The FDA's Race to the Bottom

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The partnership between government, medicine, and drug companies has been on a disastrous path for a very long time. Sooner or later something catastrophic was bound to happen and it has – the COVID-19 debacle, with all of the collateral damage it has caused. What has taken place is so egregious that trust and confidence in the American healthcare system is at an all-time low. This is a good thing, perhaps a silver lining in this awful cloud, that could end up saving lives as more and more people say "no" to useless and harmful care.

A major contributor to our disastrous system is the Food and Drug Administration (FDA), an agency that has become so corrupt that it no longer makes any effort to maintain the illusion that it objectively evaluates drugs and devices before approving them.

The partnership between the FDA and drug makers was formalized by Congress with the passage of the Prescription Drug User Fee Act, which called for industry fees to pay the FDA to review its products. The drug companies asked for and got this incredible concession to speed up the approval of new drugs. Then-President Clinton encouraged the FDA to consider drug companies as "partners, not adversaries."[1] The FDA followed Clinton's directive, lowering standards to speed up the approval process.

One of the ways in which standards were lowered was ignoring safety signals. This has resulted in more drugs being approved with black box warnings, like Paxlovid for the treatment of COVID-19, and more drugs being withdrawn after approval due to widespread harm.

Another way in which standards were lowered was the acceptance of changes in surrogate markers as evidence of benefit. In June 2021, The FDA approved a new drug, Aduhelm, for the treatment of Alzheimer's disease. It is not safe, and it is not effective, and FDA officials knew this at the time of approval. The manufacturer, Biogen, stopped both clinical trials of the drug because interim analysis of the data showed that the drug was useless. Post hoc analysis confirmed this, showing that patients only improved by 0.39 points on an 18-point scale. But the drug was also harmful, with MRI scans showing that 41% of patients who took Aduhelm experienced brain swelling or bleeding, as compared to 9% of patients in the placebo group. One out of ten patients who took the drug experienced headache, dizziness, visual disturbance, nausea, and vomiting.

Not surprisingly, ten members of the FDA Advisory Panel voted "no" for approval; one voted "uncertain" and none voted "yes." What was surprising is that the FDA ignored the advice of its panel and approved the drug anyway. Why? Aduhelm did reduce the

size of amyloid plaques in the brain, and acting FDA Commissioner Janet Woodcock stated that she was "fairly confident" that this would lead to better outcomes for Alzheimer's patients. The only problem: 27 previous studies had shown that reducing the size of amyloid plaques had failed to show clinical benefit and some had shown toxicity.[2]

The use of surrogate markers as a substitute for improved patient outcomes was the basis for the approval of COVID-19 vaccines for infants. The approval was based on the measurement of neutralizing antibodies rather than proof that the vaccine would reduce the risk of serious infection, hospitalization, or death.[3] Since the risk of serious infection, hospitalization and death in this age group is statistically zero, the vaccine provides no benefit and only the potential for harm.

Drug companies are not the only nefarious influence on FDA decisions. An April 2022 General Accounting Office review was undertaken to examine political interference on scientific integrity at the Department of Health and Human Services, the Centers for Disease Control, The Food and Drug Administration, and the National Institutes of Health. Employees of these agencies reported that they observed incidence of political interference in decision-making. They failed to report them due to fear of retaliation, and because they believed that the leadership of these agencies already knew about it.[4]

It seems that the FDA and other federal agencies charged with the regulation and promotion of public health have been in a race to the bottom. Those in charge of these bureaucracies no longer feel the need to maintain even the pretense of objectivity. They have become partners with both industry and other government agencies to promote political agendas and increased wealth for drug companies.

For good reason, most of the public today does not trust the FDA, or our government, or medicine, or public health. This is a step in the right direction. Consumers are increasingly just saying "no" to useless and harmful care. The case for InforMED Medical Decision-Making, which we have promoted for almost three decades, has never been stronger.

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[1] David Willman. How a New Policy Led to Seven deadly Drugs. *Los Angeles Times* December 20 2020 https://www.latimes.com/nation/la-122001fda-story.html accessed 10.7.2022

[2] Abramson J. *Sickening: How Big Pharma Broke Healthcare and How We Can Repair It.* Mariner Books New York pp 232-233

[3] Fleming-Dutra KE, Wallace M, Moulia DL et al. "Interim Recommendations of the Advisory Committee on Immunization Practices for Use of Moderna and Pfizer-BioNTech COVID_19 Vaccines in Children Aged 6 Months-5 Years – United States, June 2022." *Morbidity and Mortality Weekly Report* June 2022

[4] Scientific Integrity. HHS Agencies Need to Develop Procedures and Train Staff on Reporting and Addressing Political Interference. https://www.gao.gov/assets/730/720120.pdf