DRACONIAN RULES FOR SUPPLEMENTS PENDING: DSHEA REPEAL AND OBAMA'S 2011 BUDGET FOR FDA

The Athenian statesman Draco institutionalized a wide-ranging and harsh code of laws for governing and creating the moniker of Draconian rule. Thirteen centuries later, democratically-elected governments, including the United States, are not immune from command-and-control governance. Democratic-Party-controlled Congresses in lockstep with Democratic Presidential Administrations have a political history of taxing more, spending more, and expanding Federal control over citizens' rights and the exercise of individual freedoms. Republicans, in turn, have not been much better, since they have either timidly acquiesced to such power expansions or actively participated themselves.

Repealing DSHEA

The conventional political legislative thinking was that the Waxman, Dingell, Pelosi, Durbin, and Harry Reid anti-dietary supplement axis would seek repeal of the 1994 DSHEA law. Instead, Senators John McCain and Byron Dorgan have introduced S.3002, the so-called "Dietary Supplement Safety Act of 2010" (DSSA). At the time of this writing, they are the only two bill sponsors. However, it doesn't take a rocket scientist to figure out that this bill can be taken and introduced by Representative Henry Waxman and company and with Dick Durbin's help in the Senate, and Democratic control of House and Senate legislative procedures, Congressional passage could very well occur.

The NHF very strongly opposes this bill and is actively engaged with other health freedom groups in communicating our opposition to Senators. NHF members and other readers of this report are strongly encouraged to go to the NHF webpage at *http://www.thenhf.com/press_releases/dietary2010_petition.htm* and sign a Petition that will be timely delivered to the U.S. Senate. More than that, get your friends, acquaintances, and family members to sign this Petition as well.

McCain's bill highlights the mindset at the FDA, also dubbed the Fear and Denial Administration. The 1994 DSHEA law protects supplements (1) if they are food products that have been in the food supply and not chemically altered, or (2) if they were sold as supplements prior to October 15, 1994, the date that DSHEA was passed. If a supplement fits one of these two descriptions, the FDA cannot arbitrarily ban it or reclassify it as a drug. The Dietary Supplement Safety Act (DSSA) would eliminate these supplement protections contained in DSHEA. It would grant FDA arbitrary authority to draw up a list of what supplements can be sold and at what potency levels. This fits in very nicely with what has been happening in Europe, which is currently limiting both supplements and potencies. If DSSA passes, the FDA, beholden as it is to drug interests, would move to do exactly the same thing in the U.S.

The purported emergency giving rise to the need for DSSA is the issue of the safety of supplements that may contain anabolic-steroid ingredients, and illegal steroid use by professional and amateur athletes. The bill attempts to address products produced by non-FDA compliant companies and distributors, the so-called body-building supplements, marketed without FDA registration and reporting. The bill lumps "good" players into the "bad" players category, but it significantly misses the mark on other measures. These legal loopholes and misguided steps are too numerous to go into in this article. But, millions of supplement users who depend upon "good players" for safe, effective, and FDA-compliant supplement products, are being asked to pay the human and financial price for what the US Anti-Doping Agency (USADA) wants, because the

Drug Enforcement Agency (DEA), which has jurisdiction over controlled substances, including anabolic steroids, and FDA bureaucrats cannot do their respective US taxpayer-funded jobs. Or, perhaps more cunningly, the FDA has sat back and allowed this all to happen, for just this moment.

As politicians are inclined to do, the DSSA is a classic example of "don't confuse the issue of dietary supplement safety with the facts." Federal bureaucrats cannot do their jobs, so Congress should give them more authority and repeal current laws, the DSHEA and the Dietary Supplement and Non-Prescription Consumer Protection Act (Public Law 109-462) because they are also not effectively being administered. What are some of the facts that show how ridiculous the claims being made for S.3002 are? For example, in 2009, the FDA removed over 30 illegal synthetic steroid-containing supplements from the market. Why did they take until 2009 to use the powers already given to the FDA under DSHEA over 16 years ago? The supplement industry requested FDA help and guidance on New Dietary Ingredient (NDI) processes and standards for supplements in 2004, but six years later the FDA still has not given any guidance to the industry to help it police itself.

The Dietary Supplement and Non-Prescription Consumer Protection Act of 2007 established industry reporting of serious adverse events for supplements. The NHF opposed this law for a number of reasons, one of which was that adverse event reporting would be the camel's nose in the tent for more serious regulations later. In 2008, the FDA received only 1,080 adverse event reports relating to the use of millions of dietary supplements sold in the United States, all of which are currently regulated. In the same time period, there were a total of 526,527 adverse event reports stemming from the use of prescription drugs. According to Senator McCain's press release, the need for the DSSA is because six NFL players could not read supplement label ingredients, or perhaps they intentionally took supplements containing an anabolic steroid ingredient. These six represent less that one-half of one percent (0.40%) of the 1,696 active NHF players. Some baseball players have also been found guilty of taking steroids. What is wrong with the public-policy impact picture?

Again, millions of dietary supplement users, and legitimate companies are to suffer lack of access and higher prices based on the inability (or even outright refusal) of Federal bureaucrats to do their jobs under current Federal law. The idea that the more than 150 million Americans who use dietary supplements are gambling with their health by shopping at mainstream stores just doesn't stand up to scrutiny. Senator McCain's hyperbole does not lead to sound policy. This bill would further stack the deck against small supplement companies by creating new, unnecessary, even more cumbersome, and of course very expensive administrative hurdles. If enacted into law, this bill would result in the use of "science based" medical evidence as a condition for safe marketing to the public. This is a long and contentious matter in that there are no standards or definition of science applicable to supplement safety. The bill would lead to the consolidation of the supplement industry into a few big companies selling many fewer supplements at much lower doses, but with higher product profit margins. These companies would likely be acquired by big drug companies. In short, our health freedoms of choice regarding supplements would be under Draconian rule by the FDA. The drug-company cartel will have succeeded.

In the years leading up to 1994, consumers overwhelmingly told their elected officials that they wanted access to dietary supplements and trusted their own judgment to make informed decisions about which supplements are right for their needs. This uproar led to the passage of DSHEA. Now is the time for NHF members to do this again on S.3002.

Health Care Reform

At the time of this writing, the scope and policy particulars and final passage of health-care reform legislation are on hold, as the whole country knows. What has become clearer with time is that the United States cannot afford to pay the bill for the health-care plan that Pelosi and Reid tried to ram down our throats last December.

It is my belief that some form of legislation will be passed, but it is an open question on whether the Pelosi version of a Federal takeover of health-care choice versus the Reid version of less control, or a version that is closer to Republican versions of insurance market reforms will be worked out and passed. Time will tell as events more forward. You can keep abreast of things on the NHF website at *www.thenhf.com*.

More FDA Control and Bureaucratic Spending For 2011

The 2011 Obama Budget takes funding of bureaucracies to a whole new level, especially with regard to the FDA and its regulatory control over nutritional foods and dietary supplements. Every year, each President's budget request to the Congress includes an Agency or Department Appropriations Justification document, including a separate document for the FDA. The FDA Justification spells out how much money the Agency wants and what those monies would be used for, should Congress approve. To put the continued expansion of the command-and-control FDA into some perspective, in 2001, the FDA Justification document was just over 100 pages. The 2011 FDA document is now over 600 pages. The type size has not changed.

The Obama Budget for the FDA for 2011 adds significant spending increases. For example, the total budget

for the Agency, if approved by the Democrat-Party-controlled House and Senate, will be over $4 billion dollars. Yes, billion. This is an increase of around $750 million over the program level spending in 2010. It includes the hiring of 1,251 new Full Time Equivalent (FTE) bureaucrats, increasing the total FDA bureaucratic work force to 13,586 people. Remember, these are non-productive bureaucrats generally acting as a huge drag upon the productive elements of our economy.

The payroll expense alone for these bureaucrats is also increased by $146 million dollars over what the FDA army of bureaucrats are being paid this year. To be fair, only $66 million of this amount is for the mandated civil service pay raises. In par with other labor market projections for the currently down economy, Washington, D.C. and the Federal government are hiring while millions of others cannot find jobs. The FDA is making a pretty good contribution to the continued expansion of the Federal government under the Obama administration. And, with regard to the Federal budget freeze touted by the President to reduce the current 14 trillion-dollar debt, it would apply only to the 2012 budget.

The Center for Food Safety and Applied Nutrition (CFSAN) within the FDA regulates and controls conventional foods, nutritional food products, and dietary supplements, i.e., it is supposed to enforce DSHEA. In 2009, the CFSAN work force was 795 bureaucrats at the College Park, Maryland headquarters. For 2011, the Obama administration is requesting at total of 1,186 FTEs, or an increase of 391 new bureaucrats in just over three years. For CFSAN spending on monitoring and regulating dietary supplements (page 490 in the 2011 Justification), the FDA is only requesting a one million dollar increase to just over $18 million dollars per year. The cost for the new bureaucrats is not included, this is just for program operations.

On the food component of the FDA's budget, justification for spending, the pending Congressional Food Safety Modernization bills, S.510 and H.R.2749, come into play with regard to the FDA's projected revenues from new food registration and inspection fees and final Congressional passage. The NHF opposed both bills, but lobbied successfully to get exclusionary language on Codex and supplements included in the Senate bill. The House bill also included language to exclude the application of registration- and inspection-fee requirements on small nutritional/organic food growers. The Senate has, at the time of this writing, not yet voted on S.510; and a joint House Senate Conference Committee has not met to resolve fairly minor differences between the two bills. Both bills establish the collection of "user fees" supposedly on large conventional food manufacturers and foreign food importers.

In the 2011 budget justification sent to Congress, the FDA has already proposed collecting $220 million dollars for the "Transforming Food Safety Initiative." So, the FDA has the cart backed up for more money before the legislative horse is even in place to pull the cart. And, of course, the Agency is also asking for 718 bureaucrats to run the Initiative. Congress has not even given the FDA the authority yet to collect registration and inspection fees, but FDA is expecting this to happen. It probably will, but still.

Kicking the "Supplements Should Be Foods" Can Down the Road

Also in the Justification document is an issue first raised in the Winter 2008 issue of *Health Freedom News* (Vol.26:4), that is, the possible prohibition of interstate shipment of supplements. At that time, the FDA had published a Notice of Comment for Proposed Rulemaking on whether the interstate transportation of dietary supplements should or should not be exempted from the definition of prohibited food products subject to illegal interstate commerce. In the 2010 FDA spending bill, the Senate Appropriations subcommittee directly requested the FDA to dispose of this issue and explain why it would even consider this course of regulatory action when supplements are clearly regulated under the Dietary Supplement Health and Education (DSHEA) law.

The NHF has consistently opposed any FDA efforts to exercise its arbitrary powers over people's rights to exercise their own independent judgments on health-freedom-of-care choices. In this case, this means opposing FDA's circumvention of DSHEA in an attempt to regulate supplements as conventional foods.

The response by the FDA in the Justification is that it is still working on draft options that will address the requested disposition of the issue, and that the FDA's implementation of its decision will depend in substantial part on the available legal analysis. It has already been 18 months since the FDA's own deadline for issuing its decision.

In and of itself, the response is par for the course for FDA delay. Raise an issue that it may take action against the interstate shipping of supplements, put dietary supplement users, manufacturers and suppliers in regulatory compliance and access limbo, not to mention fear, and all the while pay bureaucrats generous salaries with taxpayer dollars to do nothing. Even in currently favorable Congressional legislative atmosphere for doing whatever the FDA wants, until the FDA complies with the Senate request, it will cause an issue when the FDA Commissioner, Margaret Hamburg, testifies before the Senate spending subcommittee, or it could hold up approval of the 2011 Senate appropriations bill.

There are many Congressional bills that the NHF supports and opposes under consideration. These can be viewed on the NHF website at *http://www.thenhf.com/government_affairs_federal.html.*