Food for Thought

How effective is the Food and Drug Administration (FDA) and whom are they working for these days?

The FDA was created by Congress in 1938 by the passing of The Federal Food, Drug, and Cosmetic (FDC) Act to provide guidelines for the control of cosmetics and therapeutic devices, requiring new drugs to be shown to be safe before they entered the market, eliminated the Sherley Amendment requirement to prove intent to defraud in misbranding cases, provide safe tolerance levels for poisonous substances, set standards for food identity and quality, authorization of factory inspections and added the remedy of court injunctions to the previous penalties of seizures and prosecutions. At the time this act was passed until 1992, the FDA was fully funded by U. S. taxpayers and not subject to outsider influences such as the pharmaceutical, food or cosmetic industry, the industries it was created to regulate.

This began to change with the HIV-AIDS epidemic that began in the early 1980's which was viewed by the public as a devastating and lethal disease that affected many people but as well many celebrities and sports figures. Because of the long delays in getting experimental HIV drugs studied and approved by the FDA, AIDS activists began to exert intense pressure on Congress resulting in the Prescription Drug User Fee Act that was signed into law in 1992 by President George H. W. Bush.

The act essentially opened the door for drug companies to pay a user fee when submitting applications to the FDA for drug review. Annual user fees are based upon the number of approved drugs the pharmaceutical company already has on the market. The system utilizes a complex formula with waivers, refunds and exemptions based on the category of drugs being approved and the total number of drugs in the manufacturers portfolio.

The user fees are negotiated by The FDA and the drug or device manufacturers who also negotiate the performance measures that the FDA has to meet in order to collect the user fees. Performance measures include such things as how quickly the FDA responds to meeting requests, how quickly it generates correspondence, and how long it takes from submission of a new drug application until the FDA approves or refuses to approve a drug or product. Needless to say, the additional user fees and performance measures that the FDA must meet puts them in the position of having to become more in line with drug manufacturers application requests to speed up approval. In 1987 it took about 29 months to get a new drug approved. This changed to 13 months by 2014 and 10 months by 2018. An example are many cancer drugs that previously took years to get approval but now can be used in "clinical trials" where they are in essence being tested on cancer patients to see if they are effective. More recently the Covid vaccines were approved in less that a year, and as we have documented previously, without proper evaluation.

The FDA's funding has over this period increasingly come from the industries that it was designed to regulate. Of the entire FDA budget, 45% comes from user fees while 65% of the funding for drug regulatory activities comes from user fees. In essence this means that

the pharmaceutical, food and cosmetic industries have considerable influence over how they are regulated by the FDA. In fact, the funding for this particular area of over sight was slashed during the Regan Administration who wanted to get big "Government" off of our backs. This of course set the stage for industry to become part of the decision makers at the FDA.

What has also occurred since this relationship has changed is that many of the individuals who work at the FDA find employment in the pharmaceutical, food and cosmetics industries once they retire. Certainly this cozy relationship is not lost on FDA employees who know that when they retire from the FDA a high paying position awaits them, especially in the pharmaceutical industry.

Adverse effects of the current state of affairs is that in order to get a drug approved, senior FDA officials have been known to over turn scientific recommendations to fast track a drug and to lower the burden of proof for a medication approval. This occurs in order to meet tight deadlines so user fees could be collected. Additionally, the number of new drug applications submitted to the FDA has increased from 38% in 2005 to 61% by 2018, a topic that we addressed in another Food for Thought: Why are there so many different drugs for the same condition? What benefit do they have?

All of this has some scientists as well as consumer advocates concerned that the FDA will loose its effectiveness and objectivity when it comes to regulating the pharmaceutical in particular, but as well the food and cosmetic industries. This is in part due to the significant influence industry now has on the FDA decision-making process. While user fees fund drug approval functions, they do not cover other areas such as regulation of dietary supplements and counterfeit drugs that periodically flood the market and cuts to the FDA budget have left these areas lacking.

User fee programs are reauthorized every 5 years by congress with the current agreement due for review in 2022. It becomes important that our legislators be aware of the conflict of interests that now exist between the FDA and the pharmaceutical, food and cosmetics industries and restore the original intent of the intent of The Federal Food, Drug, and Cosmetic (FDC) Act.

We encourage you to let your legislators know that this cozy relationship between industry and the FDA is unacceptable and the original intent of the Federal Food, Drug, and Cosmetic Act should be reinstated and enforced.