The FDA Settled With Us Because They Knew They Were Going To Lose

After 4 years of catastrophic health agency tyranny, physicians finally score a legal victory. I think the FDA settled because their Pharma masters were terrified of discovery. Here is the backstory.

By Pierre Kory, MD, MPA

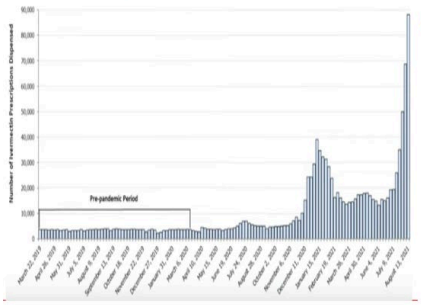
Mar 23, 2024 06:34 AM · 9 min. read · View original

In my book, *The War on Ivermectin*, Chapter 33 is called “The Horse Dewormer PR Campaign.” I invite you to see this previous post where I detail the campaign’s highly coordinated and sequentially timed actions between the FDA, CDC, AMA, APHA and corporate controlled media (i.e. late night hosts, news broadcasts, newspapers etc). Clearly, the goal of the campaign was to convince the public that ivermectin was a dangerous and ineffective horse dewormer.

In the wake of that campaign, pharmacies stopped filling valid, legal prescriptions and hospitals removed ivermectin from their formularies. Never had an FDA approved drug, one of the (if not the) safest prescribed medications in history ever been vilified or restricted to this extent. Just like hydroxychloroquine, ivermectin had to be stopped.

The FDA's role in that campaign started with the posting of the below tweet on August 21, 2021, a week after the report on the below left came out, showing a massive rise in ivermectin prescriptions in the U.S during the deadly Delta wave.

August 15, 2021



August 21, 2021

The rise in prescribing terrified the Covid cartel because if further knowledge of ivermectin's efficacy were to be gained "on the ground" (i.e from the direct, lived experience of physicians and patients) it would limit the impacts of their corrupted trials and negative statements by corrupted agency heads and professional societies.

Obviously my readers know why “they” had to bury the evidence of efficacy of ivermectin at all costs: little ‘ole ivermectin threatened both the EUA for the vaccines and the global vaccine market (north of a $100 billion). It also threatened the markets for all the competing pricey, patented, pipeline pharmaceuticals like Remdesivir, Paxlovid, molnupiravir and the monoclonal antibodies (also massive global markets in the many billions).

Pharma’s greatest weapon to attack ivermectin is the FDA. Pharma (and especially Pfizer) has near complete control of the FDA (and the CDC and the NIH). But the FDA couldn’t do it all by themselves so they called in the CDC to do some dirty work: 5 days after the FDA tweet the CDC sent out a warning advisory to all the state medical boards (which was then forwarded to every licensed physician in the country):

This is an official

CDC HEALTH ADVISORY

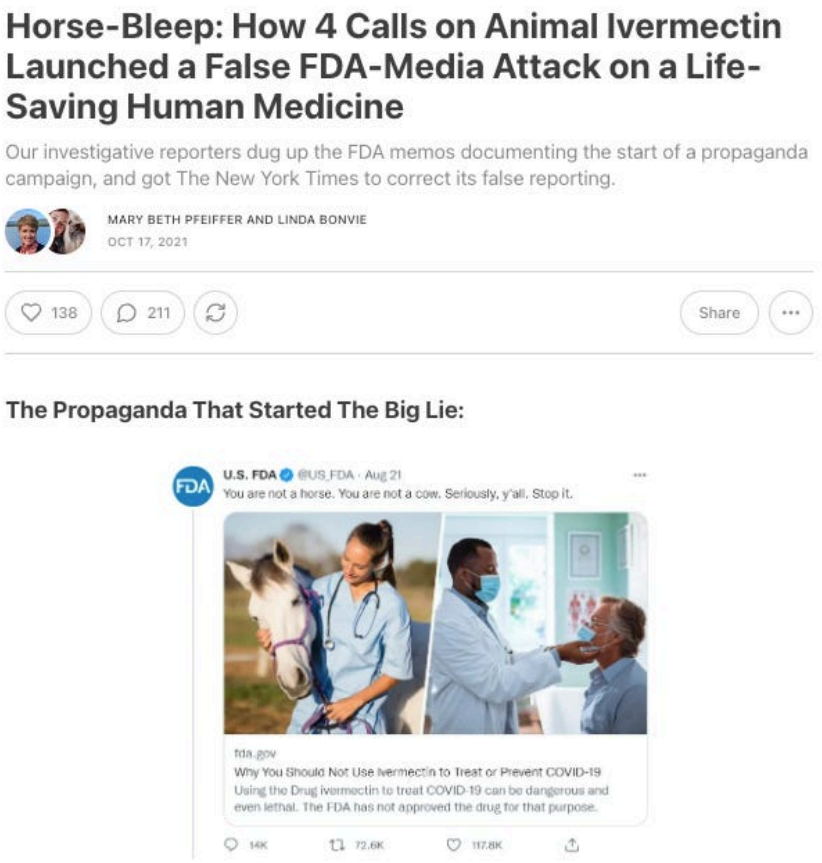
Distributed via the CDC Health Alert Network
August 26, 2021, 11:40 AM ET
CDCHAN-00449

Rapid Increase in Ivermectin Prescriptions and Reports of Severe Illness Associated with Use of Products Containing Ivermectin to Prevent or Treat COVID-19

Summary

Problem (but not really): the CDC memo was full of false and misrepresented data on a rise of “calls to poison control centers.” My close colleagues Mary Beth Pfeiffer and Linda Bonvie, both investigative journalists, did a deep dive

into the CDC advisory and published the real truth:

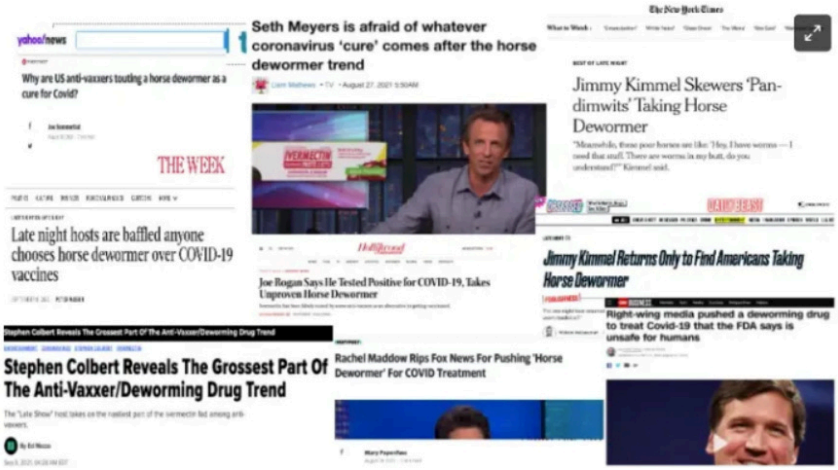


Literally, that is all they had to start a war with? A tiny number of calls to poison control centers from people asking questions about ivermectin? It turns out it is all they needed because that is when Weber Shandwick launched an all out PR campaign across the worlds media.

Anyway, 3 days after the CDC memo they then trotted Fauci out on national TV to state absurd, easily disprovable lies (please watch, it is short).

Then 2 days after that, they got three major professional societies to call for an end to using fentanyl (err, I mean ivermectin):

And then they called in for mass media firepower:

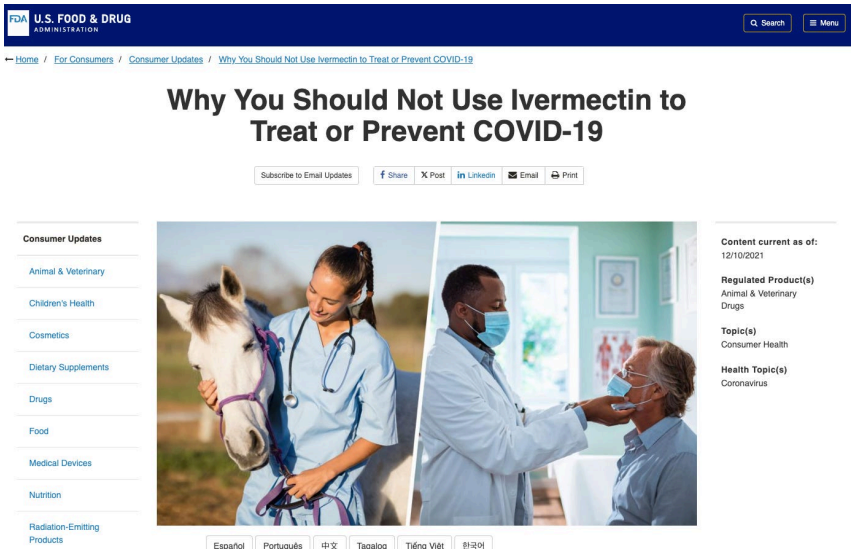


I believe (without evidence) that the tweet and the entire PR campaign was devised and executed by Weber Shandwick, the massive PR firm that simultaneously works for the CDC,

Moderna, and Pfizer (at the risk of foreshadowing, I also believe, without evidence, that the entire reason the FDA settled this case is because discovery would be severely damaging to many people involved).

I do have to hand it to Weber Shandwick though because they devised a highly effective (lethal) campaign to end the use of ivermectin. That tweet went absolutely viral and became the FDA's most popular tweet in history. I believe that tweet was the opening shot that completely turned from what had been isolated "battles" against ivermectin into an all-out war (my book details the more covert preceding actions by big Pharma).

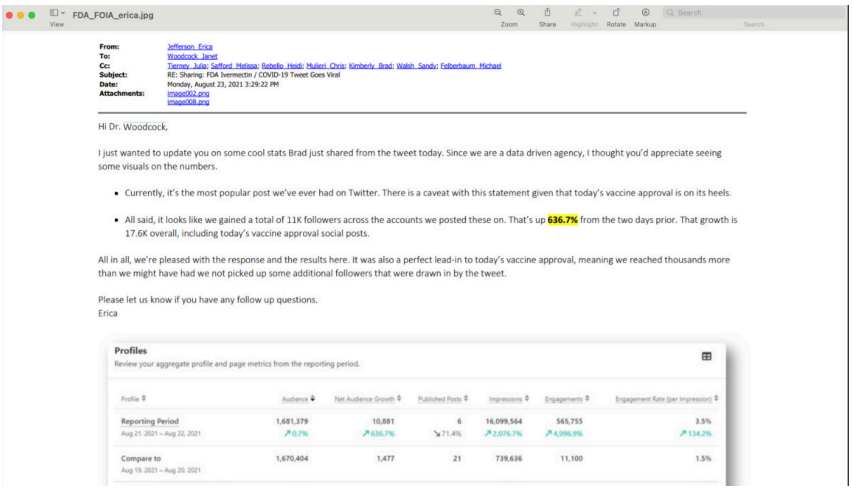
To wit, way before the FDA's famous horse tweet, in March of 2021 they posted this page on their website, later updated December of 2021:



Although the way it was written was nonsensical (conflating human and animal ivermectin and

saying that taking large doses can be dangerous (duh)) it still proved highly successful in its objective: to get everyone to know that the largest health regulatory agency in the world felt that ivermectin was dangerous, ineffective, and to remind everyone that they do not “authorize or approve” of its use in Covid.

Anyway, after the tweet started to go viral it apparently thrilled the FDA Commissioner Janet Woodcock (emails obtained through FOIA by Linda Bonvie):



FDA_FOIA_erica.jpg

From: Jefferson, Erica
To: Woodcock, Janet
Cc: Tierney, Julia; Safford, Melissa; Rebello, Heidi; Mulieri, Chris; Kimberly, Brad; Walsh, Sandy; Felberbaum, Michael
Subject: RE: Sharing: FDA Ivermectin / COVID-19 Tweet Goes Viral
Date: Monday, August 23, 2021 3:29:22 PM
Attachments: image002.png, image008.png

Hi Dr. Woodcock,

I just wanted to update you on some cool stats Brad just shared from the tweet today. Since we are a data driven agency, I thought you'd appreciate seeing some visuals on the numbers.

- Currently, it's the most popular post we've ever had on Twitter. There is a caveat with this statement given that today's vaccine approval is on its heels.
- All said, it looks like we gained a total of 11K followers across the accounts we posted these on. That's up **636.7%** from the two days prior. That growth is 17.6K overall, including today's vaccine approval social posts.

All in all, we're pleased with the response and the results here. It was also a perfect lead-in to today's vaccine approval, meaning we reached thousands more than we might have had we not picked up some additional followers that were drawn in by the tweet.

Please let us know if you have any follow up questions.
Erica

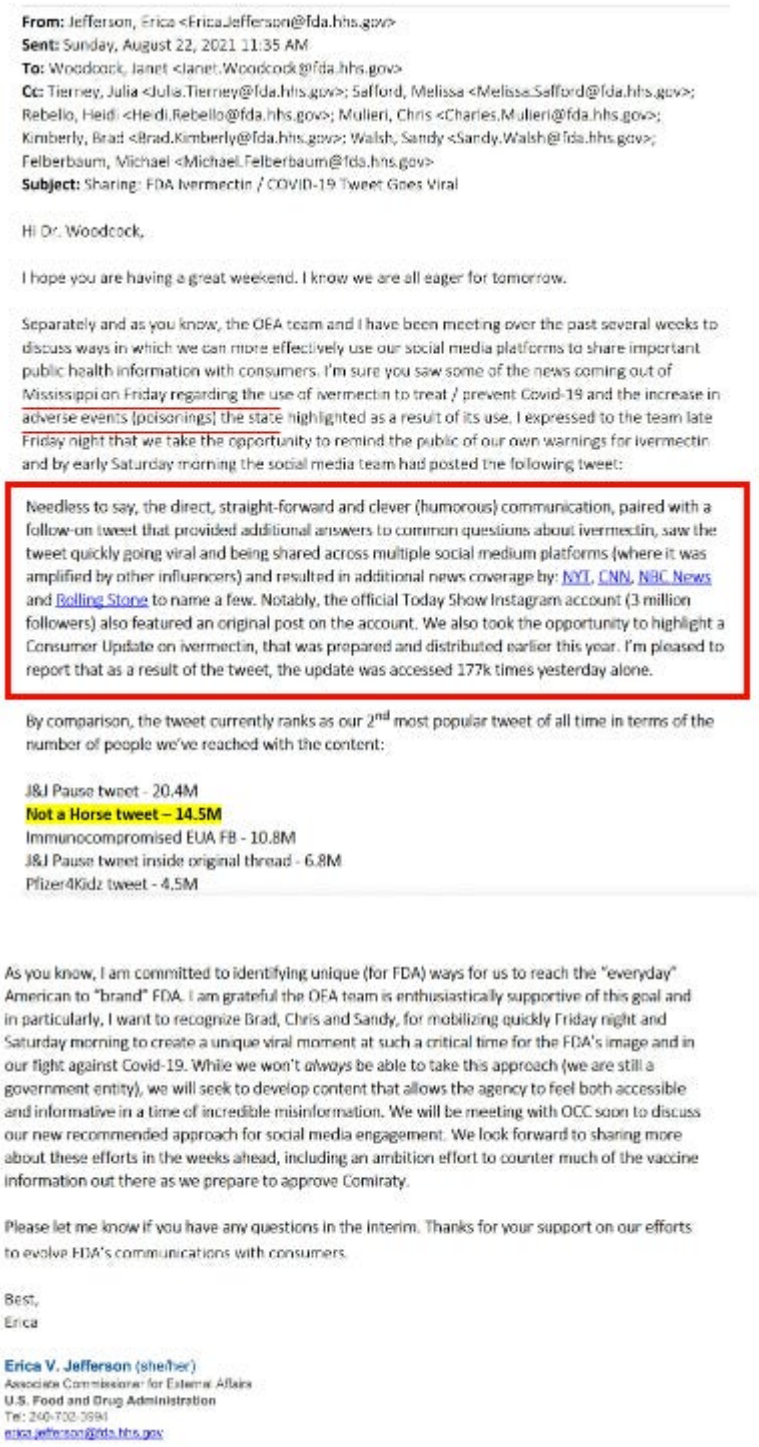
Profiles
Review your aggregate profile and page metrics from the reporting period.

Profile	Audience	Net Audience Growth	Published Posts	Impressions	Engagements	Engagement Rate (per Impression)
Reporting Period Aug 21, 2021 – Aug 22, 2021	1,681,379 ↗0.7%	10,881 ↗636.7%	6 ↘71.4%	16,099,564 ↗1,076.7%	565,755 ↗4,996.9%	3.5% ↗134.2%
Compare to Aug 19, 2021 – Aug 20, 2021	1,670,404	1,477	21	739,636	11,100	1.5%

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 1:15 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Subject: RE: Sharing: FDA Ivermectin / COVID-19 Tweet Goes Viral

That was great! Even I saw it! Agree, we need to be creative and accessible! Excellent start! jw

Their prideful celebration did not end there. Check out these FDA officials celebrating their cleverness and how “their idea” (not) for the tweet was triggered by the CDC memo regarding Mississippi:



From: Jefferson, Erica <EricaJefferson@fda.hhs.gov>
Sent: Sunday, August 22, 2021 11:35 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julie.Tierney@fda.hhs.gov>; Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Sharing: FDA Ivermectin / COVID-19 Tweet Goes Viral

Hi Dr. Woodcock,

I hope you are having a great weekend. I know we are all eager for tomorrow.

Separately and as you know, the OEA team and I have been meeting over the past several weeks to discuss ways in which we can more effectively use our social media platforms to share important public health information with consumers. I'm sure you saw some of the news coming out of Mississippi on Friday regarding the use of ivermectin to treat / prevent Covid-19 and the increase in adverse events [poisonings] the state highlighted as a result of its use. I expressed to the team late Friday night that we take the opportunity to remind the public of our own warnings for ivermectin and by early Saturday morning the social media team had posted the following tweet:

Needless to say, the direct, straight-forward and clever (humorous) communication, paired with a follow-on tweet that provided additional answers to common questions about ivermectin, saw the tweet quickly going viral and being shared across multiple social medium platforms (where it was amplified by other influencers) and resulted in additional news coverage by: NYT, CNN, NBC News and Rolling Stone to name a few. Notably, the official Today Show Instagram account (3 million followers) also featured an original post on the account. We also took the opportunity to highlight a Consumer Update on ivermectin, that was prepared and distributed earlier this year. I'm pleased to report that as a result of the tweet, the update was accessed 177k times yesterday alone.

By comparison, the tweet currently ranks as our 2nd most popular tweet of all time in terms of the number of people we've reached with the content:

J&J Pause tweet - 20.4M
Not a Horse tweet – 14.5M
Immunocompromised EUA FB - 10.8M
J&J Pause tweet inside original thread - 6.8M
Pfizer4Kidz tweet - 4.5M

As you know, I am committed to identifying unique (for FDA) ways for us to reach the "everyday" American to "brand" FDA. I am grateful the OEA team is enthusiastically supportive of this goal and in particularly, I want to recognize Brad, Chris and Sandy, for mobilizing quickly Friday night and Saturday morning to create a unique viral moment at such a critical time for the FDA's image and in our fight against Covid-19. While we won't *always* be able to take this approach (we are still a government entity), we will seek to develop content that allows the agency to feel both accessible and informative in a time of incredible misinformation. We will be meeting with OCC soon to discuss our new recommended approach for social media engagement. We look forward to sharing more about these efforts in the weeks ahead, including an ambition effort to counter much of the vaccine information out there as we prepare to approve Comiraty.

Please let me know if you have any questions in the interim. Thanks for your support on our efforts to evolve FDA's communications with consumers.

Best,
Erica

Erica V. Jefferson (she/her)
Associate Commissioner for External Affairs
U.S. Food and Drug Administration
Tel: 240-702-3991
erica.jefferson@fda.hhs.gov

*If you value the time and effort I put into researching and writing my posts, support in the form of paid subscriptions would be appreciated (know that I never put any posts behind paywalls).

Anyway, lets get to the case now. The case was actually initiated by Clayland Boyden Gray, a famous lawyer who founded one of the highest-

powered law firms in Washington D.C. He formerly worked as White House Counsel from ‘81-93 and later as an Ambassador to the European Union. He also founded the law firm Boyden Gray and Associates and he was a lovely gentleman revered by his employees and partners (I know this because he later became a patient of mine before he unfortunately died suddenly in May of 2023).

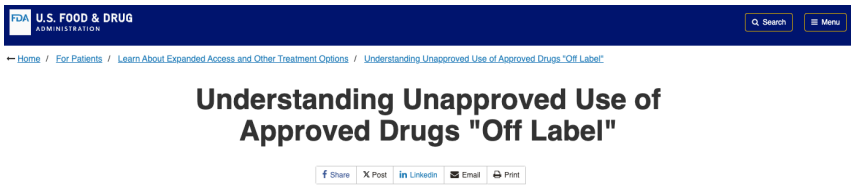
It deeply saddens me that he isn’t alive to witness his firms stunning legal victory. Note that he had a long history of suing federal and regulatory agencies for wrongdoing and he saw that what the FDA had been doing against ivermectin was illegal and harmful.

Boyden wanted to put a stop to this as he knew they were overstepping their statutory authority. But he needed plaintiffs to bring the suit and so he called my partner Paul Marik as well as Dr. Robert Apter and the amazing physician and activist Mary Talley Bowden. Mary actually had the most standing in the case as she had recorded calls and videos of pharmacists declining to fill her prescriptions by arrogantly citing the FDA’s “opinion” on ivermectin.

As we all know, the FDA’s “opinion” was misleading and deceptive - once a drug receives FDA approval for a disease, it can legally be used to treat any other disease, a practice called “off-label” prescribing. The FDA

knows this full well. They knew that no physician needed a Covid-specific “approval” or “authorization.”

Know that 20% of outpatient prescriptions and 30% of inpatient prescriptions are written in this off-label manner, and ***the FDA literally champions the practice for very sound reasons:***



**I think it is important to note this page above was last edited in 2018. I suspect they will disappear that page soon.*

Basically, many medicines have multiple pharmacologic mechanisms of action and so can be useful in different diseases. Ivermectin probably has the broadest applicability of any medicine that I am aware of (anti-parasitic, anti-viral, anti-bacterial, anti-inflammatory, and anti-tumor). As Professor Satoshi Omura, the Nobel Prize winning discoverer of the drug said in his Nobel acceptance speech, it truly is a “Wonder Drug.”

Now, beyond the tweet, the FDA also went on the warpath across all other major social media. For example, check out what they now have to pull down from the internet ***and not republish*** (from the actual settlement document)***:***

(1) FDA's ***Twitter, LinkedIn, and Facebookposts fromAugust 21, 2021*** *"You are not a horse. You are not a cow. Seriously, y'all. Stop it.";*

(2) FDA's ***Instagram post from August 21, 2021*** *(ECF No. 12, Ex. 6), that reads, "You are not a horse. Stop it with the #ivermectin. It's not authorized for treating #COVID.";*

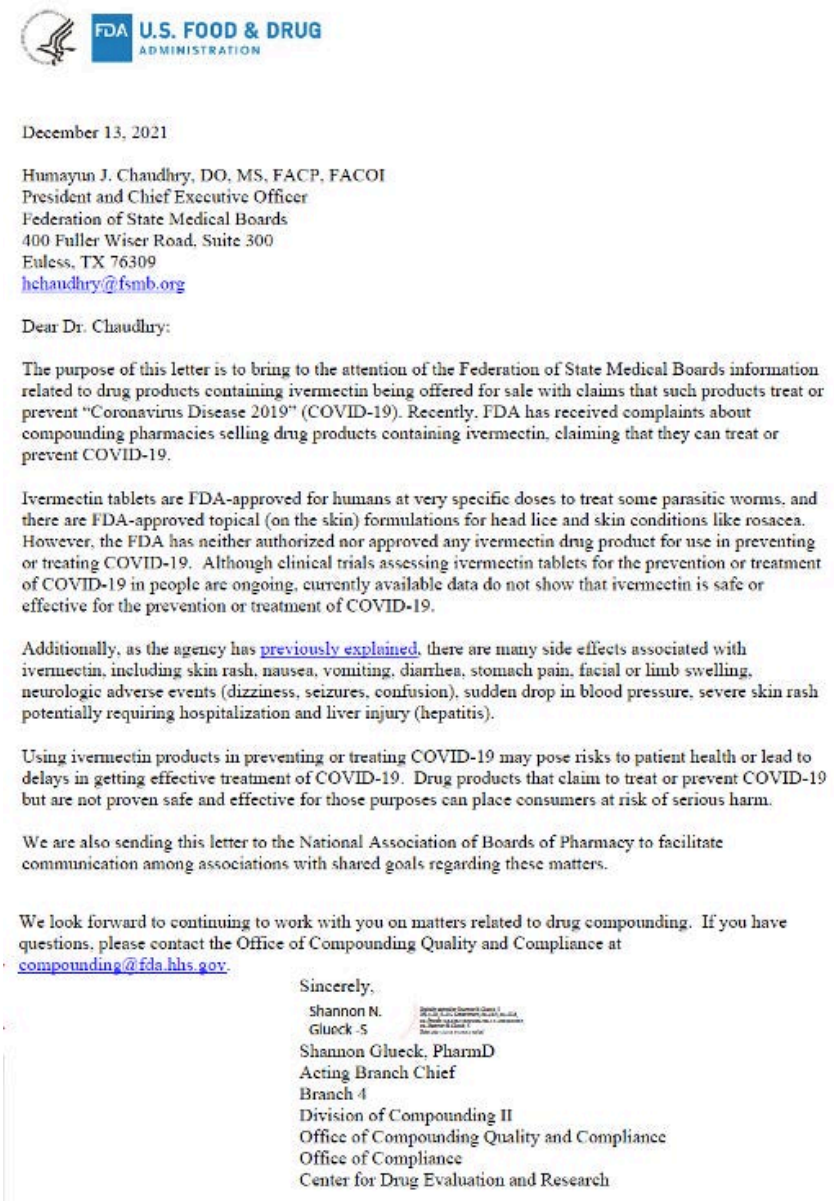
(3) FDA's ***Twitter post from April 26, 2022,*** *that reads, "Hold your horses, y'all. Ivermectin may be trending, but it still isn't authorized or approved to treat COVID-19.";*

(4) ***all other social media posts on FDA accounts*** *that link to* ***Why You Should Not Use Ivermectin to Treat or Prevent COVID-19***

The above social media campaign was not the only thing they did. Remember, this was an all-out war on one of the safest drugs in history. Although the initial salvo started on social media, it didn't end there.

4 months later, in another attempt to influence the practice of medicine, they sent letters to the Federation of State Medical Boards and the American Board of Pharmacy. If you read the below, you will see they completely over-hype the dangers of ivermectin by listing the almost unimaginably rare and more severe side effects, with the most severe only occurring in massive accidental overdoses (3rd paragraph).

This is what I mean by them being on the warpath:



U.S. FOOD & DRUG ADMINISTRATION

December 13, 2021

Humayun J. Chaudhry, DO, MS, FACP, FACOI
President and Chief Executive Officer
Federation of State Medical Boards
400 Fuller Wiser Road, Suite 300
Euless, TX 76309
hchaudhry@fsmb.org

Dear Dr. Chaudhry:

The purpose of this letter is to bring to the attention of the Federation of State Medical Boards information related to drug products containing ivermectin being offered for sale with claims that such products treat or prevent "Coronavirus Disease 2019" (COVID-19). Recently, FDA has received complaints about compounding pharmacies selling drug products containing ivermectin, claiming that they can treat or prevent COVID-19.

Ivermectin tablets are FDA-approved for humans at very specific doses to treat some parasitic worms, and there are FDA-approved topical (on the skin) formulations for head lice and skin conditions like rosacea. However, the FDA has neither authorized nor approved any ivermectin drug product for use in preventing or treating COVID-19. Although clinical trials assessing ivermectin tablets for the prevention or treatment of COVID-19 in people are ongoing, currently available data do not show that ivermectin is safe or effective for the prevention or treatment of COVID-19.

Additionally, as the agency has previously explained, there are many side effects associated with ivermectin, including skin rash, nausea, vomiting, diarrhea, stomach pain, facial or limb swelling, neurologic adverse events (dizziness, seizures, confusion), sudden drop in blood pressure, severe skin rash potentially requiring hospitalization and liver injury (hepatitis).

Using ivermectin products in preventing or treating COVID-19 may pose risks to patient health or lead to delays in getting effective treatment of COVID-19. Drug products that claim to treat or prevent COVID-19 but are not proven safe and effective for those purposes can place consumers at risk of serious harm.

We are also sending this letter to the National Association of Boards of Pharmacy to facilitate communication among associations with shared goals regarding these matters.

We look forward to continuing to work with you on matters related to drug compounding. If you have questions, please contact the Office of Compounding Quality and Compliance at compounding@fda.hhs.gov.

Sincerely,

Shannon N. Glueck -S

Shannon Glueck, PharmD
Acting Branch Chief
Branch 4
Division of Compounding II
Office of Compounding Quality and Compliance
Office of Compliance
Center for Drug Evaluation and Research

Now when the lawsuit was first filed, obviously the FDA moved immediately to dismiss, and they did so by arguing that they cannot be sued because they have “sovereign immunity.” You can’t make this stuff up. What you also can’t make up is that the District Court judge… agreed with them and… dismissed the case. What?

But Boyden Gray doesn't play. He immediately appealed the case because he knew that, although Federal law actually does gives the government immunity against legal actions, there are some exceptions such as "ultra vires," a term describing ***when an official acts outside their authority.*** Plaintiffs challenging the acts must show that the official was "acting without any authority whatever," or without any "colorable basis for the exercise of authority."

Our amazing FLCCC lawyer, Alan Dumoff wrote an amicus brief submitted by our organization (found here on the FLCCC website) and although extremely long, the table of contents lays out the arguments powerfully:

Boyden's decision to appeal was spot on because the appeals court judge was truly miffed at the FDA and immediately ruled that the plaintiffs had standing and that the lawsuit could proceed. This was a huge win back then in "our" court of public opinion, largely because the FDA lawyer had to admit in open court that physicians did indeed have every right to prescribe ivermectin off-label for Covid.

It gets even better because in the appeals court opinion, the Judge went off on the FDA with the following statements:

- "FDA can inform, but it has identified no authority allowing it to recommend consumers 'stop' taking medicine"

- “FDA is not a physician. It has authority to inform, announce, and apprise—but not to endorse, denounce, or advise.”

- “Even tweet-sized doses of personalized medical advice are beyond FDA’s statutory authority” (Ed: I love this one).

Now that the FDA has to take down every single one of their posted and/or published advice against using ivermectin in Covid, in our FLCCC Press release today, I think Paul Marik said it best:

> *“We are extremely pleased with the outcome of the settlement as it is a victory for every doctor and patient in the United States,” said Paul E. Marik, M.D., FCCM, FCCP, a plaintiff in the case, chief scientific officer of the FLCCC Alliance (FLCCC) and former Chief, Pulmonary and Critical Care Medicine at Eastern Virginia Medical School. “The FDA interfered in the practice of medicine with their irresponsible language and posts about ivermectin. We will never know how many lives were affected because patients were denied access to a lifesaving treatment because their doctor was ‘just following the FDA.’”*

However, it is my opinion that, because the case ended in a settlement, we cannot claim total victory because it allows the FDA to continue to lie with statements like this one

today claiming they are not guilty of wrongdoing:

> *"FDA has not admitted any violation of law or any wrongdoing, disagrees with the plaintiffs' allegation that the agency exceeded its authority in issuing the statements challenged in the lawsuit, and stands by its authority to communicate with the public regarding the products it regulates," the spokesperson said.*

But I trust the wider public can see right through such a statement. I mean, who will believe that they can claim innocence when they were forced to settle? You only settle when you know you are going to lose in court or... you cannot risk going through the discovery process. Like I said above, my bet is that they wanted to avoid discovery at all costs.

Either way, the plaintiffs, Boyden Gray and Associates, and the FLCCC landed a big victory today against one of our most captured federal health agencies. A win against tyranny really. They certainly don't come often of late but lets see if we can turn this into a streak!

*If you value the time and effort I put into researching and writing my posts, support in the form of paid subscriptions would be appreciated (please know that I never put any posts behind paywalls).

P.S - Proud to report that my book is gaining Best Seller status on Amazon in several countries and is climbing up the U.S Amazon rankings. *If any of you have read it, I would love if you could post an honest review!