Doctors Group Files Federal Lawsuit Against HHS and FDA Over Unlawful Attempt to Ban Ivermectin for COVID Treatment

GP thegatewaypundit.com/2023/07/group-doctors-file-federal-lawsuit-against-hhs-fda/

Jul. 2, 2023 11:50 am

Source: FDA/Twitter

A group of doctors has filed a federal lawsuit against the U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) over the agencies' unlawful attempts to block the use of ivermectin in treating COVID-19, The Texan reported.

The lawsuit, filed in the U.S. Southern District of Texas in Galveston, argues that the FDA has overstepped its authority and unjustifiably interfered with their medical practice.

The plaintiffs, Drs. Mary Talley Bowden, Paul E. Marik, and Robert L. Apter, are contesting the FDA's portrayal of ivermectin as dangerous for human consumption. They note that the FDA has approved ivermectin for human use since 1996 for a variety of diseases. However,

they allege that with the advent of the COVID-19 pandemic, the FDA began releasing documents and social media posts discouraging the use of the anti-viral drug for COVID-19 treatment.

“We’re suing the FDA for lying to the public about ivermectin,” said Dr. Bowden.

Claims were made that the initial article misrepresented the law by stating the FDA’s official stance against ivermectin use without mentioning that doctors were allowed to administer the medicine.

U.S. law is cited in the complaint, including the provision that the FDA “may not interfere with the authority of a health care provider to prescribe or administer any legally marked device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”

> November 2022 – FDA says telling people not to take ivermectin was just a recommendation
>
> August 2021 – FDA account: “You are not a horse. You are not a cow. Seriously, y’all. Stop it.” pic.twitter.com/nsR3HEJHHx
>
> — Dr. Eli David (@DrEliDavid) November 25, 2022

The Gateway Pundit reported that during a hearing last year, the agency’s lawyers argued that the FDA was only giving advice and it was not mandatory when it told people to “stop” taking Ivermectin for COVID-19.

“The cited statements were not directives,” said Isaac Belfer, one of the lawyers. “**They were not mandatory. They were recommendations**. They said what parties should do. They said, for example, why you should not take ivermectin to treat COVID-19. They did not say you may not do it, you must not do it. They did not say it’s prohibited or it’s unlawful. They also did not say that doctors may not prescribe ivermectin.”

“They use informal language, that is true… It’s conversational but not mandatory,” he continued.

However, the statement from the lawyer contradicted to FDA’s social media post, stating, “Hold your horses, y’all. Ivermectin may be trending, but it still isn’t authorized or approved to treat COVID-19.”

> Hold your horses, y’all. Ivermectin may be trending, but it still isn’t authorized or approved to treat COVID-19. https://t.co/TWb75xYEY4
>
> — U.S. FDA (@US_FDA) April 26, 2022

In 2021, The Gateway Pundit reported that Houston Methodist health officials began investigating and suspended Dr. Mary Talley Bowden for spreading “dangerous misinformation” about Covid-19 and promoting the efficacy of ivermectin, prompting the physician to resign from the hospital.

The hospital excoriated Bowden for “using her social media accounts to express her personal opinions about the COVID-19 vaccine and treatments,” NBC News reports. The suspension barred the physician from admitting or treating patients at the hospital.

Bowden repeatedly warned that it is “wrong” to mandate the experimental mRNA vaccines and continuously touted Ivermectin as a safe and effective treatment amid threats from public health officials against prescribing the drug.

In her resignation letter, Bowden doubled down on the efficacy of ivermectin.

The Nobel prize-winning, anti-parasitic drug, which has been deployed against some of the world’s most devastating tropical diseases, is far safer than the potentially lethal, experimental Covid vaccines, the Texas doctor argued.

“I have worked hard to provide early treatment for victims of COVID-19. My efforts have been successful. I have treated more than 200 COVID-19 patients, including many with co-morbidities, and none of these patients have required hospitalization. This is a testament to the success of my treatment methods,” she wrote. “Throughout this pandemic, there has been no FDA-approved treatment for COVID. Therefore I have done my best to care for patients and save lives in the absence of a clear scientific consensus.”

“Early treatment must still be part of any strategy for patient care. That is why physicians and hospitals should pay more attention to medications such as Ivermectin, which significant research and my clinical experience indicate is effective,” she continued. “I have decided to part ways with Houston Methodist because of the accusation that I have been spreading “dangerous information.” This is false and defamatory. I do not spread misinformation, and my opinions are supported by science. There is substantial evidence for the efficacy of ivermectin in treating COVID-19, and no evidence for serious or fatal side effects associated with the doses used to treat COVID-19.”

A Gateway Pundit reader has received a letter from the U.S. Food and Drug Administration (FDA) regarding a shipment containing Ivermectin that she bought from a foreign country is being held by the post office.

Trending: Tragic News: Actress Succumbs to Assisted Suicide Following Covid-19 Booster Injuries

You can read more here. Below is the copy of the letter from the FDA:

United States Food and Drug Administration

Division of Northeast Imports

Notice of FDA Action

Entry Number: ----0503195-0
Port of Entry: 4701, JFK Airport, Jamaica, NY

Notice Number: 1
December 16, 2021

[redacted]

>

<

Shipper: Unknown

A mail shipment addressed to you from a foreign country is being held by the post office at the request of the U.S. Food and Drug Administration (FDA).

Summary of Current Status of Individual Lines

No.	Product Description	Quantity	Current Status
1	KIT OF ZINC ACETATE TABLETS, DOXYCYCLINE CAPSULES IP & IVERMECTIN DISPERSIBLE TABLETS; ZIVERDO KIT	513 Tablets	Detained 12-14-2021
2	IVERMECTIN TABLETS USP; COVIMECTIN - 12	100 Tablets	Detained 12-14-2021

The shipment may also contain other items not listed above. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act (FD&CA), Public Health Service Act (PHSA), or other related acts, and does not preclude action should the products later be found violative.

[redacted]TAINED - Subject to Refusal

Examination of the following articles has been made and these articles are subject to refusal of admission into the United States because they do not appear to be in compliance with the requirements of the law as indicated below:

No.	Product Description		Respond By
1	KIT OF ZINC ACETATE TABLETS, DOXYCYCLINE CAPSULES IP & IVERMECTIN DISPERSIBLE TABLETS; ZIVERDO KIT	513 Tablets	January 4, 2022

FD&CA Section 505(a), 801(a)(3); UNAPPROVED NEW DRUG
The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a new drug within the meaning of Section 201(p) without an approved New Drug Application (NDA).

You have the right to respond by providing oral or written testimony to the FDA regarding the admissibility of these articles, or the manner in which these articles can be brought into compliance. This testimony must be provided to

FDA on or before the "Respond By" dates shown above.

Please direct your response to:

Mary G. Stenson, Compliance Officer
U.S. Food and Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

(718) 340-7000 ext. 5471
(718) 662-5662 (FAX)
MARY.STENSON@FDA.HHS.GOV

[redacted]

DETAINED - Subject to Refusal and Administrative Destruction

Examination of the following articles has been made and FDA has determined that these articles are drugs that are not in compliance with the requirements of the law, as indicated below. Additionally, FDA has determined that each article is valued at $2500 or less. Because these drugs are not in compliance with the requirements of the law and are valued at $2500 or less, they are subject to refusal of admission into the United States and are subject to administrative destruction.

No.	Product Description	Respond By
2	IVERMECTIN TABLETS USP; COVIMECTIN - 12	100 Tablets January 4, 2022

FD&CA Section 502(f)(1), 801(a)(3); MISBRANDING
The article has been determined to lack adequate directions for use. The drug is available in the US; therefore is is not permitted for personal importation.

FDA cannot assure that foreign-made versions of FDA-approved drugs such as this have been properly manufactured, are safe and effective, and are exactly the same formulation as the FDA-approved versions. See https://www.fda.gov/about-fda/fda-basics/it-legal-me-personally-import-drugs

The policy is intended to make available, through the exercise of enforcement discretion, unapproved drugs used to treat serious medical conditions for which no equivalent treatment exists in the United States, and unapproved drugs used to continue treatment begun in a foreign country. This drug does not appear to qualify for release.

FD&CA Section 503(b)(4), 801(a)(3); MISBRANDING
The article has been determined to be a prescription drug but does not include the symbol "Rx only" on its label. The drug is available in the US; therefore is is not permitted for personal importation.

FDA cannot assure that foreign-made versions of FDA-approved drugs such as this have been properly manufactured, are safe and effective, and are exactly the same formulation as the FDA-approved versions. See https://www.fda.gov/about-fda/fda-basics/it-legal-me-personally-import-drugs

The policy is intended to make available, through the exercise of enforcement discretion, unapproved drugs used to treat serious medical conditions for which no equivalent treatment exists in the United States, and unapproved drugs used to continue treatment begun in a foreign country. This drug does not appear to qualify for release.

All products of this kind must meet the requirements of the Federal Food Drug and Cosmetic Act or other laws enforced by the U.S. Food and Drug Administration. These laws are designed to protect you from, among other things, unsafe or misrepresented foods, drugs, biologics, cosmetics, devices, and other articles.

This Notice does not in any manner accuse you of violating any law.

You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the

admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above.

Please direct your response to:

Mary G. Stenson, Compliance Officer
U.S. Food and Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

(718) 340-7000 ext. 5471
(718) 662-5662 (FAX)
MARY.STENSON@FDA.HHS.GOV

If you do not wish to claim this shipment, you may disregard this notice and the shipment will be destroyed.

If the shipment is destroyed, you may be held liable for the costs of storage and destruction. However, if you are a consumer who imported these articles for your personal use, FDA will not seek to collect the costs of storage and destruction from you.

Additional Information regarding FDA's administrative destruction authority can be found at:
http://www.fda.gov/ForIndustry/ImportProgram/Resources/ucm494173.htm

The shipment may contain items not included in this notice.

Notice Prepared For: The Division Director, U.S. Food and Drug Administration
Notice Prepared By: SJ