Natural Solutions Foundation Educational Briefing Document

Congressional Choice: Health Freedom or Health Tyranny

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From the Desk of

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Re: Congressional Choice: Health Freedom or Health Tyranny

To the Members of the 110th Congress and National Decision Makers:

Summary: During the past three months supporters of the Natural Solutions Foundation – www.healthfreedomusa.org - have sent over a *half million messages* to Congress, the USDA and the FDA about health freedom issues. **This is what they complain about: FDA's Food and Drug Regulation Contaminate Each Other Causing Millions of Needless American Deaths. Food and supplements are regulated by the FDA for the benefit of industrial food producers and the pharmaceutical industry (with which they directly compete as effective, safe and inexpensive health strategies). Drugs are regulated for the benefit of the pharmaceutical industry. These two functions must be separated into two different agencies with continuing independent anti-corruption oversight.**

FOOD REGULATION

- **FDA is out of Congressional Control and is widely understood by the public to be an agency which fails to protect the Public Interest in both the regulation of foods AND the regulation of drugs.**
- **FDA regulates 1 trillion dollars worth of products per year, 35 cents of every dollar Americans spend.**
- **DRUG REGULATION hinges upon "User fees" paid by drug companies which account for most of the FDA's drug oversight operating budget**, formalizing the control drug companies exercise over FDA policy.
- Conflicts of interest between supposedly "independent and objective" scientists lead to self interested, unscientific decisions which allow **dangerous drugs on the market, killing more Americans with *properly used drugs* than the next leading causes of death**: cancer, cardiovascular disease and stroke, diabetes and obesity[1]Estimates range from Adverse Drug Reactions 106,000 deaths per year to, cost $12 billion to 420,000 annual deaths due to medication at a cost $200 billion annually.
- **FOOD REGULATION is controlled by, and serves, the supposedly regulated Agra Industry** to the detriment, (human and economic cost) of the American Public. **FDA has stated its determination to bring US food regulation into "HARMonization" with the international trade standards, "…in preference to US regulations…"** *Federal Register*, October 11, 1995) **promulgated by the World Food Code, *Codex Alimentarius*** ("Codex") **despite the fact that Codex standards violate numerous US laws**. **FDA consistently serves multinational, rather than scientific or public health, interests in the Codex deliberations** and, because of its perceived

leadership role, has served to degrade the international food supply even faster than the domestic one.

- **Codex-mandated under nutrition and toxification of the global food supply can be expected, to result in 89% of global deaths by 2020** according to a 2002 study by the World Health Organization and the Food and Agriculture Organization, **These deaths are largely preventable through adequate nutritional and agricultural practices, according to those same organizations.**[2]
- **In part because of the contaminated food supply, by 2020, 1 child in 2 faces the possibility of cancer before they turn 18.** 50 years ago, childhood cancer was virtually unknown.
- **FDA's Food Regulation consistently serves the industrialized food supply industries' interests while degrading wholesome food practices and standards.**
- **The FDA is directly responsible for the massive and deadly decline in America's health and the simultaneous increase in its illness care costs. Our health costs are the highest in the world: our health is the poorest in the developed world.**
- World Health Organization calls **cancers, cardiovascular disease, stroke, diabetes and obesity the "preventable, non-communicable epidemic diseases of under nutrition"**. [3] They are American's killer diseases which the FDA's food policies have allowed to become the primary sources of American suffering, death and health expenditure. **These nutritional diseases are most effectively treated by nutritional prevention and nutritional therapeutic responses. Where nutrition, not drugs, is used, morbidity, mortality and health care costs go down.**
- **FDA's continuing and irrational assault on nutritional and natural health strategies, wellness industry and drug-free health practices and products as protection for the interests of the industrialized food producers and the Biotech industry has driven US health to an all-time low and health costs to an all time high.** The US ranks 1st in per capita health care costs, 27th in life expectancy[4] and 36th in infant mortality.[5]
- This assault includes armed Federal Marshals with attack dogs and clubs, book burning, criminal intimidation and prosecution and other repressive techniques employed exclusively against natural health options and information **while the dangerous industrialized food supply and unsafe, ineffective drugs continue to kill Americans virtually without restraint.**
- **FDA consistently ignores public health hazards in approving industrialized foods**. For example**, FDA requires no safety testing on Biotech foods** whatsoever although their long term safety is highly suspect; **pesticide levels are permitted in foods which are well characterized as hazardous, especially to children**. Including the 7 pesticides condemned by the 2001 Stockholm agreement. [6]
- **FDA illegally manipulates labeling and related information to permit dangerous food components while withholding accurate information on food components and contamination** (e.g., forbidding labeling of genetically modified foods where they occur despite strong consumer preference to know such information, forbidding Prion testing by beef producers despite consumer demand for such information) while

suppressing information on the relationship of food and health (e.g., threatening to declare cherries an "untested drug" if independent scientific references about the success of cherry juice in treating arthritis was not immediately removed from the website of the Michigan Cherry Growers Association, issuing the recent Guidance on CAM Regulation which has the capacity to criminalize all non-drug health strategies including holy water, juices, massage, acupuncture, forbidding the labeling of milk which has been produce without artificial growth hormones, etc.)

- **FDA permits dangerous food additives and treatments, increasing industry profits while degrading the food supply and the health of Americans** including irradiation (leading to high levels of disease-promoting free radicals), the sub-clinical use of antibiotics (leading to multiply resistant microorganisms compromising human and environmental health), dangerous synthetic growth hormones, dangerous and cruel animal rearing and harvesting practices such as factory farming and non-physiologic animal feed such as offal, newsprint, egg shells and chicken bones for cattle, etc., leading to sick animals and the resultant illness of those who consume them.

DRUG REGULATION

- **FDA DRUG REGULATION is controlled by, and serves, the supposedly regulated industry to the detriment, human and economic cost of the American Public**.
- **Nearly every school shooter — students killing other students in school — in America was on long-term psychoactive medication at the time of the shooting.**
- **Foster children and prisoners can be experimented upon by drug and pesticide companies and their agents without informed consent,** in violation of the *Declaration of Helsinki*.[7]
- **FDA officials and scientists are repeatedly complicit in burying or withholding negative information on drugs** to permit and support their sale despite their human and economic costs.
- **A June 30, 2006 "Final Rule" removed the ability of Americans to seek compensation from manufacturers of harmful drugs and vaccines if the drug in question has been approved by the FDA for any purpose.[8]**
- **Direct to Consumer Advertising has resulted in vast increases in drug use by Americans** at great cost and huge numbers of side effects and deaths.
- **FDA and CDC have jointly presided over the use, proliferation and documented cover-up of unsafe vaccines** containing mercury, aluminum, formaldehyde and other neurotoxins while approving increasing numbers of medically unjustified vaccines (such as vaccinating children with mercury containing, medically useless flu vaccines to "protect" senior citizens who are also vaccinated with the same useless vaccines). The result has been overwhelming cost in care dollars, human tragedy and loss of vast numbers of productive citizens though a **totally preventable increase in autism from a rate of 4 children in 10,000 in 1970 to 1 child in 98 in New Jersey in 2007**. Other neurological diseases and disorders (which are treated with unproven, dangerous but highly profitable medications) have increased at even higher rates leading to the

drugging of huge numbers of children with dangerous drugs whose long-term effects are unknown.

- **Dangerous and unnecessary treatments, like the ill advised Swine Flue Vaccine and Human Papilloma Virus Vaccine have been rushed to market only to find that they are pose a huge marketing opportunity for their manufacturer along with little or no benefit and significant risks**.[9]
- **Effective competitors to pharmaceuticals (e.g., clean, unadulterated/organic food including high potency supplements and herbs) are ruthlessly attacked** and their purveyors are consistently attacked, especially when they make the connection between health and food explicit, even when supported by science.
- **Fast track approval of drugs generates ever more "User Fees" for the FDA (increasing its dependence on the drug companies) while putting more dangerous drugs on the market which are then withdrawn following preventable human suffering and death.**
- **Nutritional and other food-based strategies compete directly with drug strategies for dealing with diseases** substantially reducing the customer base of sick people (who buy drugs) by keeping people healthy or reversing the diseases of under nutrition which are currently the source of immense human suffering and staggering profits for the drug companies.
- **Conflict of interest in favor of drugs against foods currently requires the FDA to preside over the active degradation of the food supply, including the subclass of food known as "dietary supplements" in order to protect both the industrial food supply interests and the industry which clean foods directly threatens: Big Pharma.**

CONCLUSION

The Natural Solutions Foundation and its hundreds of thousands of supporters, along with the at least 210million Americans[10] Americans who rely on dietary supplements urge that Congress correct the basic error of the 1938 legislation which set up the FDA as an agency which regulated both food and drugs and create a new federal agency for the sole purpose of regulating foods. This new agency would have a separate anti corruption unit within it responsible for IG oversight to ensure that no regulator or scientist had any conflict of interest and that consumer advocates controlled the agency's activities in a transparent and effective fashion.

We urge Congressional hearings and legislative action on this critical issue bearing so strongly on the health, wealth and survival of the American people.

INTRODUCTION

During the past three months supporters of the Natural Solutions Foundation – www.healthfreedomusa.org - have sent over a *half million messages* to Congress, the USDA and the FDA about health freedom issues. Of these, 197,000 individual messages went to the FDA regarding its

recent "Guidance" about complementary and alternative healthcare modalities (docket 2006D-0480). Hundreds of thousands of health freedom supporters have signed onto the Natural Solutions Foundation's Health Freedom Alert and are ready to make their voices heard to agencies and to their congressional representatives "at the drop of a mouse..."

The So-Called "FDA Revitalization Act"

The House and Senate are currently conferencing the so-called "FDA Revitalization Act" - HR 2900 and S 1082. This legislation is not likely to solve the problems of the Food and Drug Administration; throwing more money and more bureaucracy at the problems caused by bureaucracy hardly ever does, but this new law is likely to further erode Americans' access to wholesome nutrition and natural remedies.

Because hundreds of thousands of citizens made their views known to their Federal Government, the Senate, without dissent, added language to S 1082 protecting products already regulated under the Dietary Supplement Health and Education Act (DSHEA) from certain provisions of the act. The House did not adopt similar language. We strongly support the retention of Section 608, the DSHEA protection language, whether or not Section 6, on food safety, remains in the final bill. Better yet would be the adoption of the Health Freedom Protection Act, HR 2117, which would assure Americans that we could receive truthful health claims information from nutrient purveyors, despite FDA efforts to prevent that exercise of free speech. The better solution for the FDA's failure to protect the food supply is to remove all food regulatory authority from the agency.

Liberty Coalition Letter: Call for Real FDA Reform

Natural Solutions Foundation's supporters have further concerns. On July 30th the Liberty Coalition delivered a letter to the chairmen of the health committees of both houses of Congress, signed by organizations representing millions of citizens. That letter supporting the retention of Section 608 states, in part.

> "Recently FDA issued two draft Guidances: the so-called "CAM Products" (Docket No. 2006D-0480) and "Health Claims" (Docket No. 2007D-0125) that also impact DSHEA products. The first tries to create a new regulatory category - *without* Congressional approval, while the second places a heavy burden on proof of health claims. These FDA Guidances could have dire and deadly health and freedom consequences since high potency nutrients are a well-demonstrated health protection strategy which

lowers morbidity, mortality and health costs."

The Natural Solutions Foundation, seeking to inform Washington decision makers about this threat to public and individual health, has criticized both of these guidances. We agree with Dr. Ron Paul are there any others? who called the CAM guidance "...an abuse of FDA power..." and call for further protections for nutrients and natural remedies. HR 2117 would make the Health Claims guidance moot and enhance consumer access.

Just as Congress did unanimously in 1994, when DSHEA was adopted, Congress needs to intervene and *really* reform the FDA. The bills that passed this session, assuming they survive conference, will not accomplish meaningful reform, especially in the area of foods. It is time to re-evaluate the entire structure of the FDA. We believe a mistake was made in 1938 when the FDA was empowered, combining oversight of foods with that of drugs in a single agency. The combination led to a confused and confusing bureaucracy which under values the role of food in health and is far too supine to the interests of the hugely powerful pharmaceutical industry. Our contacts with Members and their staffs convince us that there is real interest, among all parties and ideologies, for real FDA reform and a new approach to food (including dietary supplement) safety its value in health promotion.

Adopting HR 2117: The Health Freedom Protection Act

A good first step to real reform would be the adoption of HR 2117, supporting free speech in health claims. In the leading case of *Thompson vs. Western States*, 2002, Justice Sandra Day O'Connor stated: "If the First Amendment means anything, it means that regulating speech must be a last - not first - resort ... We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information."

The FDA is conducting the world's largest health experiment on the American people, without either their knowledge or consent. In the absence of any safety testing or review, it permits genetically modified (GM or "Frankenfood") in America's food supply and explicitly refuses to allow it to be labeled as such since it says that the truth would "mislead" consumers who would not eat GM food if they had a choice about it. GM food safety has been questioned scientifically; however, be that as it may, by withholding truthful information on what is, and what is not genetically modified, the FDA is simultaneously adulterating America's food supply and taking away the right of Americans to choose

whether they want to be part of an experiment for which they have not signed up and which may, in the long run, cost them their lives, the right to have children, give them cancer and poison the environment for all future generations - we just don't know yet. The same reasoning applies to the FDA position on irradiation of foods without notice to the consumer; or to the USDA's recent decision to permitting 38 non-organic ingredients while still allowing purveyors to label the products (sic) "organic." Not only are these agency biotech-friendly decisions dangerous, they are also illegal since withholding this information is against the law in this country. ??? Says who. These are yet more abuses of FDA power and the power of the other national and international agencies involved.

Americans understand that government agencies increasingly invade personal decisions, taking custody of children away from parents who do not want to vaccinate or medicate them and forcing drugs on the elderly and other vulnerable populations. They resent secret government access to their medical records under HIPPA and homeland security provisions which allow the government to invade their lab results and other records, checking up on diabetic's blood sugar levels, for example and identifying doctors who do not prescribe potentially dangerous drugs as "practicing substandard care" while paying them less money for their supposedly "substandard" treatment preferred by patients.

Americans are angry that the FDA and EPA have canceled their right of informed consent about human experimentation for certain powerless populations (e.g., prisoners, children in foster care) and whole populations (as long as there is secret notification of local police forces 30 days before exposing Americans to radiological, biological, frequency chemical or other experimental hazards). Forced vaccination is another example of experimentation in violation of the Declaration of Helsinki.[11].

Health Freedom is an issue that is supported by a majority of Americans; they want a new pro-freedom policy at the FDA, USDA, EPA and other government agencies which are currently threatening both the health and the freedom of Americans. Protection by Congressional enactment would mean that Americans would no longer be forced into compliance with international agencies, such as the *Codex Alimentarius* (World Food Code) serving corporate agendas, and denigrating organic standards, allowing increased levels of toxins in the international food supply in the process. We would, by adopting HR 2117 and similar laws, declare our independence from Codex and similar international mandates and, once again, lead the world toward greater personal choice in health care by the example of the freedoms our people will enjoy.

The Codex Two Step Process

This process is what the Natural Solutions Foundation calls "The Codex Two Step." *Codex Alimentarius* - the World Food Code - is a UN agency under WHO and FAO. It sets international food standards and guidelines regarding food safety and food trade. The guidelines are, under the Codex Statute, advisory only. Many health conscious countries want to support standards that are stricter than Codex might allow; others want to defend traditional foods and remedies; some countries may want to allow their citizens more freedom of choice in what they eat and how they care for their own health.

However, Codex rules are enforced through the World Trade Organization (WTO) which says Codex rules are "presumptive" evidence of the standards for decisions. Nonetheless, the WTO has refused to make Codex the sole rule of decision. In the event of a WTO dispute, if a country has not designated another standard, Codex applies. So, what is the Codex Two Step? It is the legal strategy Natural Solutions Foundation has devised to protect health friendly nations' traditional foods and remedies and American's freedom of choice.

How does the Two Step work? A country adopts its own food and health guidelines that may vary from Codex. That country then adopts science-based law enforcing its own guideline (somewhat like the US has done with DSHEA... but for a little snag we will discuss later...) - Natural Solutions Foundation has prepared model guidelines and laws for countries to use. What happens, then, if there is a dispute in the WTO involving foods and health? Since one of the countries has adopted its own guidelines and law, the WTO presumption regarding Codex standards and guidelines does not apply. Instead, the WTO judges by the science behind the dispute and each country will be judged based upon its own science-based law - a country cannot be penalized if its science is as good as the complainant's science.

No to HARMonisation! Yes to a New Start for Food Regulation!

The snag in US regulation is that the FDA declared, in an October 11, 1995 Federal Register announcement (60 FR 53078) that it would "harmonize" US law and regulation with international standards... and Congress and the people be d-----d! So, except for a very limited extent through 19 U.S.C. 3512 (the Uruguay Round anti-harmonization act) we are not protected from forced harmonization and only Congress can act to close the loophole in US health sovereignty.

And that is why the "FDA Revitalization Act" is not going to satisfy the American public. Congress must use the opportunity presented by HR 2117 to protect the health of the American people and that is our message to Congress today. The final adoption of the FDA Revitalization Act should be

delayed; hearings should be held and careful consideration should be given to HR 2117, The Health Freedom Protection Act and other measures to protect the health freedom of Americans. **It is time to really reform the FDA and free food regulation from this failing agency; the American people expect nothing less and by the thousands and hundreds of thousands are telling Congress just that.**

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