Draft

The FDA Has Been Legally Irresponsible — e.g. by Compromising COVID EUA Safety

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1 - Outline of Case Against the FDA

As a scientist (physicist) I don't make this FDA statement (*the title*) lightly — but this is the inescapable conclusion of objectively looking at the relevant facts.

We have evolved to this disturbing situation mainly because the FDA has been given deference by the courts (*via* Chevron) in determining their processes and decisions. But as of 6-28-24, SCOTUS has officially removed this shield protecting federal agencies!

The evidence indicates that the sum of the key FDA COVID-19 **EUA** (Emergency Use Authorization) actions and inactions are unequivocally **not reasonable —** warranting correction and oversight. The judiciary seems to be the most appropriate vehicle to fix this, once and for all.

Let's cut to the chase, examine the facts, and then see where the chips fall…

Fact 1: The U.S. public's health is largely in the hands of the Medical Establishment (FDA, CDC, NIH, AMA, etc.). The FDA (*Food & Drug Administration*) is a major player in that group. The others (e.g., CDC: *Centers for Disease Control*) are partners.

Fact 2: The FDA's statutory obligations are summarized in their mission statement. The gist of it is consolidated into this one sentence:

"The FDA is responsible for protecting the public health."

Fact 3: To meet this extraordinarily significant responsibility, a core obligation of the FDA is to **scientifically** make sure that their recommendations for disease **preventatives** and **treatments** (we'll call these *products*), are both **safe** and **effective** (e.g., see here).

Fact 4: The FDA has two primary ways of endorsing a product: **a)** the normal process called an *Approval*, or **b)** in an *emergency*, a more condensed process called an **EUA**.

Fact 5: In both processes **safety** and **effectiveness** are still paramount. The FDA acknowledges this obligation: here regarding Approvals, and here regarding EUAs.

Fact 6: The FDA may choose to take some shortcuts in the EUA process — but (to fulfill their statutory obligations) the FDA **must** identify to medical practitioners and the public where these shortcuts may compromise either **safety** or **effectiveness**.

Fact 7: The FDA's primary methodology of communicating to medical practitioners (and thus the public) regarding the safety of an EUA endorsed product, is with an FDA document called a *Fact Sheet for Healthcare Providers*.

Fact 8: Here are three examples of COVID-19 EUA *Fact Sheets for Healthcare Providers*: **a)** Moderna "vaccine" [a supposed preventative], **b)** Sotrovimab [an early treatment infusion], and **c)** Paxlovid [an oral early treatment].

Fact 9: A **Chronic Disease** is defined by the CDC as: health "conditions that last 1 year or more, and require ongoing medical attention, or limit activities of daily living or both."

Fact 10: On the CDC's Chronic Disease webpage, they state: "Chronic diseases are the **leading** causes of **death** and **disability** in the United States."

Fact 11: On this CDC Chronic Disease webpage, they state: "**90%** of the nation's annual health care expenditures are for people with chronic health conditions" !!

Fact 12: On this CDC Chronic Disease webpage, they state: "**Sixty percent (60%)** of U.S. adults have at least one chronic disease. Forty percent (40%) have at least two."

Fact 13: The CDC is circumspect about how many chronic diseases there are: here they show six and here there are eight. Neither the CDC nor FDA appears to have published a full list of all the important chronic diseases Americans are burdened with.

Fact 14: Other competent sources are more thorough in their analyses. For example, this medical authority lists twenty-seven chronic diseases!

Fact 15: One example of a missing chronic disease at the CDC, is Parkinson's. This is the second most common neurodegenerative disease, victimizing 1 million Americans. Inexplicably, it is not even on the CDC's extensive list of Diseases and Conditions!

Fact 16: Clearly this likely indicates that Americans with Parkinson's are **not** included in the CDC's 60% figure of Americans with chronic diseases. *In other words, due to this and other omissions, the 60% figure is likely* ***much higher!***

Fact 17: Numerous studies and reports (e.g. here and here) have emphasized that proper dealing with chronic diseases, is America's number one health concern, **by far**.

Fact 18: With all these facts at their disposal, plus their statutory obligation to protect the public's health, the FDA should be laser focused in scientifically acting to reduce pain and mortality of **the majority of Americans** (e.g., those with chronic diseases).

Fact 19: Due to having compromised immune systems, and other vulnerabilities, Americans with chronic diseases who are injected, or who are given oral or infusion treatments for a condition *different* from their chronic disease (e.g., COVID-19), are **at risk for their underlying chronic disease to get worse**, to be hospitalized, or to **die**.

Fact 20: For example, this peer-reviewed scientific study concludes that COVID-**vaccinated** adults *with chronic diseases* are at a higher risk for serious COVID-19 outcomes than vaccinated adults without any chronic disease.

Fact 21: Per the CDC: 95%± of U.S. COVID-19 deaths had an average of four (4) co-morbidities (mostly chronic diseases). *COVID is a disease of those with chronic conditions!*

Fact 22: Despite the foregoing, in granting a COVID-19 EUA, the FDA has ***no requirement*** *that clinical trials (RCTs) do any testing on subjects with chronic diseases!* In other words the FDA is allowing product manufactures to set up clinical trials where they may strategically select subjects to artificially optimize the results (e.g., only do tests on healthier persons *without* a chronic disease). **That is not reasonable or representative.**

> Note: "Randomized Clinical Trial" (RCT) does **not** mean that subjects are *randomly selected* from the public — but rather from those who ***volunteered*** **for the trial!**

Fact 23: In awarding EUAs, the FDA privately tries to justify this extraordinarily significant omission by claiming that appropriate clinical trial testing of people with chronic diseases would: **a)** cost the sponsor too much, *and/or* **b)** take too long.

Fact 24: Neither of these rationalizations for a major safety omission is consistent with the FDA's statutory obligation to protect the public's health. In short, **it is unscientific (and unreasonable) to test the healthy — and then say that it is safe for the *unhealthy* to use.**

Fact 25: The "greater good" argument says that a legitimate justification for public safety to be compromised by an EUA product, is when there is an offsetting larger *proven* public benefit (i.e., **high effectiveness** plus **no transmission**). Regarding the COVID-19 EUAs, the actual public benefit (absolute risk reduction) is **very low** (1%±: e.g., see here and here). Further, transmission was never even tested. This means that there was no proven *greater good*. The FDA miscommunicated these realities to the public, which lead to very poor public health choices. **That is not reasonable.**

2 - Summary of Acceptable FDA Remedies

Based on the above facts, the court is asked to mandate the following reasonable remedies:

A: The FDA be required to include a representative sample of chronic illness subjects in both testing and placebo groups of all clinical trials for products seeking EUAs.

Where a COVID EUA has already been granted, or when the above is (or was) not practical:

B: The FDA be required to give detailed acknowledgement in their EUA *Fact Sheets for Healthcare Providers,* of the critical omission of **inadequately** testing persons with chronic diseases. Since the majority of American adults are put at *additional* risk by taking this EUA product, the FDA must give them notice (*necessary for informed consent*) that their underlying chronic disease condition may **worsen** (including **death**) when taking this EUA product.

C: The FDA be required to include in their EUA *Fact Sheets for Healthcare Providers:*

> "This EUA was granted after a very limited scientific assessment of this product for this medical condition. As a result, the FDA has a low confidence level regarding the safety or efficacy of this product for this condition."

D: Since the safety and efficacy for the majority of Americans from such EUA products are **not** scientifically established, the FDA should be directed to prohibit any EUA product manufacturer from claiming that their product is **Safe** or **Effective**.

E: The FDA should be obligated to require that all EUA clinical trials (and subsequently the FDA) publicize *Absolute Risk* — preferably, exclusively.

> ***Note 1:*** This is consistent with an important FDA advisory publication. A key conclusion (*see page 60*) is that the public is: "unduly influenced when risk information is presented using a relative risk approach; this can result in suboptimal decisions. **Thus, an absolute risk format should be used**."
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> ***Note 2:*** The CONSORT 2010 Statement — Updated Guidelines for Reporting Parallel Group Randomized Trials states: "… **presentation of both absolute and relative effect sizes is recommended**…"

F: The FDA should be obligated to promptly develop and publicize regulations for *Informed Consent* regarding the public's taking of EUAs. (These should be comparable to the FDA's informed consent conditions for clinical trial subjects [which includes many pages of conditions and caveats: see here].) **EUA product recipients should effectively be considered to be clinical trial subjects**.

G: The FDA must be prohibited from granting an EUA based on a subset of any RCT results (e.g., like here).