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How the FDA's Lack of Transparency Undermines Public Trust



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Healthcare

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As Americans, we understand that a certain level of secrecy is required for particular aspects of the federal government such as the military, national security and related defense areas. However, this sort of confidentiality should not apply to matters of public health, FDA decisions and other health science matters.

Unfortunately, our FDA sees it differently. Anyone wanting to get documents from the FDA must go through the government rigamarole plus lengthy wait for a FOIA fulfillment. The question is: Why doesn't the FDA just share everything public-health related *proactively*? Even more problematically, when one does go through the perpetually backlogged FOIA office, records are often absurdly redacted to the point of hilarity. Here are just two examples, but there many others which I assure

you are equally comical. **(note: the (b)(4) annotation denotes a FOIA redaction of what the FDA considers “confidential”)**

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In your response, you explained that the (b)(4)

(b)(4)

FDA does not accept your explanation. (b)(4)

(b)(4)

(b)(4) These issues were brought to your attention numerous times by study monitors and (b)(4) (b)(4) yet you did not implement corrections. Your repeated failure to adhere to the protocol precluded the (b)(4)

(b)(4)

(b)(4) therefore exposed subjects to increased and unreasonable risk.

You did not conduct the (b)(4)

(b)(4)

Ridiculous FDA redactions. It reminds me of playing "Mad Libs" during my grammar school years, but ... [+] FOIA

-and-

Cleared donor tissue undergoes processing, which includes (b) (4)
The (b) (4)
. The (b) (4)
It
is at this point (b) (4)
The firm will (b) (4)
. Once (b) (4)
. The firm (b) (4)
. Once the products (b) (4)
According to the firm, all micronized injectable dHACM products have (b) (4)

Comical FDA redactions. FOIA



David Gortler: Public health and/or drug safety data shouldn't be treated as if they were CIA or ...

[+] AFP VIA GETTY IMAGES

In the same vein as its lack of document transparency, there has been a disturbing increasing pattern of the FDA refusing to honestly discuss its public health decisions.

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Most recently and egregiously, the FDA's accelerated approval of aducanumab (Aduhelm) for the treatment of beta-amyloid plaque accumulation in Alzheimer's Disease has wrought overwhelming criticism from *very literally* every news outlet covering healthcare. In aducanumab's case, the FDA granted an outrageously expensive approval poised to double Medicare pharmaceutical spending after only testing it on *a few hundred* patients. The FDA didn't require obtaining corroborating findings, (which it typically does) despite there being overwhelmingly negative clinical data in the form of [23 clinical trials](#) conducted over two decades, showing that it is not safe and/or does not work.

The FDA's response, and specifically that from the new CDER Director [Patrizia Cavazzoni](#), to these objective, science-based inquiries has been... radio silence, and/or doubling down on non-scientific assertions as if to declare: *We are the Federal Government. We know better than everyone else. We are "government royalty" and are above having to*

explain our federal decrees to anyone, what-what-what.

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In contrast, these same individuals have dragged their feet on being forthcoming on openly addressing the safety profile of Operation Warp Speed approvals (and subsequent justification of vaccine mandates) which have been administered to well *over a hundred million* Americans, plus hundreds of millions worldwide. This kind of confusing double-standard has led many people to question the efficacy and safety of the COVID-19 vaccine, and rightly so. At this point, Biden has publicly pressured the FDA to approve these vaccines many times, even “promising” Americans of its approval, prior to its actual approval, adding skepticism of concerned Americans, thereby energizing the anti-vaccine and vaccine-hesitant individuals.

Likewise, the FDA's lack of response and intelligent discourse has been the same with other questionable FDA approvals in the past including: Eteplirsen for Duchenne Muscular Dystrophy which only **improved levels of dystrophin by only 0.44 to 0.93% which is neither clinically nor scientifically noteworthy**, yet costs \$300,000 per year. The FDA also recently gave approval to Flibanserin (Addyi) which treats low sex drive and anorgasmia in women. This drug only had an **8 to 13%** placebo-adjusted improvement in women who took it in clinical trials and has *significant* safety risks. The FDA also then approved Lorcaserin (Bevliq) for weight loss which only assisted patients in losing around 5% of body weight. Although this worked for weight loss, a 5% loss is not clinically meaningful. Additionally, it didn't work for weight maintenance, meaning that patients re-gained their very modest weight loss right back after a specific time interval, despite maintaining drug compliance.

In every single one of these cases, these FDA approvals were met with an outpouring of objections from experts both inside and outside the agency, but the FDA ignored all criticism. It was almost as if the FDA didn't *seem* to care about outside academic and healthcare providers' opinions. Of note: in more than one of these decisions, **multiple FDA officials even resigned** over the FDA's decisions in protest. The FDA *never even tried* to explain its decisions to attempt to placate the *overwhelming* public outrage. The FDA's response was always to close ranks, ignore questions, release canned responses through its **"bullying" press office**, refuse to address or simply ignore legitimate calls for explanation and transparency. The FDA leadership appears to have forgotten its obligation to answer to the taxpayers who fund its salaries.

A huge part of the lack of transparency at the FDA is its press office,

(including the fact that it feels like it needs one) and specifically, the press officers the FDA employs, and the sterilized, canned responses it gives to legitimate scientific inquests. *Scientific American* wrote an enlightening account of how the FDA press office bullies and manipulates the free press and restricts news independence and only gives briefings to reporters that, in turn, promise *not to* obtain outside public health expert opinions which haven't been pre-approved by the FDA. That effectively makes the FDA's opinion the only one that the press is allowed to publish. Such a dystopian, anti-intellectual pronouncement is outrageously unacceptable in an American society — let alone within a federal agency! As Americans, we are entitled to a free press.

This type of Stalinist-type behavior negatively affects public trust in the FDA and in turn, the entire federal government. It makes no sense that federal employees — let alone top public health scientists at the FDA — would treat fellow American academics with valid inquests in such a manner. Perhaps it's the communist influence of the dreadful *Soviet-type architecture* of Building One at the FDA in which the FDA commissioner's office and the rest of the Senior Executive Leadership Team are housed...?

These examples of FDA's lack of openness regarding public health matters are unacceptable to academic scientists like myself who care about public health and drug safety, and follow FDA decisions. I know that I am not alone when I say *I personally need to understand the FDA's scientific reasoning in making its decisions so I may feel confident recommending it to patients and other providers*. Is that asking too much? Any taxpayer-funded public health agency like the FDA ought to naturally feel obligated to be scientifically forthcoming when fundamental, principled

questions come up. Not doing so negatively affects the FDA's perception and Americans' public health.

All areas of public health and science should be open to discussion and debate from various qualified experts and clinicians. As the arbiters of drug safety and efficacy, we all entrust the FDA to conduct comprehensive reviews of data and transparently share what they learn. In turn, the FDA ought to embrace the public's legitimate concern and welcome scientific discussion regarding its decisions. After all, the FDA has many talented scientists and clinicians, but they are not royalty handing down edicts, or beyond making omissions or errors.

Scientific transparency on matters of public health is the ethical and right thing to do.

Scientists / clinicians like me shouldn't have to write op-eds demanding it.

Dr. David Gortler is an FDA and health care policy scholar at the [Ethics and Public Policy Center](#) in Washington, D.C. He was a professor of pharmacology and biotechnology at the Yale University School of Medicine and an [FDA Medical Officer](#) who was later appointed to serve on the FDA's Senior Executive Leadership Team as senior advisor to the FDA Commissioner for drug safety, [drug epidemiology](#), FDA science policy, and FDA regulatory affairs.

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