GlobalResearch
Center for Research on Globalization

We Tried to Improve COVID Vaccine Labeling — The FDA Said 'No Thanks'

By Dr. Peter Doshi, Prof. Linda Wastila, and Kim Witczak
Global Research, June 13, 2023
The Hill 9 June 2023

Region: USA
Theme: Media Disinformation, Science and Medicine

***

Health care providers rely on product labeling for accurate, unbiased and up-to-date information on medical products. But current Food and Drug Administration (FDA)-approved labels for the Pfizer and Moderna COVID-19 vaccines are obsolete, misleading and out of touch with regulators elsewhere. Whatever one thought of the initial shots, people are now getting boosted indefinitely with little reliable information about scientific developments.

Take the ongoing uncertainty over whether vaccines reduce viral transmission. We asked the FDA to clarify in labeling that there isn't substantial evidence that mRNA vaccines reduce viral transmission. This was an easy ask — the FDA has repeatedly stated that effectiveness against transmission remains unproven. The agency said so in December 2020, when vaccines were first authorized, and again in August 2021, when it fully approved Pfizer's vaccine. The agency still states on its website today: "While it is hoped this will be the case, the scientific community does not yet know if Comirnaty will reduce such transmission."

Viral transmission is just one of multiple vaccine-related issues for which the FDA has not updated product labeling.

In January, a group of us — current and former FDA advisers and academics from around the country — tried to fix this problem by asking the FDA to make critical changes to official product labels. But four months later, in a 33-page response letter, the agency denied almost every single request.

In doing so, the FDA failed to follow the lead of regulators elsewhere, including in Europe and Japan. For instance, we cited the European regulator's addition of heavy menstrual bleeding to product information as a potential vaccine adverse reaction. The FDA's response was a sophisticated version of "who cares!" "Foreign regulatory agencies' expectations and regulations regarding product labeling can differ from those of the U.S. FDA," the agency

wrote. The FDA also said the European Medicines Agency hadn't proven causality with respect to that side effect.

The FDA also failed to warn about the documented risk of sudden death, even though myocarditis is now a well-recognized side effect, particularly among young men. To support adding "sudden death" to product labeling, we pointed to multiple autopsy studies on lethal vaccination-associated myocarditis. (Since our petition, another such study, with Korean public health officials as co-authors, was published last Friday and found eight cases of sudden cardiac death attributable to COVID-19 vaccination-related myocarditis.)

The FDA again rejected our request, arguing that the evidence "is not sufficient to demonstrate a causal association between sudden cardiac death and vaccination," declaring "alternative causes of death…may not be apparent on autopsy."

Federal law requires that product labeling lists adverse reactions that recipients may potentially experience. Of course, not every adverse event type reported in the postmarketing period needs be listed on the label (some may be totally coincidental) but instead "only those adverse events for which there is some basis to believe there is a causal relationship."

With this in mind, we asked the FDA to add seven adverse event types to product labeling: multisystem inflammatory syndrome in children (MIS-C), pulmonary embolism, sudden cardiac death, neuropathic and autonomic disorders, decreased sperm concentration, heavy menstrual bleeding and detection of vaccine mRNA in breastmilk.

For each of these, there is some basis to believe a causal relationship exists. For MIS-C, a serious medical event requiring hospitalization, a published study by CDC and FDA authors identified six children who developed MIS-C following vaccination that could not be explained by anything other than vaccination. (The children had no evidence of SARS-CoV-2 infection, previous MIS-C history, or alternative diagnoses.)

The FDA rejected our request, once again arguing that causality had not been definitively established. In other words, the FDA is not following its own rules. In refusing to add these adverse events to the label, the FDA invokes the strictest of standards (demonstrating causality), contradicting federal law that calls for using the "some basis to believe" standard.

Is it possible the FDA has failed to read the part of federal law that makes clear that "a causal relationship need not have been definitely established" prior to warning? Certainly, alternate explanations for observed adverse reactions should always be considered. But 100 percent proof of causality is a nearly impossible standard to meet, and the "some basis to believe" evidentiary standard was amply met by the peer-reviewed publications that we cited.

As to whether the vaccines block viral transmission, we thought it was fairly obvious that there is substantial public confusion over just what the vaccines can and cannot do. We pointed to messaging from public health leadership. Anthony Fauci, until recently director of the National Institute of Allergy and Infectious Diseases, stated the vaccine turns individuals into virus "dead ends" and Rochelle Walensky, director of the Centers for Disease Control and Prevention (CDC), declared "vaccinated people do not carry the virus."

Such messaging creates widespread misunderstanding about exactly what these products can and cannot do, and we urged the FDA to use product labeling to help set the record straight.

But the FDA instead fired back, alleging we chose "selective statements" when quoting Fauci and Walensky. "Your Petition also does not account for countervailing statements made by some of these officials," the reply stated. "Dr. Fauci has stated that the vaccines were not developed to protect against infection, and Dr. Walensky has stated that high viral loads in vaccinated individuals 'suggest an increased risk of transmission.'" Meanwhile, the CDC's website still informs people the vaccines are effective at "limiting the spread of the virus."

Despite all the mixed messages, the FDA apparently thinks the public is somehow clear-eyed about all this. "We are not convinced that there is any widespread misconception about this," was how the agency put it.

There was, however, one point the FDA did grant: our request to add data on the results from the manufacturers' randomized trials of bivalent boosters. But there was a catch — it could do this only for Pfizer's vaccine. For Moderna, the FDA said it was unable to update health care providers because "FDA has not conducted an evaluation of the data." Yet somehow, the agency seems to have no issue with authorizing and recommending this booster, which it began doing last August.

The FDA's double standard — failing to warn about potential harms, while simultaneously doing nothing to stop a sister agency from making unproven claims of benefit — harms patients and undermines the public's trust in governmental institutions established to act in their interest.

Product labeling should be informative and accurate, not promotional. The law requires it, and following the law shouldn't be optional.

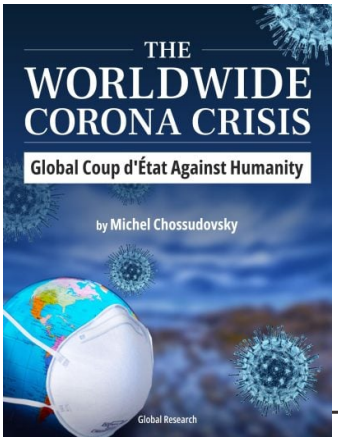
*

Note to readers: Please click the share button above. Follow us on Instagram and Twitter and subscribe to our Telegram Channel. Feel free to repost and share widely Global Research articles.

Peter Doshi and Linda Wastila are faculty members at the University of Maryland School of Pharmacy.

Kim Witczak is a drug safety advocate and serves as a consumer representative on an FDA advisory committee.

Featured image is from Children's Health Defense



The Worldwide Corona Crisis, Global Coup d'Etat Against Humanity

by Michel Chossudovsky

Michel Chossudovsky reviews in detail how this insidious project "destroys people's lives". He provides a comprehensive analysis of everything you need to know about the "pandemic" — from the medical dimensions to the economic and social repercussions, political underpinnings, and mental and psychological impacts.

"My objective as an author is to inform people worldwide and refute the official narrative which has been used as a justification to destabilize the economic and social fabric of entire countries, followed by the imposition of the "deadly" COVID-19 "vaccine". This crisis affects humanity in its entirety: almost 8 billion people. We stand in solidarity with our fellow human beings and our children worldwide. Truth is a powerful instrument."

ISBN: 978-0-9879389-3-0, Year: 2022, PDF Ebook, Pages: 164, 15 Chapters

~~Price: $11.50~~ Get yours for FREE! Click here to download.

We encourage you to support the eBook project by making a donation through Global Research's DonorBox "Worldwide Corona Crisis" Campaign Page.

The original source of this article is The Hill

Comment on Global Research Articles on our Facebook page

Become a Member of Global Research

Articles by: Dr. Peter Doshi,
Prof. Linda Wastila, and
Kim Witczak