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COVER STORY

Need to Reform The FDA

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In a series of blatant abuses of power, the Food and Drug Administration unwittingly offers the public compelling reasons for its immediate reform. Their actions show that the FDA and the multi-billion dollar pharmaceutical industry have one goal in common: Increasing profits from prescription drug sales.

Not only do the FDA and the drug lords daringly loot the pockets of the American consumer, they do so without any regard to the laws and regulations designed to ensure fairness and honesty. As a comparison, imagine you are in court, suing a large company (call it the Megabig Corporation.) The evidence is clearly in your favor, but when you reach the courtroom, half of the jurors work for Megabig! In addition, the judge is the president of Megabig! Guess who wins? Unfair? Unconstitutional? Undemocratic? Yes, but that is exactly the situation that exists today when the FDA makes a decision about a prescription medication.

The FDA exercises its power through 18 different "Expert Committees," made up of scientists with the experience needed to examine varying classes of drugs. These panels evaluate and recommend actions regarding medications that are worth millions, even billions of dollars to the pharmaceutical houses that invented, imported or modified them. Any one decision by a panel can move a drug company's stock up or down quickly, and the committee members are well aware of the significance of their choices. Obviously, the drug lords are also knowledgeable as to how each panel can influence their careers and their collective fortunes. Because of these factors, there are government regulations in place to protect the American public from biased or even corrupt panel members. The rules state that a person cannot sit on a committee if he or she has an obvious conflict of interest, defined as a situation in which a ruling could make a significant financial impact on that person. This seems to guarantee a relatively unbiased decision making process, but never underestimate the power of a greedy corporation and a corrupt government agency.

Despite all the safeguards, over 50% of the FDA's Expert Committee members are people with direct financial ties to the pharmaceutical industry. This astounding disregard for federal regulations was first uncovered and published in USA Today on September 25, 2000. Their investigative report showed that 54% of all those serving on FDA committees have a direct financial interest in their own decisions. These conflicts include receiving direct fees from the drug company, owning its stock, having a spouse employed by the company up for review or having their research funded by the same company whose drugs they are evaluating. Even participating "consumer representatives" were found to be on the drug lords' payrolls.

How does the FDA get away with a behavior that the Ralph Nader-founded Public Citizen's Health Research Group calls "outrageous"? They accomplish this modern highway robbery through the generous practice of granting "waivers." The FDA is permitted to waive the conflict of interest rules if an expert's value outweighs the potential financial conflict. This sounds reasonable until you learn that 803 waivers were granted over a two-year period starting in 1998. In fact, the report determined that there were financial conflicts in 146 of 159 FDA advisory meetings during this time.



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The FDA's rationale for these incestuous relationships is that the most qualified experts for their committees are those people within the drug companies doing the research and testing on that drug. This is patently ridiculous. No reasonable person would believe that there are no other qualified chemists, biologists, pharmacists, cardiologists or other specialists available except for those obligated to the drug manufacturers. But the FDA, in its arrogance, expects the public to believe whatever it says. A case can be made that the FDA experts are exactly the wrong people to be placed in such important positions. Even children learn that you don't hire a fox to guard the henhouse.

Unfortunately, this corruption is deep-seated and unlikely to change without direct congressional action. To prevent additional publicity that might damage their cozy, lucrative system, the FDA plans to stop revealing financial conflicts on their committees in the name of "personal privacy."

The FDA pretends to carefully investigate new drugs for safety and efficacy. The reality is that those responsible for recommending FDA approval often have a financial interest in the very drugs they are supposed to be independently evaluating. Is it any wonder that drugs the FDA declares "safe" kill more than one hundred thousand Americans every year?

When it comes to determining whether a drug is "effective," this provides an even greater opportunity for drug company insiders (who sit on FDA committees) to make biased decisions. This means that bad drugs can get approved by those with the right connections, while more effective medications are sometimes never allowed to be sold in the United States.

In deciding what new drugs are to be christened with FDA approval, scientific objectivity is replaced by the economic influence of large pharmaceutical companies. The consumer is thus denied access to innovative medications offered by smaller biotech companies, while large drug companies can push their products through FDA committees comprised of people who have a significant financial interest in the drug gaining FDA approval.

The drug approval system in the United States is riddled with corruption, causing Americans to pay inflated prices for mediocre medications. Despite this economic pillage suffered by the consumer, the public has remained surprisingly apathetic to this abusive drug approval process. At the end of this article, we propose several ways to reform this disgraceful system that is causing Americans to needlessly suffer and die from bad medicine while being forced to pay the highest prices in the world for their healthcare.

FDA opposes fair market pricing

In contrast to its public role as a consumer watchdog, the FDA has done everything possible to support higher and higher drug prices, ensuring record profits for the pharmaceutical industry. The House Commerce Committee recently estimated that the American public and the governmental agencies which purchase medications (Medicare and Medicaid) are overpaying by an astronomical one billion dollars yearly. Some of this is also the result of a "deeply flawed" HCFA (Health Care Finance Administration) purchasing system which invites abuse, according to this same House Committee.

Certainly, if any Medicare prescription plan becomes law, there must be a major revision in the way prices are determined. The primary problem, however, remains the anti-consumer stance of the FDA. Their policies have resulted in skyrocketing drug prices, the driving force behind the yearly 15-20% increases in health care costs. Senator Paul Wellstone (D., Minn.) stated that the drug industry looks only "to make huge profits on the misery and illness of consumers." This misery reaches well beyond the actual struggle to afford critical medications. With the escalation of drug prices, health plans drop their sickest patients or go bankrupt, more and more people go without insurance and small businesses disappear because they cannot afford the increased cost of employee benefits. The New York Times reports that basic health insurance premiums could be raised by as much as 30% in certain regions of the country.

The FDA has shown fanatical opposition to the free market reimportation of prescription drugs, one way in which overall drug spending might be lowered. ("Reimportation" refers to the consumer purchase of legitimate drugs from foreign pharmacies. The medications are sold by U.S. manufacturers at lower prices to other countries because of the buying power of such large group entities.) The FDA finds any reason to block a U.S. citizen's right to buy back medications at that cheaper price from these countries, including nations with standards equal to ours, such as Canada and England. They are opposed even if the drug is exactly the same as sold in the United States, is made by the same company and was approved by the FDA the day before it was shipped. They have gone to the extreme of having 11 former FDA commissioners write personal letters to Congress, urging Representatives to vote against reimportation. Fortunately, Congress has seen through these efforts and has supported reimportation. Some House members have even arranged for their constituents to travel to Canada to make prescription purchases. In response, the FDA has waged a media campaign warning the public about possible "counterfeit" or spoiled drugs, though no such cases have been found. Had the FDA found evidence of spoiled or inferior medications, they would have trumpeted the news to bolster their fragile position.

Despite both Houses of Congress voting to allow Americans to purchase lower-cost prescription drugs from overseas sources, Donna Shalala at the very end of year 2000 used a loophole and announced that she was declining to implement this new law or to submit a budget justification for the \$23 million Congress made available specifically for this purpose. This enabled the FDA to declare the law unworkable and effectively killed the legislation that was so overwhelmingly supported by the House, Senate and the American public. The drug companies got their way because the FDA refused to implement the law passed by Congress. This means that the American consumer continues to be raped by having to pay the highest prescription drug prices in the world. (Refer to the last page of this article to see what outraged members of Congress are doing about this matter).

The FDA continues to argue (without providing any evidence) that drugs from other countries are somehow “dangerous.” A close look reveals that the true danger lies in the neglect and incompetence of the FDA itself. The agency is charged with ensuring the purity and safety of the raw ingredients used in the manufacture of approved drugs. These ingredients often come from foreign sources, and are supposed to be inspected by the FDA. Shockingly, the Wall Street Journal published a report on September 12, 2000 showing that at least 57 separate companies had shipped “misbranded” ingredients to American drug manufacturers. Representative Thomas Bliley (R., Va.) called the FDA’s efforts “ineffective” and “limited.” In other words, the FDA says it is “dangerous” for an American to obtain a finished drug product sold at a Canadian pharmacy, but the FDA shows little concern with “misbranded” raw materials being imported into the United States that wind up in the expensive drugs that are sold in American pharmacies. So while they were alarming the public about the hazards of buying the medications from foreign sources, the FDA was falling down on the job by allowing the wrong raw materials to be used in the manufacture of “safe” American drugs.

What is obvious is that the FDA’s concern for the American public is simply lip service. Their neglect of true drug safety, their public campaign against cheaper drug prices and their tainted expert committees show their true priorities to be preserving their own bureaucracy and protecting their allies in the drug industry.

Drug companies drain Medicare funds

The real drug lords of America are the pharmaceutical companies who abuse the antiquated purchasing system of our government. They take advantage of the willingness of Medicare and HCFA to accept the publicly announced price of dozens of expensive drugs, despite the fact that these prices are arbitrary, inflated and completely fictitious. When doctors purchase these medications, they often pay the pharmaceutical company less than 50% of this announced price. The doctors then charge the phony “average wholesale price” to Medicare or Medicaid, and make a great profit. The drug lords have been found to raise their announced prices just to inflate the doctors profits, leading the physicians to choose those medications over less expensive substitutes. Based on the findings of the House Commerce Committee, as reported in the Wall Street Journal on September 27, 2000, most of these price increases have no basis in increased costs of materials, marketing or staff salaries. Their only purpose is to add incentives for the prescribing doctors, at the expense of Medicare.

What makes this situation even more grievous is that most of the medications in the report are designed for AIDS and cancer patients.

Medicare only pays for medication in these extreme, doctor-administered cases, such as chemotherapy that is administered in an oncologists office. It is easy to see the massive abuse that awaits a complete Medicare prescription plan if these practices are not corrected.

We pay, they prosper

The combined efforts of the FDA and the drug lords are aimed at an enormous prize. Spending for medications has become the nation’s bottomless pit. When a 20-tablet bottle of the allergy medication Claritin costs \$8.75 in Europe, but \$44.00 in the United States, it becomes extremely obvious that there is no actual cost-basis for drug pricing. Certainly, the drug lords would not sell at a cheaper price in Europe if they were losing money. Why is the United States the “cash-cow” of the pharmaceutical industry? The sad answer is that they know their actions are insulated and protected by the FDA.

The drug companies defend their unfair pricing by claiming that they need more research funds. This is an attempt to play on our fears of death and aging. There always will be tremendous financial motivation to develop new, more effective and safer drugs. It is easier, though, to attempt to extend the expiring patent rights on drugs such as Claritin, a huge profit center for its manufacturer, than to worry about research and development. Fortunately, the FDA’s efforts to achieve such an unfair advantage for their drug friends were thwarted by an increasingly alert Congress. However, patents for drugs are complicated issues involving multiple components. As a result, the drug companies are able to delay the expiration of many profitable patents for indefinite periods of time.



"He has erected a multitude of new offices and sent hither swarms of officers to harass our people and eat out their substance."

Failing to protect the food safety

The General Accounting Office (GAO) issued a report to Congress on February 13, 2001 indicating that the FDA was not adequately inspecting seafood for potentially lethal bacterial contamination. According to this report, more than half the seafood firms are failing to follow food safety standards and FDA inspectors are not cracking down on these violations.

Even when FDA inspectors found a serious violation, they failed to move quickly to make the company correct the problem. As far as imported products, when the FDA finds a problem at foreign seafood firms, it does not automatically check the food that is entering US ports from these very same companies. The FDA moved to block food from being imported from nine foreign companies only after GAO investigators raised the issue. The GAO report to Congress stated that, "The potential health risks associated with these violations are significant."

Americans suffer an estimated 114,000 seafood poisonings each year and the FDA is failing to comply with a food inspection program it announced in 1997 that was supposed to cut this number in half.

The FDA track record on food safety inspections grows more appalling each year. According to FDA records there were 21,000 food inspections in 1981, but by 1996, the number dropped to only 5,000. This 76% reduction in food safety inspections occurred during a time when the FDA admits there is a lot more food to inspect.

The FDA attributes its failure to adequately inspect food to "budgetary constraints," yet the agency is squandering millions of dollars a year in litigation expenses in a futile attempt to suppress the free flow of information to the consumer. While the FDA suffers one defeat after another in Federal Court, 9,000 Americans die each year from food poisoning that FDA inspections are supposed to prevent.

The time to reform the FDA is now

With the backbreaking cost of medicine threatening to destroy our healthcare system, with the potential of Medicare prescription abuse and with the very life of many citizens at stake, solving the FDA/pharmaceutical company dilemma must begin now. Any reform has to begin with the FDA, since it maintains and supports the "robber baron" practices of the drug companies. As a government agency, it can and should be held accountable to the Congress and its various committees. There are several possible ways to improve the situation, the most severe of which is to simply abolish the FDA. The best argument for abolition is the thorough and deep-rooted corruption described in this article. This leads to a search for the FDA's necessity for existence, and whether it does more harm than good. It is possible that other agencies could assume the more beneficial functions of the FDA.

The second possibility is FDA reform, though it may be asked if this is possible, given its present, well-entrenched structure. Certainly, if the FDA is allowed to exist, consumers must demand a complete investigation of the abuses being uncovered on a regular basis, as well as a new and reputable Commissioner to enforce ethical guidelines. This would be a lengthy and expensive process, and might allow the current regime and its friends too much time to wring even more undeserved profits.

A third option is far simpler and much less expensive: Make the FDA a voluntary organization. Allow a free market economy to thrive by converting the FDA into a consumer-information agency. Those people desiring the FDA stamp of approval could choose to purchase only those medications that receive such an acknowledgment. Others could seek out other sources from this country and reputable foreign prescription and non-prescription suppliers. It would be expected that other organizations would arise to offer different evaluations of the same drugs, providing alternative educational health statements for the consumer to weigh. This is the same situation that consumers find themselves in when they look to purchase almost everything other than medicine. Considering the number of deaths associated with FDA-approved drugs, it is difficult to see the negatives in such a democratic drug marketplace. Consumers are smarter than the FDA thinks. They can only do well without a corrupt FDA controlling their health and their lives.

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What YOU Can Do To Fight The FDA

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FDA reform is crucial because our very lives are at stake. If we don't tear down FDA barriers against new drug development, those of us alive today may not benefit from the breakthrough therapies that are being discovered in research laboratories. We are also facing an economic healthcare crisis because FDA policies are denying Americans access to lower cost medications.

We are asking all Foundation members to send President Bush the letter that appears on the next page. This letter urges President Bush to force the FDA to implement the law passed by Congress last year that allowed Americans access to lower priced drugs sold in other countries. The importation provisions of this law were nullified on a technicality by Donna Shalala before she left office, BUT, President Bush can reverse Secretary Shalala's decision and implement these provisions that would drastically lower the cost of prescription drugs.

On the page following the letter to President Bush is a letter you can send to your Congressional Representative to support a bill that would enable Americans to gain greater access to life-saving medications that are bogged down in the FDA approval process. The name of this bill is the Thomas Navarro FDA Patient Rights Act (H.R. 3677). This bill would amend the law to restrict the authority of the FDA to issue clinical holds regarding investigational drugs or to deny patients expanded access to such drugs. Thomas Navarro is a child dying from cancer who is being forced to first undergo toxic conventional treatments before the FDA will allow him to try a non-toxic approach that has a good track record of success. We will be featuring a story on the heroic efforts of Thomas Navarro's parents in a future issue of this magazine, but we are asking members to write their Congressional representatives to get this bill signed into law immediately.

Corrupt bureaucracies will trample basic human rights as long as the citizenry remains passive and apathetic. Please sign the letter on the next page and mail it to President Bush at the address that appears at the top of the letter. Then sign the letter on the following page and mail it to your member of Congress. To find out who your Congressional Representative is, call the U.S. Capital Switchboard at 1-202-225-3121. If you want to discuss this with your Congressmen, you can be connected to his office directly. You can also find out who your Congressional Representative is and send an e-mail version of this letter by accessing the Home Page of The Life Extension Foundation (www.lef.org).

The letter that supports the Thomas Navarro FDA Patient Rights Act can be mailed to:

The Honorable (Your Congressman's name)
United States House of Representatives
Washington, D.C. 20515

You can also e-mail them here.

Date: _____

President George W. Bush
The White House
Washington, D.C. 20500

Dear Mr. President:

In the year 2000, legislation overwhelmingly passed in both Houses of Congress that allowed the wholesale importation of prescription pharmaceuticals made in FDA-approved facilities.

This law was designed to drastically cut healthcare costs by enabling American consumers to obtain their prescription drugs at a fraction of the price that is being charged in the United States.

In late December 2000, HHS Secretary Donna Shalala unilaterally decided not to implement the provision of this law that would have given Americans access to lower cost medications. Shalala turned down 23 million dollars Congress had appropriated for the FDA to implement this provision that would have lowered the price I pay for my health insurance and prescription drugs.

Secretary Shalala's decision means that it is illegal today to import wholesale quantities of FDA-approved prescription drugs into the United States. U.S. consumers are thus forced to pay the highest drug prices in the world because the free market competition this law was supposed to create does not exist.

Your administration does not have to abide by Secretary Shalala's decision to thwart implementation of the wholesale importation provisions of the new law. Based on your comment in the St. Louis debate that allowing importation of lower cost prescription drugs "makes sense," I request that you instruct HHS Secretary Tommy Thompson to immediately implement the wholesale importation provision of the law passed last year.

You have repeatedly stated that you believe in the free marketplace. As long as the FDA can block the wholesale importation of lower cost prescription drugs, a virtual monopoly will continue to cause me to pay inflated prices for my prescription drugs and health insurance.

I respectfully urge you to instruct Secretary Thompson to implement this law that was enacted by the United States Congress at the behest of American consumers who were fed up with paying grossly inflated prices for medications they need to stay alive.

Please let me know your position on this issue.

Signed: _____

Name: _____

Address: _____

City: _____ ST: _____ ZIP: _____

Date: _____

The Honorable (Your Representative's Name)
United States House of Representatives
Washington, D.C. 20515

Dear :

I am writing to ask that you vote to pass the Thomas Navarro FDA Patient Rights Act (H.R. 3677).

This bill would amend the Food, Drug and Cosmetic Act to restrict the authority of the FDA to issue clinical holds regarding investigational drugs or to deny patients expanded access to such drugs. Passage of this that would enable Americans to gain greater access to innovative therapies that are bogged down in the FDA approval process.

Thomas Navarro is a child who was told he was dying from cancer. He has been denied a promising therapy because of an FDA ruling that states he must first endure radiation and chemotherapy. Thomas Navarro has to wait for these toxic treatments to fail before being allowed to try promising therapies that are not yet approved by the FDA.

In as much as millions of American lives are at stake, I respectfully request that you expeditiously ask your fellow members of Congress to vote this bill (H.R. 3677) into law so that American citizens do not have to die while potentially life-saving therapies already exist.

Please reply to let me know your position on this issue.

Sincerely,

Signed: _____

Name: _____

Address: _____

City: _____ ST: _____ ZIP: _____

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