

## THE FDA: AN AGENCY OUT OF CONTROL

By Byron J. Richards, CCN, February 9, 2007

The FDA is steamrolling its way to a grand vision of repressive health care based on profits for Big Pharma and new biotech companies at the expense of human health.

Human death means little to the FDA, permitting mass killings of Americans while protecting Big Pharma profits. This year the FDA is being given more money (federal funding up 5% to 1.5 billion) without any accountability or effective Congressional oversight. This means that instead of using the money to meaningfully improve drug safety, the FDA will carry on its pet projects that include forwarding the health component of the Bush administrations [North American Union](#), limiting health freedom by [harassing dietary supplement companies](#) so as to reduce access to safe and effective drug competition, and actively [turning the FDA into a drug company](#).

A current case in point is the heart bypass drug, Trasyolol, a medication often given so patients don't bleed too much during surgery. [A study published in the February 7, 2007 issue of the Journal of the American Medical Association](#) showed that Trasyolol was found to significantly increase the risk of death in the subsequent five-year period following heart bypass surgery. The data predicts that for the 246,000 Americans receiving this drug in 2005, over 19,000 will needlessly die in the following five-year period. FDA warnings in early 2006, weak as they were, curtailed the blockbuster growth of the drug, and it appears the drug lost about 20% of its sales compared to 2005. This means that roughly 15,000 Americans receiving Trasyolol in 2006 will needlessly die over the next five years because the [FDA twiddled its thumbs to protect Bayer from an avalanche of lawsuits](#), even while Bayer lied point blank to the FDA (the Justice Department should be investigating). You heard me correctly, the head of the FDA, Andrew von Eschenbach, made an administrative decision to leave Trasyolol on the market to protect Bayer, brushing aside a blatant Bayer cover-up. Of course, the problem is ongoing in 2007, exposing innocent Americans to unnecessary risk that is likely to result in an additional 1000 deaths per month (over the next five-year period).

Bayer was expecting Trasyolol to be its next blockbuster drug and was in Phase III trials to use the drug for all kinds of common operations (these trials were dropped in January 2007). While Bayer made \$291 million on the drug in 2005, the drug generated over 1.2 billion in treatment fees for the friends of Bayer due to all of its damaging side effects. This information was published in a January 2006 article in the [New England Journal of Medicine](#). The study showed that Trasyolol doubles the risk for kidney damage, causes 10,000 patients per year to require dialysis for life, increases heart attack risk by 48%, increases heart failure risk by 109%, and increases the risk of stroke by 181%. I mean really, what would you expect from a drug that promotes clotting in someone with clogged arteries??? Thus, since at least January of 2006 the FDA has had the data, heart surgeons have had the day, and Bayer executives have had the data. At what point does criminal neglect enter in to the picture? Following this information Bayer did its own independent study, hid the results from the FDA because they were so bad, and lied to an FDA advisory panel telling it that Trasyolol was safe (see link in previous paragraph). Yet, von Eschenbach still didn't take the drug off the market.

Trasylol has been on the market since 1993 with about 4 million users worldwide. Based on the statistical evidence in the new study, this translates to about 320,000 unnecessary deaths around the globe (almost half are Americans). What punishment is there for German executives who kill Americans? And what about the doctors who are well aware of Trasylol risks and use it anyway (never informing the patient)? What motivates them? How much is Bayer paying them in perks to use the drug? The Justice Department should be investigating. There are older drugs that are 1% to 4% of the cost of Trasylol, work by a different mechanism, do kill people, and do generate the additional billion or more in treatment costs each year.

Andrew von Eschenbach, as head of the FDA, has some serious explaining to do. Yes, this is the same Andrew von Eschenbach that was permanently appointed head of the FDA by the Senate in the lame duck session of Congress. Both sides of the aisle sold out American citizens (see [how your senators voted](#)), allowing the von Eschenbach appointment to go through (paid for by the Big Pharma lobby). The only Senator with any significant fortitude and honor was Charles Grassley (R-IA), whose Senate confirmation testimony regarding Andrew von Eschenbach on December 7, 2007 was accurate, frank, and to the point:

People ought to be ashamed of saying Dr. Andrew von Eschenbach has done a superb job in the position he is currently occupying [acting head of the FDA]. That is an insult. In my interactions with the Department of Health and Human Services and the FDA these last 8 months, I have seen a complete and utter disrespect for congressional authority and hence the law. This body [the Senate] should not walk hand in hand with the executive branch and sit idly by as instances of abuse and fraud continue to endanger the health and safety of American people. Under Dr. Von Eschenbach, the FDA has not only avoided transparency, it also has threatened those who are trying to desperately expose the truth.

America has huge problems with health care and the quality of care. Big Pharma owns both political parties and the White House. Big Pharma owns the FDA. The head of the FDA is now a Big Pharma biotech sales rep. Big Pharma owns the American Medical Association. Big Pharma sponsors numerous scientific journals as well as funds the research they publish. Big Pharma owns the researchers in many academic institutions. Big Pharma owns the pen and pencil of almost every doctor in America. Big Pharma owns the mainstream media, and will use it to downplay problems and openly attack dietary supplements (their only real competition). The FDA is headed on a path of becoming a full fledged drug company. Big Pharma is stealing the profits of corporate America and the wealth of American citizens through the creation of a sickness industry paid for by corporations and taxpayers, and fully sanctioned by the federal government. Yet, the American public is unable to act while Rome burns. It is truly a sad state of affairs, rotting away the very pillars of our democracy.

In order to have any faith in the human spirit I need to take the view that the American public is simply uneducated and that ignorance is bliss, from the point of view of Big Pharma. All I can do is try to inform. To do so I am taking the rather unusual step of publishing my expose book, [Fight for Your Health: Exposing the FDA's Betrayal of America](#), on NewsViews.com. Each week I will release a chapter or two, along with a few brief comments as to the current situation with any topics discussed in the chapter. If enough people actually comprehend what is going on we may be able to rise above the rather significant problems that challenge our nation. This is a gift; please pass it along to your friends.

Here is what you can do: e-mail me ([byron@truthinwellness.com](mailto:byron@truthinwellness.com)) your personal story of drug-induced side effects (yourself or a family member). I am particularly interested in stories about ADHD drugs, antipsychotic drugs, bone drugs, statin drugs, and blood pressure drugs although any story is fine. Please keep stories to 250 words, include your name and mailing address, and whether it is OK to publish your name. Each week I will publish some of the stories following my chapter. If I use your story I will send you a free autographed copy of *Fight for Your Health*. If enough Americans read the experiences of other citizens it may help break through the collective numbness that has been induced by the bombardment and reporting of war-related death and injuries on TV and in the media. This week I will begin with the introduction to *Fight for Your Health*, written in April of 2006. There is very little gratitude

in saying I told you so when the message is rather grim. Yet, every point brought forth in this introduction is closer to full implementation.

### **Fight for Your Health - Introduction**

THIS IS A STORY ABOUT HEALTH. It is not your typical health story; it is the real story of how your health and the health of your children are being seriously compromised.

This year the Food and Drug Administration (FDA) is celebrating one hundred years of service to the American people. It considers itself to be the guardian of public health. The safety of twenty-five percent of all products in use in the United States is under the watchful eye of the FDA.

The real story shows that the FDA has spent the last hundred years boosting the profits of drug companies and eliminating competition to those companies, acting as a misguided police force that has little to do with public safety. The trend has progressively worsened over the hundred-year period and reached a new low in 1992, when President William Jefferson Clinton allowed the FDA to accept millions of dollars in drug company money to help approve drugs, a practice that continues to this day.

The problems worsened in recent years, as President George W. Bush actually turned portions of the FDA itself into a drug company, responding primarily to the interests of Wall Street. He installed a new FDA chief and second-in-command who have multiple connections to drug companies and Wall Street (Andrew von Eschenbach, M.D., and Scott Gottlieb, M.D.). Public safety is low on the list. Citizens rights are low on the list. Rushing new and expensive unproven drugs onto the market is now a top priority. Of course, stamping out competition remains an important duty.

The quality and safety of health care are major concerns for Americans, especially regarding our children. Consumers actively look for the best options to maintain their health. Our society uses a combination of traditional medical and alternative approaches in an effort to harness the best of both worlds. This is all about to change; there is a new vision for American public health. It is a plan sponsored and promoted by the Bush administration, the FDA, and drug companies. It is based on the new politics of the emerging global economy, at the expense of personal health freedom.

### **Health Care for Profit**

Wall Street, international bankers, President Bush, pharmaceutical companies, new biotech companies, the Rockefeller empire, and the FDA have created a new plan for public health. It is a grand vision based on profit. It will use the FDA and, as needed, the Department of Homeland Security as the regulatory police force that ensures compliance in the name of public safety. Legitimate objections may be overpowered in the name of national security.

The definition of *terrorist* will be expanded to include American citizens who disagree with the governments plan. This is a new way to stamp out competition. Any person who speaks out against the plan could be harassed, because health care and national defense are now being connected through the threat of biological weapons.

One example can already be seen. If pandemic bird flu strikes (H5N1), the president already has in place laws that require the use of experimental treatments and/or vaccinations, with no legal recourse for people who might be damaged. Quarantines will be enforced in the name of public safety, deploying the National Guard and even the military forces against our own citizens.

What we are seeing is a blending of government agencies that relate to health care, biological weapons, and national security. Individuals simply protesting the ineffectiveness of government-sponsored health programs may find themselves talking to Homeland Security.

Many plausible reasons are given to support the new plan, most of them playing on public fear. Vested interests are spending billions of dollars on research to build this new plan, so it is safe to assume that there are plenty of strings attached, favors to pay, and claims already staked.

Fear is the weakness. Public safety is the excuse. Government-backed police power is the means. And the result is not improved health it is profit for the elite, at the expense of the health of the majority.

## The New Public-Health Plan

There is no need to guess at the nature of this plan. There is no need to hypothesize a grand conspiracy against the rights of individuals. The plan is being clearly and openly stated. The actions of government officials are consistent with what they are, in fact, saying. The plan is a matter of public record.

The new public-health plan amounts to a declaration of war on health freedom *and* the rights of people to receive the health care that is most likely to relieve their problems. Any doctors who *truly believe* in giving their patients the best possible care "the legal and moral obligation of every doctor "will soon find themselves joining the fight for health freedom.

The intention of those currently in control is that within five to ten years this plan will be firmly established as the model of future health care for Americans.

### The Plan:

1. The personal health data of all Americans will be registered in a national data base owned by the government. This will begin in the summer of 2006 with new bar-coded drug labels and will progress until the database includes every persons complete medical history.
2. By the time a child enters school, a comprehensive mental-health screen will be performed and appropriate medication will be dispensed, part of a national mental-health initiative. All data will go into the national database, branding a child for life. The pilot project for this step in the plan is called [TeenScreen](#) , already operating in 43 states.
3. A computer chip will be implanted in every American and be required in order to receive health services. It will contain a persons health history; it will be programmable (and prone to viruses and computer hackers), and it could have multiple other uses including tracking the persons whereabouts as desired by government agencies. Such devices are already approved by the FDA. One example, Verichip, is now being marketed to doctors and hospitals as the VeriMed Patient Identification System. As of March 2006, eighty hospitals and several hundred doctors were already signed up. In addition to storing data, it is a global positioning identification chip.
4. Doctors offices will become one large *clinical trial* for rapid deployment of new and unproven drugs and monitoring of existing drugs. This means a patient going to the doctor may receive care based on a new or ongoing drug trial, not on the best available care. In many cases, patients will be guinea pigs. The FDA considers this step to be their top priority for the next five years. It is called the Critical Path to Personalized Medicine Initiative. In 2006, it received its first federal funding.
5. Individuals will have no personal rights to sue if they are damaged by a drug. Protection currently offered to U.S. citizens by state law is actively being overturned by the FDA. The FDA is now working on the side of drug companies and against the safety of the people it is supposed to be protecting.
6. The DNA of every citizen will be on file with the FDA. Newly developed drugs, based on the new sciences of proteomics and nanotechnology, will require analysis of protein molecules based on the persons DNA and cellular function. Under the false guise of progress and safety, Americans will be conned into handing over their DNA to the federal government. This will lead to all manner of superiority/racial profiling based on DNA, promoting the new eugenics for the 21st century the Rockefeller dream.
7. New international patent laws are allowing large multinational companies, with the help of aggressive law firms, to control all meaningful life-science inventions. They are specifically trying to control patents relating to natural life processes in the body, as well as the processes by which nutrition and herbs work in the body (realizing these are oftentimes superior to current drugs). Beware of any company seeking patents relating to natural life function.
8. The availability of beneficial nutritional supplementation as a health option will be gone. Large drug companies, with

the help of various governments (including the U.S. government), are seeking to force companies selling high-quality nutritional health options out of business. Once gone, they plan to take over the business for themselves, restricting useful options that compete with best-selling drugs and jacking up the prices on what remains. They will also try to patent natural health options, turning them into expensive pharmaceutical drugs. The European example already shows elevated supplement prices for low potency and poor quality, a sign of things to come in America.

Each of these points is fully underway. Solutions are possible, but not if Americans fail to understand what is occurring.

### **The Attack on Natural Health**

The largest barrier to implementing this grand plan, which is actually a global plan, is the citizens of the United States. Americans currently enjoy more health freedom than any other country in the world. The alternative health-care industry is fueled by small supplement companies that promote safe and effective natural health options the true champions of the peoples cause. Under the pretense of public safety the FDA, Bush administration, and various congressional leaders are attacking alternative health care. This is a concerted and well-planned aggressive attack on health freedom in America, part of the global effort to control health-related profits. The natural-health industry is attempting to fight back. Despite overwhelming support by the majority of Americans, it remains an uphill struggle. On November 10, 2005, a bill was placed before Congress by Ron Paul (R-TX) as H.R. 4282, the Health Freedom Protection Act. This bill and any similar legislation need massive public support. What is the real reason the FDA is actively suppressing alternative health options? One of the values of nutrition is that it offers great hope with little risk. Drugs, not vitamins, are killing 100,000 Americans a year and sending 1.6 million people to the hospital with adverse reactions. High-quality alternative health options actually might help someone get well. Drug companies profit from people remaining sick. My extensive investigation into this issue shows that the FDA's actions are part of a much broader campaign to control health. The attack on the natural-health industry is intentional. It is part of a larger attack on many of your rights.

### **A Call to Action**

My goal has always been to help others. I have always sought to speak the truth. Now I have the obligation to expose the truth. I find myself with a new mission a duty and responsibility to help my fellow citizens in a much broader way. Your health and the health of your children and grandchildren are at stake. And the training of my life to be particularly suited to the task at hand. I am one of a handful of people who can actually explain to you how to regain healthy function of your body using natural options for health. I also have a background in advanced computer systems, as a pioneer in the field of artificial intelligence, enabling me to easily understand what the FDA is attempting to do.

I am a clinical nutritionist by trade. I have spent the greater portion of my working life exploring the details of psychoneuroimmunology and metabolism. I understand the nature of hormones working at the genetic level. I understand how the new science relates to nutrition. I have helped thousands of people regain or attain healthy function of their bodies. The battle for control of your health is now under way. It is time to understand the nature of the plan. The future well-being of our citizens is at stake.

I draw my sword in the form of a [book](#).