

## U.S. Health Freedom on Verge of Collapse

★ take action now

### Major Expansion of FDA Powers will Target Dietary Supplements

A new attack against health freedom, drug safety, and dietary supplements was launched last week by Senator Edward Kennedy (D-MA) with major support from Michael Enzi (R-WY). It is called the Food and Drug Administration Revitalization Act (S1082). This legislation was planned over the past few years working hand-in-glove with the FDA's dysfunctional management and legal team – meaning this legislation was written for the profits of Big Pharma and Big Biotech AT THE EXPENSE OF SAFETY AND HUMAN HEALTH.

S1082 is a Trojan Horse bill that *pretends* to address safety issues. Unbelievably, the bill turns the FDA into a drug development company that will expose Americans to new and dangerous biological drugs that have little testing to prove safety or effectiveness. And to top it off, the bill gives broad new regulatory powers to the FDA that can be used to frivolously attack dietary supplements and forward the FDA management's anti-American globalization agenda.

On April 18, 2007, S1082 was approved by the HELP committee (which Kennedy and Enzi control) and now moves to the floor of the Senate. In a slick move, Kennedy has attached his long-planned FDA/Big Pharma "reform" measures to the renewal of PDUFA (Prescription Drug User Fee Act). Current PDUFA law expires later this year and must be reviewed by Congress. PDUFA allows Big Pharma to pay the FDA fees to speed the approval of its drugs. The new Kennedy bill will increase these FDA bribes to 380 million dollars in 2008, well over 50% of the FDA budget for new drug approvals. This is like paying the mob for protection. Kennedy, by replacing the existing PDUFA law with this new bill (S1082), is ensuring that his twisted legislation is the one that will be put before the Senate for a vote.

### The FDA Drug Company, an Agency with New Regulatory Power

It is hard for anyone to comprehend that the agency that is supposed to be in charge of drug safety is about to become a drug company. It is astonishing that the FDA will now manage a full scale business activity that uses a "non profit" foundation as a shield to avoid international patent problems, protect proprietary rights of its commercial drug-development enterprise, and massively expands FDA regulatory powers to quickly remove anything from the market that is competition to its own products and licensing agreements.

This new FDA business enterprise is called the Reagan-Udall Foundation for the Food and Drug Administration (see pages 105-125). In previous versions of the Kennedy bill it was going to be an independent drug company within the FDA (the Reagan-Udall Institute for Applied Biomedical Research). In the current bill it is a "non profit" collaboration of the FDA, private industry, government funding, and private funding. It is run directly by the FDA even though it pretends to not be part of the government. Under this scam taxpayers will foot the bill for drug development and then be charged outrageous prices for the drugs. Furthermore, the new bill seeks to allow a massive expanse of FDA regulatory power through this new foundation. For example, on pages 106-107 the bill states:

"The purpose of the Foundation is to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety....The Foundation shall [take] into consideration the Critical Path reports and priorities published by the Food and Drug Administration, identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness, including post approval, of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics."

Through this foundation the FDA is seeking broad new regulatory power that it currently does not possess. This will include the authority to attack any dietary supplement (which are food ingredients) as unsafe based on its use of "Critical Path" technology. This means the FDA will use proteomics (the advanced study of proteins in biological systems) to assess changes in biomarkers (the change in the state of a protein at the molecular level) in order to establish whatever it wants to consider as a risk. The FDA can slant this technology, based on their own personal opinions, to make anything they want appear as a risk – including your favorite dietary supplements that you use to stay healthy.

## **Deceiving the Public**

This new bill panders to concerns of Americans regarding the safety of drugs. This legitimate worry is used by Kennedy and Enzi to garner support when in reality the bill does just the opposite - exposing Americans to almost unfathomable new drug risks and dangers while simultaneously making it possible to remove super safe, therapeutic, and helpful dietary supplements. The entire Critical Path initiative is a plan to race new and untested powerful biological drugs onto the market and experiment on patients all over the country – throwing caution to the wind as far as drug safety is concerned.

While S1082 also pretends to address the issues of drug safety, in reality all the needed Big Pharma loopholes are firmly in place. Additionally, the establishment of a clinical trial database as written in this proposed law will enable Big Pharma to hide experimental and undesirable side effects. Instead of full disclosure we will have a sterilized clinical trial database that will have the net effect of being used as a tool by Big Pharma to promote off label use of drugs. This is a far cry from disclosure that results in safety.

In response to the Kennedy con Charles Grassley (R-IA) immediately attacked the legislation on the floor of the Senate:

“The bill [S1082] does not address the outstanding critical problem that the office responsible for post-market drug safety lacks the independence, lacks the authority to promptly identify serious health risks and take necessary steps that will protect the public. As I think we all agree, the FDA is in desperate need of major overhaul.”

The problem for Grassley, and all Americans, is that his true safety reform measures for the FDA are being held hostage by the HELP committee which is under the control of Kennedy and Enzi. His proposed legislation is S. 468: Food and Drug Administration Safety Act of 2007 and S. 467: Fair Access to Clinical Trials Act of 2007. As Grassley told the Senate:

“Let me be clear: Big Pharma does not like these bills. FDA management does not like these bills. Lobbyists are spending hours upon hours lobbying against these bills...What is wrong with establishing a separate center within the FDA--not outside the FDA, within the FDA--with its only job being that of a watchdog for those drugs already in the market?...What is wrong with supporting a clinical trial registry and results database that also requires sponsors to reveal their negative trials?...I propose there is nothing wrong with any of these proposals.”

The situation is rather grave for all Americans. Kennedy has attached repressive legislation to replace the PDUFA funding thereby ensuring that his agenda will come before the Senate for a vote. The only real opposition to the legislation is coming from Grassley, who is attacking the weakness in FDA reform regarding drug safety and clinical trials. An even greater threat to the public – turning the FDA into a drug company and creating new regulatory powers that can be used to attack dietary supplements and remove them from the market – is being ignored by everyone – until now. Kennedy knows he can defeat Grassley and keep Grassley’s bills from ever seeing the light of day. Can Kennedy defeat the American public? Solving this problem is up to you.

## **The Secret FDA Agenda – Government Against the People**

The FDA is a puppet organization. Its management is a revolving door with Big Pharma, Big Biotech, and Big Agriculture. The behavior of its management team, set by its current leader Andrew von Eschenbach – but fully entrenched in its long and ugly history, is one of acting as a police-force bully to forward the profits of those with money and stamp out all competition (under the false guise of consumer protection). The FDA management fully believes it is above any law that is in its way or any attempt at Congressional oversight. It gives lip service to its safety mission. It is a cult unto itself.

The anti-American FDA is actively seeking to undermine U.S. laws and harmonize our dietary supplement laws with Mexico and Canada. This is being done through the Trilateral Cooperation Charter – an illegal agreement set up with health regulatory agencies in Mexico and Canada. It is part of the campaign towards a North American Union, one which would be a catastrophe for health freedom in this country as dietary supplement laws in Canada and Mexico are far more restrictive than in the U.S.

The FDA would also like to harmonize our dietary supplement laws with the evolving international standards set by Codex, thus branding therapeutic nutrition as dangerous and risky and needing to be sold by Big Pharma or removed from the market altogether (if it competes with a blockbuster category of drugs). Codex is planning to use the same proteomics and biomarker technology that will be used by the FDA’s Critical Path Initiative to remove therapeutic dietary supplements from the international market and force their policies on America, thereby superseding the sovereignty of American law on threat of trade sanctions. The FDA fully supports draconian Codex guidelines to regulate dietary supplements and is working with the Germans to concoct technology to brand nutrients as drugs. The FDA management is as bad as any government agency can get. Under the leadership of Andrew von

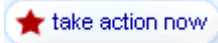
Eschenbach it has plummeted to an all time low.

## What You Can Do

1. Call, fax, phone, and write your Senators and tell them you are opposed to bill S1082 - Food and Drug Administration Revitalization Act. Tell them you want no legislation of any kind that will enable the FDA to frivolously attack dietary supplements. Tell them you do not want Big Pharma funding the FDA with user fees for drug approvals. Demand an independent office within the FDA to monitor drug safety. And tell them you want full disclosure by Big Pharma of all their clinical trials. Tell them you support the Grassley legislation (S467 and S468) which offers true reform of the FDA.
2. Tell your Senators you are completely opposed to any law that would enable the FDA to act as a drug company, such as S1082, which is proposing the formation of the Reagan-Udall Foundation for the FDA.
3. Sign this petition demanding congressional oversight of the FDA's Trilateral Cooperation Charter – a key point the FDA is using to illegally support the formation of the North American Union while at the same time undermining health freedom. This is the FDA's front line attack that undermines American law and seeks to harmonize us with the laws of other countries. We must win this battle to stop Codex and preserve our health freedom – including access to therapeutic dietary supplements and all alternative health options.

If S1082 becomes law and the FDA is allowed to enter relationships with foreign countries without any Congressional mandate or oversight we can kiss health freedom goodbye – as well as our dietary supplements. It is time for dietary supplement companies and trade groups to get their heads out of the sand and quit jockeying for position in the New World Order at the expense of the future well being of their own customers.

The issue of health freedom is an issue for all Americans who believe in our constitution and our founding documents. America is the last bastion of health freedom on earth. If we fall, the world will be plunged into a Dark Ages of health. Our future health will be dictated by a multinational sickness industry driven by profits for drug and biologic companies with little to do with real quality of health. This is a crossroads – a moment in time. Health freedom is fundamental to all other freedoms as without health freedom the minds and bodies of a population are easy to control.



**This article has been reprinted with permission from Newswithviews.com**

Copyright © 2007 Truth In Wellness, LLC All Rights Reserved

All Contents Copyright © 1995-2009 Life Extension Foundation All rights reserved.

**LifeExtension**<sup>®</sup>

These statements have not been evaluated by the FDA. These products are not intended to diagnose, treat, cure or prevent any disease. The information provided on this site is for informational purposes only and is not intended as a substitute for advice from your physician or other health care professional or any information contained on or in any product label or packaging. You should not use the information on this site for diagnosis or treatment of any health problem or for prescription of any medication or other treatment. You should consult with a healthcare professional before starting any diet, exercise or supplementation program, before taking any medication, or if you have or suspect you might have a health problem. You should not stop taking any medication without first consulting your physician.