

How Can We Eliminate The Current Cozy Relationship Between The Pharmaceutical Corporations and The FDA Regarding Drugs They Are Continually Approving?

It doesn't make a lot of sense to have an agency established to regulate the approval of drugs, when the very same company that is seeking their approval, is allowed to conduct the study on the drug's effectiveness and safety. It makes even less sense when the majority of the agency's income is actually derived from the fees paid by the companies that benefit from their approval. You might say that the FDA is actually employed by the very companies seeking their approval, (basically their employee).

Another question that immediately comes to mind is: How does the FDA determine what fee (often huge) might be appropriate? This kind of symbiotic relationship tends to encourage unjustified approval, and certainly opens the door for corruption. The FDA tends to carry the banner for the drug industry (their benefactor) by overlooking the problems associated with drugs already approved, unless proven beyond a doubt to be extremely serious. They also attempt to control, and whenever possible even remove, natural supplements, (the competition), even when they have been proven perfectly safe, as well as beneficial, from years of use.

One example is the amino acid L-tryptophan (something we all need), and how it was conveniently banned when it was becoming too popular with many doctors for controlling depression, and sleep disorders. Incidentally, that was shortly before the SSRI antidepressant Prozac™, with its 575 side effects (listed with the FDA), was about to be announced. The goals of the drug companies and the FDA are basically the same: Eliminate any competition at all costs (and they both have adequate financial resources, and combined they have even more). Together, they are waging an all-out war against any potential competition. Then, worst of all, they are using Federal funding to do so, (thus the tax payers are unknowingly supporting their devious effort).

Sometimes, identifying a particular problem is much easier than providing a viable solution, (something drugs are not capable of). I believe we can easily see how the current FDA approval process doesn't really make a lot of sense, and that the current organization would by its very nature, tend to actually support the very industry it was created to oversee. This is without question, contrary to the public's best interest, and especially a serious issue when not only our health, but even our very lives are often at stake. We should all be assured that any potential for corruption would be reduced to an absolute minimum, which is obviously not the case under the current set of rules. Thus, a major change is in order, and in my opinion, far overdue.

A case-in-point is the approval of the drug Prozac™. In the April 1997 issue of *Life Extension* magazine, the editor, Saul Kent, wrote an editorial titled "What's Wrong with Prozac?" regarding the book titled *Talking Back to Prozac*, by Peter R. Breggin and Ginger Ross Breggin. In that editorial, Kent noted that **"One of the main studies the FDA used in approving Prozac is based on data from only 11 patients! And it was conducted by a doctor who has been accused of fraud in other trials,"** and that

“None of the studies lasted for more than 6 weeks, and patients frequently rated Prozac as no better than placebo.”

In her book *Prozac: Panacea or Pandora?* (1991/1994), Dr. Ann Blake Tracy warns of serious problems associated with Prozac™ and its 575 potential side effects listed with the FDA. And, in spite of the tens of thousands of serious reactions associated with Prozac™, filed with the FDA many years ago, they somehow deemed Prozac™ perfectly safe for our children’s use! Talk about out-and-out corruption! And worst of all, absolutely no one has held them accountable for such unscientific, and totally inappropriate conduct. How could the FDA possibly allow Eli Lilly to aggressively market Prozac™ for young children, and even pregnant mothers, placing the fetus at serious risk? And how can we possibly trust the decisions of an agency whose primary objective is promoting the approval of risky drugs, rather than any real concern for their safety?

Now, back to our proposed solution. First, an entirely different approach to financing the drug approval process is an absolute must. If we just consider the “highly inflated” prices of drugs charged by the companies, and that they insist on charging approximately twice what the same drugs sell for in Canada, I believe that taxing the drug companies a percentage of the sale price for all drugs they produce, would likely be the best, and most equitable option. Even if they were charged 50% they would still be making as much profit as the companies in Canada. I couldn’t think of a faster way to pay off the national debt, which the drug companies actually helped create. Although our objective in this case would be limited to funding the drug approval process, thus it would obviously cost them considerably less. Drug companies have also begun conducting more studies overseas, where drug benefit and safety are much cheaper to “purchase”. It’s much easier to “buy the results” they are looking for in other countries.

One potential solution would be to establish an entirely new regulatory commission that would be well regulated, and open to scrutiny, and thus above reproach. None of the employees should have been employed by any pharmaceutical company in the past, and would also have to agree not to do so in the future. They would not be allowed to hold stock in any pharmaceutical company, (directly or indirectly). Neither their spouses, nor any members of their immediate families could be employed by, or in any way associated with any pharmaceutical company or their subsidiary. There must be absolutely no more incentive to ignore a drug’s risk, or expedite its approval.

Currently, huge sums, set by the FDA, are required for drug approval. At times, the husband might work for the FDA and his spouse for a pharmaceutical corporation, or visa versa, (sometimes referred to as the revolving door). This opens the door for collusion. Also, any FDA employee that is helpful in expediting the approval of drugs (basically user friendly), can be assured a very generous salary by some pharmaceutical company, after leaving the FDA. The more influence they might have in the FDA approval process, the greater their potential salary with a pharmaceutical company would be.

An entirely new agency, established with strict guidelines to prevent any possible conspiracy to encourage the inappropriate approval of any drug, should have an independent funding source. The taxing structure should provide adequate funding to

allow the agency (not the company requesting approval) to conduct independent adequately controlled studies, allowing for a sufficient amount of time to better assure the drug's safety.

The agency could also establish a separate website for each drug approved, listing any other drugs that could interact negatively, (contraindications that many doctors all too often overlook). They would also be required to list any vitamins, minerals, or beneficial nutrients depleted by the drug, as well as any known benefits associated with each nutrient depleted. I recently discovered something quite interesting. Just evaluating the symptoms associated with a deficiency of each nutrient depleted by a particular drug, helps explain the majority of its potential side effects.

We have a valuable resource in the internet, which we could and should take more advantage of. Doctors could also use this database as a resource when evaluating the potential for drug interactions. As I noted, this is a concern that some doctors tend to overlook. A list of serious reactions associated with each drug, as reported by patients or their doctor, could also be prepared, along with the number of complaints filed for each. The filing of complaints should be simplified, so more people would be inclined to report them.

Apparently, it is thought that currently, only about one percent of problems associated with medications are normally filed with the FDA. The agency should provide a website with a database to post all complaints, and assure its ease of use. A toll-free number could also be available to provide assistance for those unfamiliar with computers, such as many senior citizens. They could request a printout of the information available, which could then be mailed out. There are obviously ample financial resources to fund such an organization. All the pharmaceutical companies would be assured of equal treatment, so they could devote more of their time and resources toward providing safer and more effective drugs, rather than on devious ways to get potentially dangerous drugs approved.

The better informed the public is, the more responsible the companies will have to become. All potential FDA employees' backgrounds should be thoroughly screened, and they should be encouraged to report any suspected impropriety. The primary objective would be to assure that the agency would be above reproach. Due to the tremendous profit in prescription drugs, the potential for corruption will always exist. For that very reason, diligence by the regulatory agency must become a top priority.

At least, if I owned a pharmaceutical company, preferred to be honest in my dealings, and was concerned regarding the public's safety, I would welcome the change. Those most likely to object are those who have successfully perverted the system in the past. It might possibly cramp their style initially, but I am sure they could learn to adjust. It should help provide a much more relaxed atmosphere. There would be much less paranoia regarding the competition, as they would all be required to play by the same ground rules. That is something I personally would welcome, and be much more comfortable with.

Once a company's representative can no longer bribe or otherwise coerce the regulatory agency into approving a potentially dangerous drug, we can all rest more easily. Also, allowing a company to conduct their own controlled study on a drug they are seeking approval of, makes absolutely no sense. The study would obviously be biased, and the outcome could be easily manipulated in favor of approval. No real sense of security on the part of the public is the result, especially since so many potentially dangerous drugs are being tested on the public, after their approval, thus placing them at undue risk. At times, thousands of lives are unnecessarily sacrificed, before the FDA finally insists that a drug be pulled. At times, rather than removing a drug from the market, a Black Box Warning is instead added, at the insistence of the manufacturer, of course.

I would hope that things are currently much different in Korea today than they were when I was there over 50 years ago, during the Korean War. It appears that I might be straying from the subject a bit, but just stay with me for a moment. The point I am attempting to get across is the sense of pride and security I had always been thankful for in my country back then. At that time, no such security existed in Korea. Very few people could be trusted. You had to be constantly vigilant, and could never quite relax. For example, I had my watch snatched off my wrist one evening, and the police didn't seem the least bit concerned. Both the customs and police officers expected bribes. I later discovered that if I had offered the police \$10, they could have found and returned my watch, which was worth considerably more.

I think at times we often tend to become complacent, and overlook obvious injustice, or possibly even corruption for the sake of profit, even when we are aware that it exists. We assume it's just something we have to live with. Unless we want our country to gradually become more and more corrupt, and less and less secure, instead of how it once was years ago, when a man's word or handshake was sufficient, and a written contract was often unnecessary, we must all do our utmost to assure that we don't digress to the point that Korea once was, many years ago. We are very blessed to live in a land where we all enjoy the sense of freedom, and security that is missing in many other countries. We must all do our part to prevent any dishonesty or corruption, which could easily undermine the moral or ethical structure of the most blessed land in the world. If we all do unto others, as we would have them do unto us, we can continue to enjoy our freedom, and feel more secure. Our vigilance, and willingness to become involved, might at times be necessary.

For that very reason, I am suggesting a major overhaul of our current drug approval process. A far more effective program would better protect the public, and assure that the approval process for drugs is more equitable, and truly effective, and that the potential for corruption would finally be eliminated. This approach would at least be a step in the right direction, toward restoring the confidence of both the doctors and their patients, in the FDA approval process, (something that has rapidly eroded – especially the last few years).