The 100th Anniversary of the FDA: 
The Sleeping Watchdog Whose Master is Increasingly the 
Regulated Industries

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Publicly, the FDA is bragging, with good cause, about its 100 years of history that include many noteworthy accomplishments. But, like misleading prescription drug ads that frequently understate the risks while overemphasizing benefits, the FDA's 100th anniversary propaganda campaign hides and denies the many ways the agency is engaging in an unprecedented assault on the American public on behalf of their drug, device, food and other industry "clients".

But the public is becoming extremely concerned about the direction the FDA is going and its opinion of the agency’s job in protecting people is plummeting.

Given increasing public awareness of published evidence of 2 million serious adverse drug reactions a year including 100,000 deaths from adverse reactions ---making these largely preventable tragedies one of the five leading causes of death in the U.S---the public has recently added its diminished respect for the FDA to the older views that the drug industry is not to be trusted.

• 58 percent of 2,371 people surveyed in an April Harris Poll thought that the Food and Drug Administration (FDA) does only a fair or poor job ensuring the safety and efficacy of new prescription drugs, a significantly worse assessment than two years ago.

• 82 percent of those polled thought FDA decisions were to a great extent or some extent influenced by politics rather than medical science.

• 76 percent of people were somewhat or very concerned about the FDA’s ability to effectively communicate safety concerns about prescription drugs to doctors and the public

Until 20 years ago, there was massive, ongoing congressional oversight investigations and hearings concerning the FDA. From the late 60’s through the late 70’s---in little over a decade---one Senate committee, the Senate Small Business Subcommittee, held 135 days of FDA oversight hearings. They were but one of a much larger number of congressional committees then engaged in FDA oversight and regularly having hearings. In those days, if the FDA made a serious mistake----approving a drug despite knowledge of its dangers, failing to promptly ban a drug when evidence had mounted that its risks outweighed its benefits, failing repeatedly to enforce the provisions of the FD and C Act---the
agency would have to "pay" for these health-endangering lapses by having to face well-prepared congressional committees, thereby moving the FDA towards a more publicly responsive position and away from their tendency to side with industry.

Now instead of having to "pay" for their mistakes by enduring congressional oversight, the FDA is literally getting "paid" for making increasingly industry-favorable decisions. This takes the form of the ever-expanding industry users fees to the FDA, first authorized in 1992 (PDUFA) and now amounting to $380 million in FY 2006, with an additional $22 million requested for FY 2007, according to testimony by Acting Commissioner Andrew von Eschenbach. This now includes drugs, medical devices (MDUFA) and animal drugs (ADUFA). Former Drug (CDER) Center Director Dr. Janet Woodcock has correctly stated that PDUFA has created a "sweatshop mentality" in CDER. Increased FDA funding to safely expedite the approval of those few drugs and devices with real promise of being therapeutic breakthroughs is too important to be left to this massive amount of industry funding with all of the explicit and implicit strings attached. Congress dropped its appropriations responsibility to adequately fund the agency and the industry rushed in.

No Evidence of Learning from Past Prescription Drug Mistakes

The virtual absence of the kind of intensive Congressional oversight of past decades makes the failure of the FDA to carefully examine its seemingly never-ending number of mistakes concerning drugs and devices even more dangerous. In recent testimony to an Institute of Medicine committee reviewing drug safety problems, both prior to and after FDA drug approval, I cited 13 instances of drugs which, in the past decade, should either not have been approved (6) or should have been taken off the market or restricted much more quickly than they were (7). I am not aware that in any of these cases the FDA has done a thorough autopsy to find out what went wrong. As a result, it keeps making the same kinds of mistakes, to the detriment of the public health.

Two Tobacco-Related FDA Law Enforcement Failures in the Past Week

As the study by Congressman Waxman’s staff shows, the central FDA office is quite adroit at negligently rebuking law enforcement proposals by its own field staff. However, the failure by the FDA to enforce the law extends considerably beyond this and is caused by a lack of perception by agency officials of their law enforcement duties to the public as opposed to their need to please regulated, FDA-funding industries. Thus wrong, health-damaging decisions that do not even involve FDA district offices are often made by the Washington-based FDA Centers.

Although the courts have held there are some limits on FDA’s authority to regulate tobacco-containing products, such is not the case for medical devices intended to help with smoking cessation or nicotine-containing products marketed as nicotine replacement treatments such as chewing gum, nicotine patches or nicotine-containing beverages.

**Freedom Laser Smoking Cessation Devices: Where is the FDA?**

Last Thursday, we petitioned the FDA to immediately stop five companies from illegally marketing and promoting laser treatment for smoking cessation on the grounds that this device has never been approved by the FDA for this purpose and that the medical evidence, in the form of properly conducted clinical trials, demonstrates that its effectiveness is indistinguishable from that of a placebo. With considerable web and TV hype, especially by Freedom Laser Therapy, promoting a 30-minute treatment for $399, the public is led to believe the device is effective. To the extent that people are diverted from proven effective, FDA-approved smoking cessation products such as nicotine gum or patches, arguably fewer smokers will be helped to stop and lives and health may by lost.

Laser Therapy, the company monitoring clinical trials with these devices done by companies such as Freedom Laser was warned two years ago about lax monitoring of clinical trials using these products. An October 4, 2004 letter from the FDA stated that “There is no evidence of having ensured proper monitoring of any of the study sites.” A company spokesperson, in response to an Associated Press reporter, stated that Freedom Laser’s ongoing clinical trials (described on the web site), did not involve collecting data. Thus these studies are poorly disguised efforts to illegally market and advertise this unapproved device.

Later last Thursday, after our petition was filed, Laser Therapy reduced the web price of the 30-minute treatment to $349, from $399 and the next day, took down most of material on the web site, stating that “Freedom Laser Therapy’s advertising materials are being reviewed by our Institutional Review Board to insure compliance.” Where is the FDA?

**Addictive NICLITE (nicotine-containing beverage): Getting Kids Started with Nicotine Addiction—Will this Lead to Cigarettes?**

From 1999 through early 2002, nicotine-containing beverages were illegally sold, because of non-existent FDA enforcement, as dietary supplements (the addictive drug nicotine requires them to be sold only if they are approved as drugs). The

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manufacturers of nicotine water had never sought approval as drugs, but other nicotine-containing products such as gum and patches had been previously approved as drugs. Thus, a December 2001 citizen’s petition\(^3\) from the National Center for Tobacco-Free Kids and former FDA Deputy Commissioner William Schultz asking the FDA to declare them to be drugs resulted in FDA declaring them as drugs on July 1, 2002.\(^4\) Since they had never been approved as safe and effective drugs, the finding meant that they could not be legally marketed.

This month, however, marked the start of a new massive marketing campaign for NICLite, described by its manufacturer’s web site http://www.nichonica.com/product_info.asp as:

"NICLite® is the World’s only Nicotine Replacement Drink! It is the amazing result of more than seven years of extensive research and testing. Each 8 oz. bottle of NICLite® contains 4 mg of purified nicotine [the equivalent of two cigarettes] infused in pure grade water with a hint of lemon flavoring added. It tastes just like refreshing lemon water and people love it.

NICLite® is perfect for places where smoking is not allowed such as airports, restaurants, bars, movie theaters, sporting events, public buildings, while at work, and around the people you love and care about.

NICLite® is classified as a Dietary Supplement by the FDA (emphasis supplied), and is the only Nicotine Replacement Product that has the added health benefit of drinking purified, clean tasting water."

There are only two possibilities to explain this apparent 180 degree shift from nicotine being declared illegal as a dietary supplement four years ago but now being advertised as "classified as a Dietary Supplement by the FDA".

The first possibility is that the company is lying, that the FDA has not reversed itself and they are being illegally sold, once again, as dietary supplements. In this case, the FDA should have, but has not, taken the legally mandated enforcement action to immediately stop the sales.

The other possibility is that the FDA, contrary to its own legal opinion of 2002, declaring this nicotine product to be a drug that had not been approved by the FDA and was therefore being illegally marketed, has now decided to change its interpretation of the law and regulations and nicotine has been, as the company claims, “classified as a Dietary Supplement by the FDA”.

In either scenario, the FDA is, again, extremely negligent in its responsibilities to enforce the law and regulations. Selling highly addictive nicotine as a beverage, with the tantalizing “added health benefit of drinking purified, clean tasting water”

\(^3\) Petition from National Center for Tobacco-Free Kids and former FDA Deputy Commissioner William Schultz, December 18, 2001
is worrisome since they can clearly become addicted to the chemical and might well find that a cigarette is easier to find to ease their addiction than a bottle of NIC-Lite. The company has stated that they plan to “roll out the refreshing product in more than 50 airports in the U.S.” The proviso that it will only be sold to smokers 18 and older rings hollow from an enforcement perspective. Where is the FDA?

In summary, the FDA seems to forget all too often that it is a regulatory agency with legally mandated responsibilities to protect the public. As we celebrate the 100th anniversary of this important agency, there are too many instances in which it appears to be moving back into 19th century when industry did what it wanted rather than into the 21st century. Without significantly increased congressional oversight and a repeal of the damaging industry user fee legislation, both of which would signal a return to the necessary countervailing force that the Congress must exert against the pressures of regulated industries on the FDA, the 21st century will look more and more like the 19th.