shedding:
    - We acknowledge your written commitments as described in your letter of August 21, 2021 as outlined below:
    - 10. Study C4591022, entitled "Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry." https://www.fda.gov/media/151710/download
    - This document is titled: Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products Guidance for Industry. It includes shedding as an issue of study. https://www.fda.gov/media/89036/download
    - We will have more on shedding and gene therapy soon…