HEALTH

The Real Reason the FDA Greenlit COVID Vaccines

Now, it all makes sense.

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By A Midwestern Doctor

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Guest post by A Midwestern Doctor

Recent whistleblower testimonies have revealed the anatomy of corruption within the FDA.

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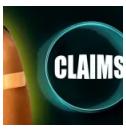

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The medical field has always had a problem holding onto dogmatic traditions and attacking physician dissidents who risk their careers to point out why those practices are unsafe and ineffective. To address this, in the 1960s, physicians began pushing for medical practice to be dictated by scientific evidence rather than entrenched interests, and in 1991, "evidence-based medicine" was born.

This mindset quickly caught on and overturned many disastrous medical dogmas, but unfortunately, gradually succumbed to the same issues that had created it in the first place, with "evidence-based medicine" becoming its own dogma and the rest of the medical system (e.g., pharmaceutical dollars) restructuring itself to provide more and more fraudulent evidence to sustain the current dysfunctional medical dogma while simultaneously attacking any contrary views as "pseudoscience" "lacking evidence."

Note: much of this is a result of RCT fundamentalism (a belief that only prohibitively expensive large RCT's can constitute "evidence") despite the fact those expensive trials are notoriously for consistently finding results that favor their sponsors and a 2014 Cochrane review proving that smaller (affordable) observational trials will get the same results as larger RCTs. Likewise, there's a widely held belief that data is only valid if published in a major journal despite those journals having massive financial conflicts of interest, which cause them only to publish things that reinforce their existing narratives.

In turn, one of the main reasons this publication exists is that the harms of many routine medical practices significantly outweigh any benefits they provide. However, despite decades of evidence showing this, the medical system has continued to hold onto them. For example, in this publication, I have covered massive issues with:

- NSAIDS, Opioids, and Gabapentin for pain relief.
- Spinal surgeries for neck and back pain.
- Benzodiazepines for anxiety
- SSRI Antidepressants for depression
- Sleeping pills for insomnia
- Stomach acid blockers for acid reflux
- Statins to prevent heart disease
- All of the blood pressure medications
- Osteoporosis medications (e.g., Fosamax)
- Ozempic for weight loss
- The HPV vaccine for cervical cancer
- Hormone blockers for blocking puberty of gynecologic issues
- Tamiflu and flu shots to treat the flu.

Sadly, while each of those stories is outrageous (particularly since safe and effective treatments already exist for those conditions), they barely scratch the surface, as there are so

many established medical practices the existing evidence strongly argues against to the routine use of. Even more troubling, these issues escalated dramatically during COVID-19, as any semblance of evidence-based decision-making was swiftly abandoned in a frantic rush to implement one profitable yet detrimental intervention after another while countless therapies that could have treated COVID were rapidly abandoned.

Because of that rapid escalation, many everyday physicians were put into a position where they could either go along with much of what they'd been trained to do being thrown out the window or speak out and be branded as a radical far-right extremist (despite holding views that had been mainstream beliefs in medicine until just a few years ago).

Note: beyond the well recognized physicians who spoke out against the COVID-19 policies and were targeted for doing so, many more doctors (e.g., including some I knew personally) did as well, but did not attract national attention since they had smaller platforms.

Philip Krause

One of the most important whistleblowers to come forward was Philip Krause, who had worked in the FDA for 30 years. This was because Krause along with his direct superior Marian Gruber, had been the most senior FDA officials in charge of America's vaccines, and at the end of August 2021, in the middle of arguably the FDA's most critical vaccine assessment in history, they abruptly resigned (which was a seismic enough event the mainstream media covered it and even mentioned it being due to political pressure from White House for the COVID boosters). Following this, Krause and Gruber published an article in the Lancet. Krause also published a series of editorials (e.g., this one, this one, this one in the Washington Post) arguing against the current booster program.

Following this, he testified in front of Congress about how the COVID vaccines were handled.

Note: Dr. Gruber also provided information to the Congressional Committee.

Most recently, he was interviewed by Rav Arora (who authors The Illusion of Consensus on Substack) and provided an even more in-depth summary of what happened (which can be viewed here).

Collectively, Krause's testimony highlighted a few critical points.

First, as I discussed in a previous article, in 2022, Congress's watchdog, the Government Accountability Organization (GAO), investigated aspects of the COVID-19 response. This included scientific integrity within the four major branches responsible for the response (CDC, NIH, FDA, and ASPR). From interviewing employees in each agency, the GAO found that political interference repeatedly overrode government scientists following the available science and that employees in each agency rarely reported it as they felt their supervisors were already aware of it and that no whistleblower pathways existed in any of the agencies (which is a huge problem). In contrast, their superiors denied all of this and disingenuously argued that the lack of reports of violations of scientific integrity meant no violations were occurring.

While these are quite heavy allegations to direct against the government, in my eyes, Krause's testimony provides the most substantial proof we have that this scientific interference was happening, and if anything was systemic.

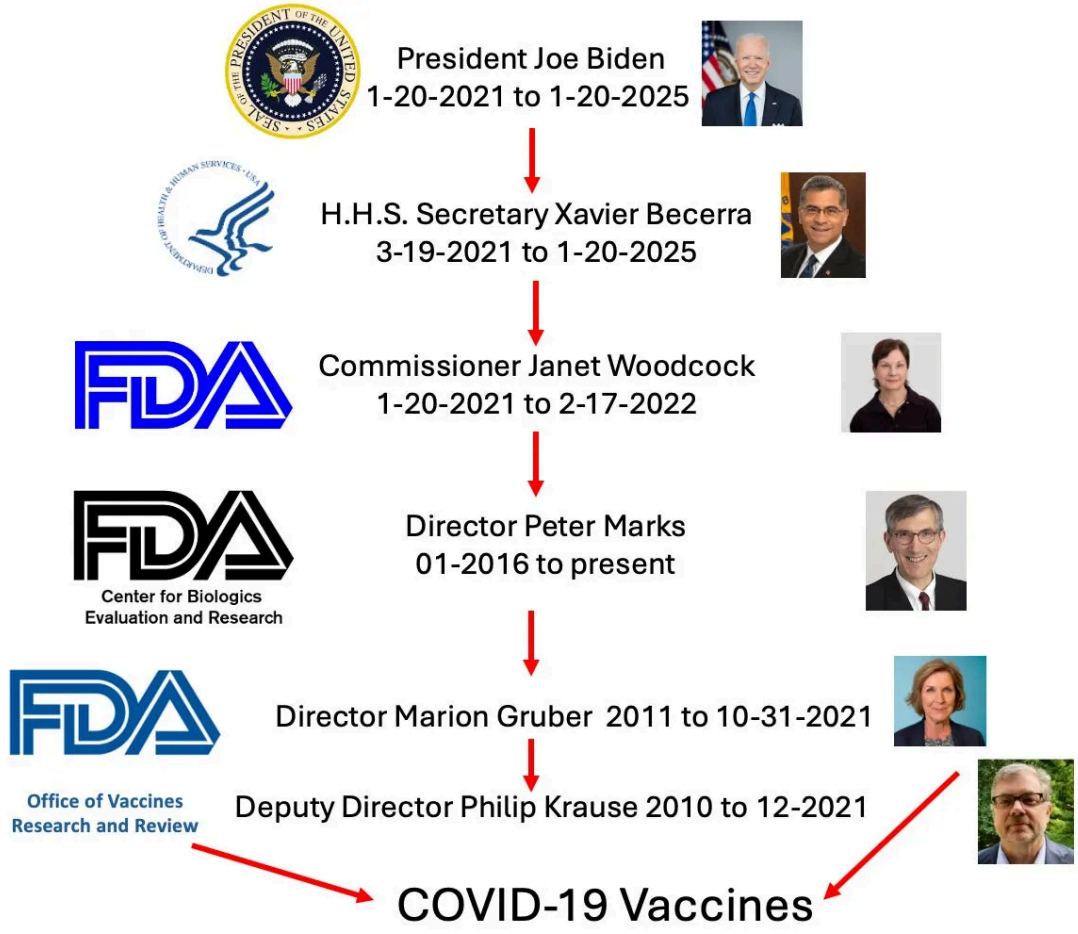
Second, Krause is very pro-vaccine (e.g., he presided over other vaccine debacles at the FDA, and after leaving the FDA he's continued to work for the vaccine industry). As such, his resignation and him publicly speaking out about the FDA's actions (which almost never happens) demonstrate just how bad the FDA's conduct was.

Third, throughout COVID-19, many felt our healthcare authorities lied to us (even as the media claimed otherwise). Krause's testimonies not only show that this was the case, but also that America's political leadership had an incredibly poor understanding of the vaccines they were promoting and nonetheless chose to keep on doubling down on them regardless of what evidence was brought forward (e.g., that the vaccines did not prevent transmission).

Finally, the GAO report was not the only indication that something was seriously amiss at the FDA.

The FDA's Leadership

If you know the key individuals involved, much of what follows will be much easier to understand.



Note: this is a small snapshot of the Federal Government (e.g., H.H.S. oversees 13 agencies including the CDC, the FDA has six Centers and several offices, the FDA's Center for Biologics has six offices including one for vaccines, which has a couple hundred employees).

Concerning these individuals, it's worth mentioning that:

• Biden and many of his staffers were directly responsible for the unconscionable vaccine mandates pushed on America and the demonization of the unvaccinated—much of which were based on things that were known to be lies at the time Biden announced his mandates.

• To my knowledge, none of us were ever able to reach Xavier Becerra.

• Janet Woodcock (to her credit) engaged limited communications with the vaccine injured (where she was repeatedly informed about the severe injuries many had experienced) and did a bit to have their injuries be evaluated (e.g., see this Congressional testimony and NYT article) but admitted she did much less than she felt she should have for them (possibly due to political pressure from above). Additionally, Steve Kirsch reached her, but she dismissed his concerns about COVID vaccine data as misinterpretation without ever explaining how.

• Peter Marks repeatedly communicated with those injured by the COVID-19 vaccines. He expressed empathy with what they were going through, but consistently set impossible benchmarks for any of their injuries to be linkable to the vaccines regardless of the evidence presented to him (e.g., see this leaked recording).

• No one in my network was able to reach Marion Gruber (despite directly contacting her), but Gruber did testify to Congress about the issues she observed throughout the approval process.

The COVID-19 Vaccine Approval Timeline

Since pharmaceuticals typically take 10-15 years to bring to market, it was unlikely one could be appropriately brought to market before a natural herd immunity to COVID-19 set in. To bypass this, three steps were taken:

• Vaccine companies were paid to make their vaccines before it was proven effective and safe, so that when one of them was approved, a supply would already exist that could be distributed (rather than waiting for it to be produced). Likewise, a system was implemented so they could be rapidly distributed the moment they were approved.

• An alternative approval process (an Emergency Use Authorization or EUA) was put into place that allowed the vaccine to be "approved" if preliminary evidence showed it might help under the condition that it would then be extensively tested for safety later on (which, as you might guess, never happened).

• Many corners were cut to expedite the approval process, which proved problematic (e.g., poor production resulted in highly variable vaccine lots, which were often more dangerous or contaminated with synthetic bacterial DNA).

Because of these issues, many were concerned about the vaccines (e.g., the editor of a leading medical journal published a series of ignored editorials in 2020 that accurately identified many of the significant issues with the COVID-19 vaccines). More remarkably, due to the political polarization of the time, many prominent Democrats (e.g., Kamala Harris and Joe Biden) stated they had immense distrust of "Trump's Vaccine" but once the first EUA came out, they flipped and instead became its most ardent proponents.

Note: during COVID-19, while the Trump administration initially tried to explore alternative therapies for COVID-19 (which would have ended the pandemic), due to the pushback they received from the media (e.g., with hydroxychloroquine), they eventually settled on doing everything they could to get a vaccine to market before the election. One of the most remarkable things about this was that at the last moment, Pfizer bumped its approval back, to right after the election, which arguably cost Trump the election. Fortunately, it also greatly damaged Pfizer's standing with the Trump administration (which I suspect is one of the reasons why RFK Jr. has been able to overtly challenge the pharmaceutical industry).

At the time the Pfizer and Moderna's vaccines received their initial EUA, they were claimed to be 95% effective, and an almost religious jubilation passed through the medical field (e.g., I heard many people say "we'd hoped they'd be effective, but we never imagined they would be that effective"). Despite many serious issues with the vaccines, the belief that vaccines were our salvation was so powerful that I quickly realized it was a lost cause to warn my colleagues about it (even some who'd previously had concerns about other vaccines).

Note: this was primarily due to the vaccines being marketed based on, nothing else working for COVID and us hence needing to lockdown until the vaccines came out, which made individuals very receptive to vaccinating so "things could return to normal."

These claims however, were lies. This was partly due to statistical manipulation (e.g., on 1/4/21, immediately after the Pfizer's trial was published, the BMJ pointed out the vaccine's actual efficacy was 19%—thereby making it ineligible for an approval) and partly due to

outright fraud as whistleblowers showed all the major vaccine manufactures concealed a myriad of severe reactions to their COVID vaccines and a trial supervisor for Pfizer pointed out their trial was not blinded and was deliberately inflating the efficacy of Pfizer's vaccine. Furthermore, it was well known that the SARS-CoV-2 virus was rapidly mutating, so any benefits created by the vaccine were likely to be short lived.

Note: one of the biggest lies that emerged at this time was that the COVID vaccines stopped viral transmission (which in reality they had never been tested for, and based on the vaccine's design was unlikely to happen).

As such, once the "safe and effective" vaccines came to market, the vaccines (like many before them) quickly failed to perform as promised, so the goal posts were rapidly shifted and before long the vaccines only "prevented severe illness and death" (much of which I believe was due to inaccurate hospital data erroneously stating hospitalized COVID patients were unvaccinated).

Because of the mounting injuries and repeated vaccine failures, the public became more reluctant to vaccinate. To combat this, a series of increasingly aggressive measures (e.g., bribes and then exclusion from social events) were implemented to sustain vaccine sales. However, by summer 2021, it became clear this would not work, so the next phase (mandates and boosters) was pivoted too. This in turn, required a formal FDA approval for at least one vaccine and an approval or EUA for at least one booster.

Unfortunately, the existing evidence did not support this, to the point that the staunch supporters of vaccination, Dr. Krause and Dr. Gruber (our two top vaccine experts) felt they could not go along with it as:

• The existing data showed that while general immunity from the COVID vaccines was disappearing (as the virus had mutated), it was still protecting against death. As such, since the only thing the boosters (which were identical to the original vaccines) could do was protect against death, there was no point in giving boosters to individuals who had already been vaccinated or had already had COVID-19 (and who were not at high risk of a severe COVID-19 infection).

Note: they also highlighted that the lack of booster efficacy at preventing infections from the current strains (seen throughout the existing literature) was likely due to the booster not matching the current strain.

• Since vaccine supplies were still limited, it made much more sense to give them to those who were unvaccinated and could benefit from them rather than to boost those already vaccinated.

• Giving boosters such a short time after the initial vaccines would shake public trust in the original vaccines and undermine vaccination efforts (as pivoting from "95% effective" for life to "stops working after 8 months" does not inspire confidence). Additionally, it could create distrust with the rest of the vaccine program if injuries followed.

• Some "rare" side effects (e.g., myocarditis or Guillain-Barre syndrome) had been detected from the vaccine, which became more frequent with successive doses.

Let's now look at what transpired.

Note: much of what follows is further detailed within this Congressional report.

Pfizer's Vaccine Approval

On May 18, 2021, Pfizer submitted an application for licensing of its vaccine. Under normal circumstances, this review would take around 12 months to complete, but due to it having a priority review status, that was shortened to 8 months (resulting in an expected approval around January, 18, 2022). This was a considerable problem for the FDA leadership (and the Biden administration) as they needed the approval much earlier.

Because of this, Gruber and Krause began being subjected to continual pressure to find a way to accelerate the approval of Pfizer's vaccine, while their repeated pleas to their superiors (e.g., Woodcock and Marks) not to do this were ignored. Initially, they set the approval for mid-October 2021, but after significant pressure from Marks, they agreed to shorten it to September 15.

Following this, Marks said that was still too long (which Krause felt suggested pressure from outside the FDA caused Marks to change his timeline), and demanded it be shortened further. Immediately afterwards, on July 15 2021, Gruber emailed Marks to (accurately) explain why that would not be possible without "cutting corners" and why doing so was likely to create a significant number of issues such as:
• Destroying public trust in all vaccines.
• Diverting FDA staff from other critical projects.
• Interfering with the necessary review for concerning symptoms that were emerging or determining how different groups (e.g., the children and the immunosuppressed) responded to the vaccine.
• Prevent the FDA from doing in house testing of the vaccines (which was standard procedure for novel vaccines and likely would have caught many of the poorly produced hot lots we saw after their rushed mass production).

Marks then forwarded the email to Dr. Woodcock to ask for a phone call to discuss the situation, to which she instead stated she wanted Marks to take over the vaccine approval, and on the 19th she convened a meeting with the four of them at which point Gruber and Krause were taken out of their leadership role on the vaccine approval.

Note: Krause stated that their removal from the approval was highly unusual (e.g., in the entire time he'd been at FDA, he'd never seen anything similar.

Marks did as asked, and Pfizer's vaccine was ultimately approved on August 23, 2021, for everyone 16 and above. Vaccine mandates then began being enacted (starting with the military on August 24, 2021, along with New York City around that same time period).

Given that the FDA's two most experienced vaccine reviewers felt that fast of an approval was impossible (and furthermore they were excluded from participating in or managing the review process) I believe it is fair to assume many critical steps were skipped in a review process which ultimately took a third to a half as much time as it should have. In turn, after extensively investigating the events that transpired, the Congressional Oversight Committee concluded that this accelerated timeline was done to enact those Federal, state, and workplace mandates and was a result of significant pressure from the Biden administration to ensure their target mandate date could be met.

Note: on July 8, 2022 the FDA fully approved Pfizer's vaccine for children ages 12-15, while on October 29, 2021, it gave an EUA for children 5-11, and on June 17, an EUA for children 6 months to 4 years of age. These approvals are noteworthy, as young children have close to a 0% risk of dying from COVID (making it difficult to categorize it as an "emergency" requiring an EUA). At the same time, the existing vaccine schedule gives infants multiple COVID vaccines in the first few weeks of life (despite vaccines not being FDA-approved). Likewise, college students were required to get boosters despite having no FDA approval.

Booster Approval

On August 18, 2021, the Biden and the H.H.S. leadership (including Dr. Woodcock) announced a plan to offer all Americas booster shots on September 20, despite neither the FDA or CDC review times (or their advisory panels) having yet come to a conclusion on if the boosters should be recommended, nor Pfizer or Moderna having applied for the boosters (after which several months would normally be needed to review the applications). Shortly after Dr. Gruber (on 8/27) and Dr. Krause (on 8/30) submitted their resignations (but continued to work at the FDA.

Note: Krause stated he resigned because he could see outside interference short-circuiting the approval process, resulting in him being constantly overruled whenever he tried to do his job.

On August 31, 2021, The New York Times reported that Dr. Gruber and Dr. Krause would leave the FDA by the end of September. Both were reportedly unhappy with the Biden administration's recent recommendation that adults receive a COVID-19 booster eight months after their second shot, believing there wasn't enough data to support the decision. They also saw the announcement, which President Biden strongly promoted, as pressure on the FDA to approve booster shots quickly.

On September 13, Dr. Gruber and Dr. Krause (and 16 other scientists) wrote an article in the Lancet that used the existing data to strongly criticize the COVID-19 boosting program and said boosters were only appropriate for specific high-risk groups.

Note: on May 13, 2024, Dr. Janet Woodcock stated that she never read that article as she "was very well aware of all the data." "I know these folks, and I did not feel the need to read their argument."

On September 17, the FDA's advisory panel voted against authorizing a booster for the general population, and then in a subsequent vote, authorized it only for high-risk groups, including those in "high-risk" occupations (which the FDA enacted on September 22).

Note: after publication of the September 13 article, Dr. Marks removed Dr. Gruber from managing the advisory panel and thus directed the September 17 meeting where he invited Israeli researchers to present booster data to the committee they had not been provided with beforehand (which was highly unusual) and had significant issues that overestimated their benefits.

On September 23, the CDC's ACIP voted to recommend the booster for high-risk groups, but unlike the FDA, felt "high-risk" occupations (e.g., being a teacher or healthcare worker) did not need the vaccine. However, the next day, in a "highly unusual" decision (which came as a surprise to her staff), the CDC's director overruled its panel and recommended the boosters to "high risk" workers as well.

During ACIP's meeting, experts who voted against the measure argued that there was insufficient data to support the recommendation, that it was too narrow and premature, and that there was little marginal benefit in acting then rather than waiting for better data. They also said that they felt they were being pulled into an "emotional decision" and that this decision could undermine confidence in the primary vaccine series.

Restoring Transparency

In speaking out, Dr. Krause has repeatedly emphasized the importance of restoring trust in the Federal Health Agencies and highlighted how the conduct we saw throughout the COVID-19 vaccine campaign was incredibly detrimental to that trust.

In turn, he argues that:

• The decisions made at the FDA must be transparent, particularly those relating to EUAs (e.g., breaking down exactly how a novel therapy qualified for that designation).

• If independent advisory committees are not allowed to make decisions on approvals or vaccine requirements, it dramatically undermines the public's trust in them.

• Individuals who have a vested interest in determining a regulatory outcome must not be put into positions of power at the agency (which amongst other things, is why the system was structured so that the FDA approves vaccines but the CDC recommends them).

• There needs to be a robust appeals process that allows scientists who were politically overruled by their supervisors to challenge that decision, as the immense power senior FDA leaders wield to overrule review teams has a corrosive effect on the agencies credibility.

Note: Krause also cited Peter Marks overriding a FDA review team in 2024 to approve a multi-million dollar gene therapy that failed its clinical trials, and a similar event happening in 2016 where Janet Woodcock (not yet the FDA director) overruled another FDA team. Likewise, in 2021, after the FDA's panel voted against approving a controversial Alzheimer's drug (as it didn't work but caused brain bleeds), FDA leadership (including Peter Marks) overrode the panel and approved the drug, which led to members of the panel resigning, others labeling it the worst drug approval in history, congressional investigations, and the costly drug ultimately being taken off the market because no one wanted to use it.

Conclusion

While I agree with many of Dr. Krause's points (excluding that the vaccines were fairly safe and effective), I also believe he ignored a more significant issue.

Ethically, it is tough to justify a vaccine mandate, and as such, if it is done, great care must be taken to ensure it has a very strong justification. In contrast, it would be terrible to mandate a vaccine that:
• Provides no benefit to either the vaccinated individual or those around them.
• Has a high enough injury rate that over half of the country believes they are dangerous.
• Used for an easily treatable illness that does not pose a significant risk to most of the population.
• The population did not feel their leaders were truthful or transparent about.

As each of those applied to the COVID-19 vaccines, it was a foregone conclusion that there would be a massive loss of trust in our medical authorities, and to some extent the political class and mass media as well. At this point, while efforts are starting to be made to restore that trust, I still do not believe most of our political leadership or the medical profession grasps just how much trust has been lost or that the old playbook (berating people with and endless stream of "experts") will no longer shift things.

Note: this is best demonstrated by a recent large JAMA study which found in April 2020 that 71.5% of American adults trusted doctors and hospitals, but in January 2024, only 40.1% did—which is a genuinely profound loss of trust.

In turn, I hope that this profound loss of trust (and the alternative medical sales it creates) will begin forcing the medical system to start providing actual transparency (e.g., currently we are not allowed to see most of the data that determines if a drug will be approved) and switch to promoting medical products that help people rather than profitable ones that harm them. For example, as I show here, much in the same way the FDA has forced through through unsafe and ineffective treatments, over the decades, it has also gone to extraordinary lengths to suppress many different remarkable therapies which would have completely transformed the practice of medicine and greatly helped a lot of people (but could not be allowed to enter the market as they would have outcompeted the unsafe and ineffective therapies the FDA approved).

Fortunately, the immense greed of the pharmaceutical industry was enough to wake the world up (e.g., here I showed that the nation's two top vaccine scientists accurately predicted many of the issues that would arise from rushing the vaccines through but nonetheless were sidelined because they were getting in the way of vaccine sales) As such, we now live in an unprecedented time where previously impossible things that can actually shift things (e.g., the MAHA movement and RFK Jr.) are beginning to appear. In order to make something of this moment, permanent shifts will need to be made within our institutions. Because of this, it is my hope that this dissection of some of the corruption we witnessed throughout COVID-19 has provided some helpful insights into what needs to be addressed (e.g., Peter Marks is still CBER's director) while we have the window to change it.

I cannot describe how disheartening it has been to work with the FDA over the years (e.g., quite a few of us were repeatedly stonewalled when we tried to get the FDA to look at already available treatments for COVID-19). For that reason, I am incredibly grateful a once-in-a-lifetime opportunity has been created that can shift much of this and for all of your support, which has made it possible for me to be a part of making this change happen.

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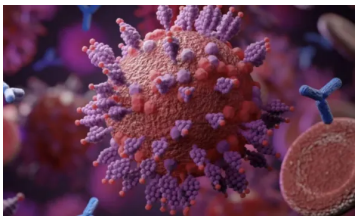

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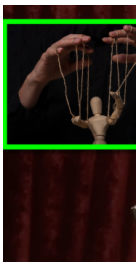

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