FDA should protect the American people, and Pharma should pay!

Joshua Freeman, MD

This article originally appeared in Dr. Freeman's blog, Medicine and Social Justice.
https://medicinesocialjustice.blogspot.com/

The Food and Drug Administration (FDA) regulates drugs, and, I guess, food, although I don't know much about what they do in that area. It also does not approve certain drugs because they are not classified as drugs, but rather "nutritional supplements" or in new jargon "nutriceuticals". This is odd, because such a classification does not make them either safe or effective. If they ARE effective, do the good that is claimed for them, then of course they could have other effects, which could be bad. If they are biologically active, they could be harmful. The only way they can be presumed safe is if they have no effect. Oh, well.

The FDA has been prominent for several things in recent years, most commonly regarding the approval (or not) of drugs to treat COVID, and often for demonstrating that proposed treatments, even those endorsed by high-level elected government officials, were not effective. It also made news (and this blog, FDA approves Alzheimer's drug against the recommendation of its scientific panel. Be very concerned, June 21, 2021) by its approval of the Alzheimer's drug, Aduhelm, against the recommendation of its committee of scientific experts (eventually Medicare, the largest payer, refused to routinely pay for it, although it will in some situations).

A recent article in the *New York Times,* F.D.A.'s Drug Industry Fees Fuel Concerns Over Influence, discusses the controversy over "user fees" that the agency charges drug and medical device makers to help fund its work. Well, "help" may be incorrect, because such fees account for 75% of its budget. This requires annual negotiation between the agency and the trade organizations for the industry, and those negotiations often lead to concessions to the manufacturers. At the least, it creates a situation in which it appears that the manufacturers, rather than the public, are the agency's clients. The *Times* notes that 'The user fee program traces its roots to 1992, when AIDS activists pressed the F.D.A. to hasten drug approvals. About a decade later, drugs moved through the pipeline more quickly, averaging about 10 months from roughly 19 months,' seen at the time as a big victory for AIDS patients. Of course, it is important to note that speedier approval is only a good thing if the drugs being approved work for their intended purpose; speedier (or any) approval is *not* a good thing if the drugs do not work, no matter how much people with AIDS or any other disease, or their advocates, or physicians or scientists or drug manufacturers, wish they did.

If the pharmaceutical and medical device industry are going to pay for the costs of running the FDA, they should be charged enough to ensure that adequate staff and time are available for thorough review of drugs. The agency would otherwise be funded by general tax revenue, and it seems entirely just that the industry that makes money from those approvals (an INCREDIBLE amount of money; the drug industry is regularly by far the most profitable in the US) should pay for them rather than the rest of us. What is wrong is for those payers to have any influence on how the agency operates, what it does, or certainly what drugs are or are not approved. It is an insane idea to think that they should have influence because "they are paying for it" as if it were a business deal, and yet this seems to be the perspective of some influential politicians, such as Sen. Richard Burr (R-NC). *'Mr. Burr, a business-focused conservative, complained that the program burdens companies with negotiating with the agency over the fees, which he predicted would rise even higher.'* They should rise as high as they need to in order to fund the agency and the industry should have zero input into their policy decisions (as, indeed, the tobacco industry apparently does not over the 1200 FDA employees in its tobacco division, although the division is entirely funded by user fees).

This issue with the FDA is one (important) example of how, when industries are unsuccessful in "persuading" the government (though large cash donations) to entirely privatize a public function, they seek control of it anyway. In some cases this is a win-win for the industry and the government: the industry not only gets effective control of policy but very large influxes of money from the government to their business, and also gets to deny complete responsibility since it is a "government program". (See, for example, Medicare Advantage and the DCE/REACH program, "Private Equity": Profiteers in nursing homes, Medicare Advantage, DCEs, and all of healthcare, September 16, 2022.) Of course, there is a lose-lose part of the equation that involves the other two parties: the sick people who need treatments that are both effective and affordable, and the rest of us who are funding these donations to corporate coffers. Guess which group, winners or losers, has more people? Guess which gives more money to politicians?

It is tempting, when the nation's people want something done right (like protecting them from unsafe and ineffective drugs) but do not want to pay more taxes to make it work,

to enact things like "user fees". This is certainly fairer; it is why, for example, semi-trailers pay higher highway taxes than cars -- because they travel so many more miles and are so much heavier they cause far more damage to the roads. (You used to see bumper stickers on them that announced how much, until, presumably, they realized, that the other folks driving on the highway had little sympathy and probably cheered and felt it wasn't enough!) Thus charging the pharmaceutical companies who make so much money on drugs to pay for the FDA makes sense and is the way it should be, as long as they have no influence on the process. But that lack of influence is what irks Mr. Burr, and the drug makers who fund him.

Obviously, Burr is wrong, and so is the current process. Of the two sets of interests – the health of the American people and the profits of Big Pharma, the first should be the sole responsibility of the FDA, and the money to fund it should come from the second. Pharma will still make an exorbitant amount, no matter how much they and Sen. Burr cry that they do not have enough clout in the process to make even more, and they will continue to spend far more on marketing than on research and development.

And this should be the process for all government agencies. Fund them to protect the people from the profits of the companies that benefit.