COVID Vaccine Boosters: A Regulatory Gamble

If the following events occurred during the last presidential administration, there would be widespread condemnation from leading academic medical voices. Instead, the silence is deafening. Consider the timeline of boosters, the massive White House Pressure behind boosters and the open safety question:

In early April 2021, Albert Bourla, Pfizer's CEO was quoted as saying boosters will be necessary within 12 months.


HOME > SCIENCE

People will likely need a booster shot of Pfizer's vaccine within 12 months, Pfizer's CEO said

Aria Bendix Apr 15, 2021, 11:29 AM

Immediately there was push back from Fauci, and other government officials that evidence was needed prior to such an announcement.


HOME > NEWS

Fauci says a COVID-19 booster shot is a 'public health decision' and not up to companies like Pfizer and Moderna

Connor Perrett Apr 18, 2021, 7:23 AM

PRESS

In July 2021, Bourla specified that his company would seek FDA authorization for boosters in August.


HEALTH • COVID-19 VACCINES

Pfizer will seek FDA approval of a COVID vaccine booster shot in August

BY ROBERT LANGRETH AND BLOOMBERG
July 8, 2021 3:40 PM PDT

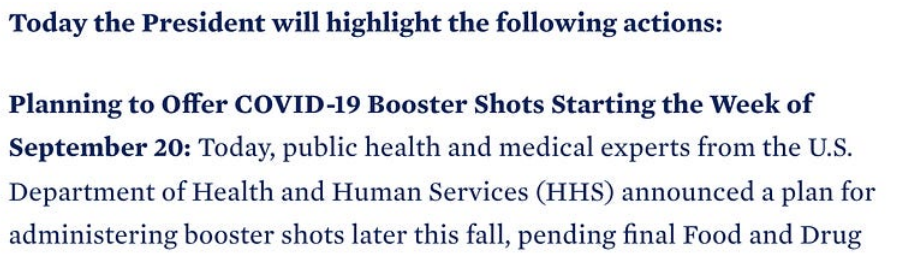
There again was pushback from senior officials, and a few days later, there was a private meeting between Pfizer executives & senior scientists part of the administration


By Sheryl Gay Stolberg and Sharon LaFraniere

Published July 12, 2021 Updated Aug. 3, 2021

Representatives of Pfizer met privately with senior U.S. scientists and regulators on Monday to press their case for swift authorization of coronavirus booster vaccines, amid growing public confusion about whether they will be needed and pushback from federal health officials who say the extra doses are not necessary now.

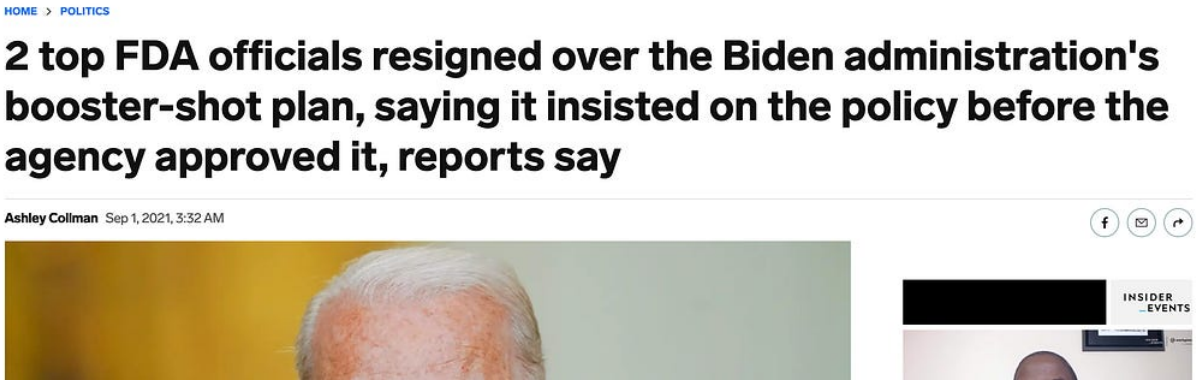
Shortly thereafter, the White House launched a media campaign pushing for boosters. (We all remember the Sunday show bonanza). The White House decided the deadline would be Sept 20.


Today the President will highlight the following actions:

Planning to Offer COVID-19 Booster Shots Starting the Week of September 20: Today, public health and medical experts from the U.S. Department of Health and Human Services (HHS) announced a plan for administering booster shots later this fall, pending final Food and Drug

On Sept 1, 2021, it was reported that Marion Gruber and Philip

Krause, two long-time officials in the FDA's office of vaccine products, and the Director and Deputy Director, would resign.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2 top FDA officials resigned over the Biden administration's booster-shot plan, saying it insisted on the policy before the agency approved it, reports say

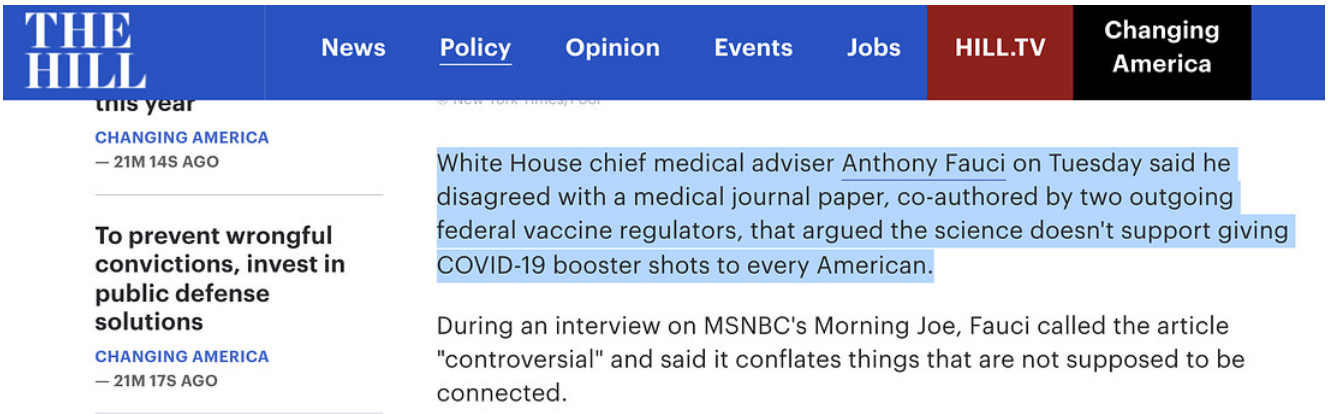
Ashley Collman Sep 1, 2021, 3:32 AM

INSIDER EVENTS

Multiple news outlets reported that this decision, after decades working at FDA, was due to the fact that the white house had launched a media campaign promising American's boosters for all by the end of the month.

This decision was coercive to the employees of the FDA who could no longer consider the application impartially, as they faced strong political pressure to authorize.

The two senior FDA scientists joined others in a Lancet paper arguing why boosters were not supported by solid science, to which Fauci was critical.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this year

CHANGING AMERICA
— 21M 14S AGO

To prevent wrongful convictions, invest in public defense solutions

CHANGING AMERICA
— 21M 17S AGO

White House chief medical adviser Anthony Fauci on Tuesday said he disagreed with a medical journal paper, co-authored by two outgoing federal vaccine regulators, that argued the science doesn't support giving COVID-19 booster shots to every American.

During an interview on MSNBC's Morning Joe, Fauci called the article "controversial" and said it conflates things that are not supposed to be connected.

Yet, based on this controversy, the White House was advised to walk back their plan for boosters.

Health officials advise White House to scale back booster plan

By Kenzie Dillow Sep 3, 2021 0

The advisory committee to the FDA is held, but the committee does not sate the White House. They vote for a smaller proposal of boosters in older people and select high-risk populations– not boosters for all Americans.

> FDA Advisory Committee Votes Unanimously in Favor Of COMIRNATY® Booster for Emergency Use in People 65 and Older and Certain High-risk Populations
>
> Friday, September 17, 2021 - 07:21pm

The FDA can authorize boosters, but the CDC's ACIP provides more tailored recommendations. That group was reluctant to recommend boosters for younger people– even those at high risk due to occupation. (Note: this is because as you are younger and healthier, the benefit/ harm balance is more uncertain, more below)

Yet, the CDC director, a White House Appointee, overrode that decision!

The CDC's Advisory Committee on Immunization Practices on Thursday recommended the boosters for all people 65 and older and for those 50 to 64 who have medical conditions.

THE WEBMD NEWSROOM

lated News About COVID ccine Boosters

C Chief Overrules visory Panel on Pfizer osters

A Authorizes Pfizer osters for Seniors, ential Workers

Though the committee voted against broadening the recommendation for people 18 to 64 who are at higher risk because of their occupations, Walensky overrode that decision. Those include front-line workers like health care staff, grocery store employees, and teachers.

In November 2021, the FDA, without the influence of Gruber and Krause, moved to approve boosters for all >18 [without advisory committee](#).

November 12, 2021
3:50 PM PST
Last Updated a month ago

Healthcare & Pharmaceuticals

U.S. FDA may approve COVID-19 booster without outside advisory panel opinion -CNN

2 minute read

Reuters

On Nov 19, the CDC held an advisory meeting of ACIP to tailor recommendations and:

CDC Expands Eligibility for COVID-19 Booster Shots to All Adults

Media Statement

For Immediate Release: Friday, November 19, 2021
Contact: Media Relations
(404) 639-3286

Today, CDC Director Rochelle P. Walensky, M.D., M.P.H., endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) expanded recommendations for booster shots to include all adults ages 18 years and older who received a Pfizer-BioNTech or Moderna vaccine at least six months after their second dose.

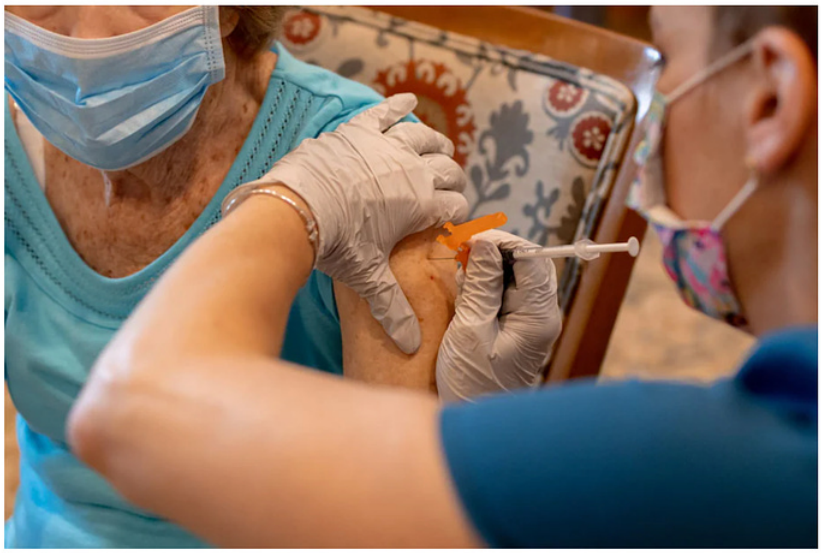
The Food and Drug Administration's (FDA) authorization and CDC's recommendation for use are critical next steps forward in our country's booster program – a program which will help provide increased protection against COVID-19 disease and death.

Paul Offit (a Member of FDA vaccine advisory committee, but not ACIP) and, Marion Gruber and Philip Krause (the two officials who resigned) wrote a stinging rebuke in the Washington Post, critical of the decision

PostEverything • Perspective

We don't need universal booster shots. We need to reach the unvaccinated.

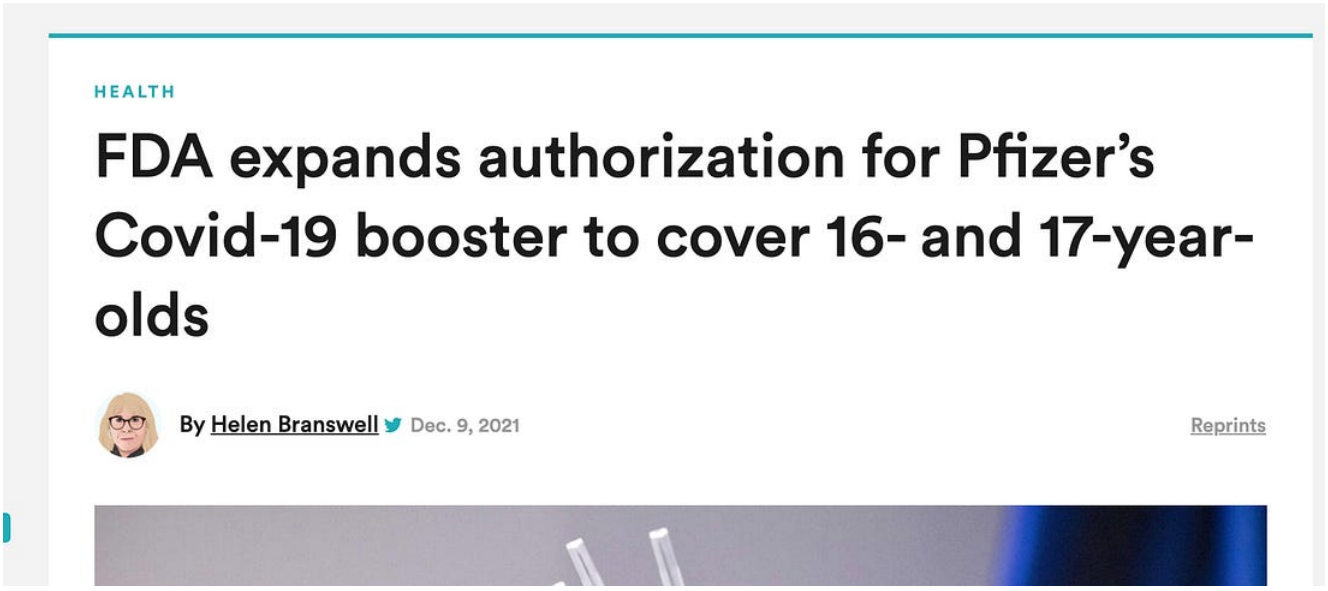
The case for boosters for healthy younger adults is not strong — and those shots would do more good elsewhere



A health-care worker administers a third dose of the Pfizer-BioNTech coronavirus vaccine at a senior living facility in Worcester, Pa., on Aug. 25. (Hannah Beier/Bloomberg News)

By Philip R. Krause, Marion F. Gruber and Paul A. Offit
November 29, 2021 at 6:00 a.m. EST

In December, this time without any advisory committee (neither VRBAC nor ACIP), the FDA expanded boosters again to 16 and 17-year-olds with scant data.



Philip Krause (the resigned Deputy Director) and Luciana Boro (former FDA senior scientist) penned a blistering op-ed in dissent in WaPo.

> *FDA vaccine deputy director who resigned over WH pressure on boosters is writing op eds critical of pushing boosters for teens without Ad Com.*
>
> *WH is acting seriously reckless. If the last administration did this, all experts would be outraged. https://t.co/JRTsDUzHij*
>
> *— Vinay Prasad MD MPH (@VPrasadMDMPH) December 17, 2021*

Meanwhile, while this was happening:

- Mounting evidence showed myocarditis is far more common than initially thought.
- Estimates from Ontario, Canada, Israel and other locations show rates as frequent as 1 in 3 to 6k. The FDA confirms this with an Optum analysis.
- Myocarditis affects men > women
- The highest risk age is 12-40 with 16-24 the peak demographic
- Moderna has higher risks than Pfizer
- Several European nations suspend Moderna in the young

- Data from Ontario shows that greater time between is associated with less myocarditis
- Safety experts, such as Walid Gelad, follow this issue with expert precision

https://twitter.com/walidgellad/status/1467319220308529156?s=20

What does all this mean?

There is little doubt that the risk-benefit profile of a dose 3 is likely to be favorable in older individuals and those with comorbidities or who are immunocompromised. There is also no doubt that the risk/benefit profile is entirely uncertain in younger individuals.

A thin, healthy 16 to 40-year-old man with no medical problems has something to gain and something to lose from taking a booster. The potential benefit is a short-term reduction in mild symptomatic disease (that's known with some confidence). The uncertain benefit is whether there is a reduction in severe covid or hospitalization in this age group. At the same time, there is something to lose, a 3rd dose could precipitate myocarditis. Myocarditis, like all AEs, falls across a distribution. Many events will be mild, and most may self resolve, but some will not be mild, as the nature of idiosyncratic adverse events, and some may lead to long-term issues.

In regulatory science, the bar to debut products in healthy young people is very high. We do not promote mass campaigns without knowing with some confidence the benefits outweigh the risks. In a pandemic, it is reasonable to have a more permissive standard, but we cannot actually recommend vaccination to any person if there is a net health harm in that cohort.

For boys/men 16-40, there is massive uncertainty whether or not the third dose will confer net benefit, and that is not suitable for regulatory science. This is why the top 2 vaccine

experts at FDA resigned, and why they keep writing op-eds.

Meanwhile, Twitter experts engage in propaganda campaigns. The principal ways they lie are the following: they never present myocarditis data by age and sex, but lump together all people (this dilutes the safety signal). They assert that the virus is always more likely to cause myocarditis than the vaccine (this lie has been contradicted by UK data for dose 2 Moderna). They do not seem to understand that the upper bound reduction in severe disease may diminish with each additional dose (i.e.) less and less myocarditis is enough to offset the potential benefit.

Finally, the White House is not an impartial agency. The white house is facing plummeting approval ratings, supply chain issues, and inflation. COVID19 case counts hurt their political prospects, but myocarditis does not. They are in no position to adjudicate which is worse and where the balance tips. Somehow, we understood that the last president should not decide when vaccines were approved. Why is it hard to understand that this president should not decide when boosters are mandated?

Fear is a powerful drug, and it blurs your vision. When you are afraid you cannot see clearly. Approving a vaccination scheme that turns out to, on average, harm boys or men of a certain age would be a catastrophic blunder. Confidence in vaccination will reach new lows, and vaccines as a culture war issue will intensify. America may not survive it. The 2 officials were right to resign. I would not want this on my watch.

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