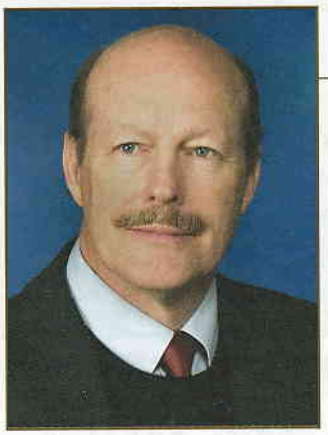

IF ONLY JOHNNY COULD READ

By Scott C. Tips

"There is nothing more frightful than ignorance in action." – Johann Wolfgang von Goethe

Only a few short weeks after introducing his so-called "Dietary Supplement Safety Act," Republican Senator John McCain was already feeling the heat – so much so that, like Custer at the Little Big Horn, he felt compelled to dismount his high horse and defend his hugely mistaken foray into hostile Native territory. Short of ammunition and evidently just as shy on literacy, Johnny McCain issued a Senate Floor Statement that accused his opponents of the very faults he himself is displaying.

"[O]pponents to this bill and their well paid Washington lobbyists," his Senate Floor Statement of February 22nd dissembled, "have spread false statements and rumors about the legislation, which is really a disservice to consumers, and instead proudly boast that they remain largely untouchable by the Food and Drug Administration (FDA). This legislation," it continued, "would simply require dietary supplements to list all ingredients on the packaging, mandate that all dietary manufacturers register with the FDA to ensure the FDA knows what is being sold and provide the FDA mandatory recall authority of any dietary supplement if the FDA finds the supplement to be hazardous to one's health."

It is sad enough that Senators in Washington, D.C. rarely read other Senators' bills before voting on them, but when they do not even read their own, or worse do not even understand what they have read of their own, then it is long past time for that politician to perhaps take that overdue remedial reading course. Or, as John McCain has just done on March 4th, admit that he has made a mistake and withdraw support from his own bill.

How It All Began

There are bad actors in any industry. Just look at the U.S. Senate. Yet, somehow, because the dietary-supplement industry has long been an increasingly competitive thorn in the side of the pharmaceutical industry, its few bad actors can be used to justify the harshest draconian clamp-down by the best politicians and regulators that drug money can buy. Never mind that properly-approved drugs and state-licensed medical doctors and hospitals kill nearly one million persons a year, "dangerous" and "unregulated" dietary supplements that cause fewer deaths and injuries every year than bee stings or even lightning strikes must be *regulated*. Of course, the long-standing fact that supplements *are* already regulated and that the FDA already possesses the authority and power to track down and eliminate the bad actors is rarely, if ever, mentioned by the mainstream media.

So it was that the Senate Committee on the Judiciary Subcommittee on Crime and Drugs held a hearing last September 29th to discuss the problem of "enforcement barriers" to body-building products and hidden steroids within them. A dog-and-pony show of witnesses favorable to increased drug-like regulation of the supplement industry was put on for the subcommittee, with witnesses from the FDA, the Drug Enforcement Agency and the World Anti-Doping Agency. (See here *http://judiciary.senate.gov/hearings/testimony.cfm?id=4081&wit_id=8223* and *http://judiciary.senate.gov/pdf/09-09-29%20Tygart%20Testimony.pdf*.) No one, to my knowledge, appeared to testify to the contrary. The impression given to the subcommittee was that existing laws and powers were inadequate to rein in designer steroid drugs and that the Dietary Supplement Health and Education Act of 1994 (DSHEA) was to blame.

The Final Solution

Ostensibly because some highly-paid professional as well as some amateur athletes took dietary supplements that were illegally spiked with steroids, Senators John McCain (R-AZ) and Byron Dorgan (D-ND) introduced their Senate Bill 3002 on February 4, 2010, to require: (1) comprehensive registration of ***all*** manufacturers, distributors and holders of supplements; (2) prohibition of sale of any dietary supplement ***not*** on an FDA-approved positive list; and (3) burdensome reporting of each and every adverse event, whether serious or trivial, affecting dietary supplements. (See the bill text itself at *www.thenhf.com/government_affairs/federal/s3002billtext.pdf*.)

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Looking at its disparate elements, S.3002 clearly constitutes overkill. As the Washington, D.C. Law firm of Venable LLP has pointed out, the bill would impose *significant* administrative and compliance requirements on the dietary supplement industry, the costs of which would be passed on to consumers, including the following.

A dietary-supplement facility (meaning "any business or operation engaged in manufacturing, packaging, holding, distributing, labeling or licensing a dietary supplement for consumption the United States") would be required to register with the FDA and disclose all of its trade names. It would also have to file a list of all supplements manufactured, packaged, held, distributed, labeled or licensed by the facility with all of their ingredients and a copy of the labeling for each product (Section 2(b)(2)(B)(i), p. 3–4). Note that under this definition, even an individual multi-level marketer would have to register as a "dietary-supplement facility."

The dietary-supplement facility would then have to update its registration annually, and update its registration of any new dietary supplements or reformulations of existing supplements on or before the date it is marketed (Section 2(b)(2)(B)(ii), p. 4).

Importantly, the proposed legislation changes the definition of the term, "new dietary ingredient." A new dietary ingredient would henceforth mean any dietary ingredient that "is not included on the list of 'Accepted Dietary Ingredients,' to be prepared, published, and maintained" by the FDA (Section 2(c)(2), p. 5–6). The bill does not provide any guidelines or guarantees as to which ingredients would be placed on this list. This provision could have significant consequences if enacted since a large majority of ingredients that are now considered "grandfathered" could be considered "new" and subject to the notification provisions. To my mind, the "Accepted Dietary Ingredients" list sounds suspiciously like the overly restrictive European Union's Positive list for accepted vitamin and mineral food supplements. And I can almost guarantee you that if it does not start out as an all-encompassing positive list, then it will end up that way.

For any supplements containing new dietary ingredients, the bill further requires that any person submitting information to the FDA must maintain a scientifically-reasonable substantiation file relating to the dietary ingredient's safety. The dietary-supplement facility or *retailer* must obtain adequate *written* evidence from the preceding responsible entity that the product is registered and the information-submission requirement for new dietary ingredients has been met, and maintain such compliance records for inspection by the FDA (Section 2(c)(3), p. 6).

Amazingly enough, McCain also wants every single manufacturer, packer, holder, distributor, labeler, and licensee of a dietary supplement whose name appears on the product's label to submit each year to the FDA a compilation report of *all serious and non-serious adverse events* associated with the use of the product in the United States! The Bill fails to define what a non-serious adverse event even is, making it possible that reporting would be required for everything from a cut finger while opening the bottle to a consumer's objection to the smell emanating from an opened bottle. Evidently, the FDA was not receiving enough adverse event reports on supplements before, so this is its way to increase the numbers – report everything! Unfortunately, taxpayer-funded bureaucrats would then have to sort through non-serious adverse event reports when they could be doing far more-important tasks. Reporting of serious events is already required under the law; and, as previously predicted, the law that mandated that camel's nose in the tent is the precedent allowing this follow-up nonsense.

Of course, with these increased regulatory demands go increased regulatory penalties. In addition to other penalties, non-compliance could bring a civil penalty of twice the gross profits or other proceeds derived from the sale of the dietary supplements (see Section 2(d), p.7).

And with that considerable financial club, the FDA would be given a second hefty club: the power to make its own, arbitrary determination that there is a "reasonable probability" that a dietary supplement would cause serious, adverse health consequences or death, or is adulterated or even just misbranded. In those cases, the FDA could immediately order the company to cease distribution and to notify others of the FDA order with instructions to stop their own sale and use of the product (see Section 2(f), p.9). The FDA already has the power to halt the sale of any dietary ingredient that risks illness or injury, can get an injunction blocking the sale, and can prosecute those responsible. But McCain's bill encourages abusive and arbitrary use of this extended regulatory power by the FDA since it lacks normal, due-process requirements. Any FDA stop-order could remain in effect *for years* before there is a trial on the merits, making it very costly for any company to contest it.

This hodge-podge bill supports Milton Friedman's contention that the government solution to any problem is usually at least as bad as the problem itself. McCain's solution is no solution at all, just a gimmick for his re-election campaign into which DSHEA-restrained bureaucrats could join in their own bid for more power.

The Real Solution

Now, suppose, as scientist and author Durk Pearson has done in an alternate scenario, that after the failed attempt of Richard Reid (the terrorist shoe bomber) to blow up a transatlantic airplane, the government had reacted in the same way as McCain is proposing to do now.

That is, did Reid's attempt mean that the United States needed to register shoe stores and shoe salesmen? Did it mean that the United States needed to create more regulations on shoe manufacturers? Did it mean that all new shoe designs had to be approved before sale by a shoe-design czar? Did it mean that the shoe-design czar had to have recall authority over all shoes?

No, of course not! What could be sillier? It simply meant that more testing needed to be done at airports to make sure that people were not walking onboard airplanes with bombs on their feet disguised as shoes rather than with legitimate shoes. Had the government followed the McCain "solution," the law would have done nothing to prevent the next bombing attempt. Shoe bombers would have simply ignored the restrictions, violated the law, and walked onboard airplanes with already-illegal explosives in their shoes.

If McCain's intentions had been truly honest, and if his bill were not simply a pure power grab or an effort on behalf of wealthy special-interest groups, then the government would test for anabolic properties all of those products advertised to increase muscle mass or size. This kind of testing would not interfere with legitimate dietary supplements.

How do you test for new synthetic anabolic steroids? Durk Pearson suggests that you put out a bid for a test that costs under $10 per analysis and that quantitatively measures the activation of the human testosterone and dihydrotestosterone receptors on genetically engineered bacteria. If the material has testosterone-receptor activation properties stronger than 0.1% of testosterone, it is banned as an ingredient in dietary supplements. If it doesn't activate the human testosterone or dihydrotestosterone receptors, then *it is not an anabolic substance.* Use existing laws that the FDA has already been slow to enforce. End of problem.

Useless Law

The 18th-century French philosopher and satirist the Baron de Montesquieu once observed, "Useless laws weaken the necessary laws." S.3002 is one such useless law, which, by way of just one small example, would divert regulators' attentions away from those serious adverse events hidden within an ocean of trivial "adverse" events. It also creates many senseless compliance requirements that take companies' time and attention away from real quality control.

Rather, all this useless law would accomplish is to weaken the economy and health of the United States and its population. To save a handful of well-paid athletes, McCain's scattergun approach would instead seriously harm the health of millions of supplement users and erase from the health world many existing supplements as well as most of those as-yet-to-be-discovered supplements. It is absolute madness and typical for our times where no good bills are ever passed, only bad ones.

Broken Law?

If John McCain is keen to stop lawbreakers, then perhaps he should just turn around and look at his own supporters. Are any of them in violation of the law? We do not know, but as the National Health Federation's lobbyist, Lee Bechtel, has noted, "The U.S. Anti-Doping Agency (USADA) receives $7 million in a direct Federal grant and an additional $3 million from a contractual agreement with the United States Olympic Committee. In general this $10 million is Federal money appropriated by Congress. USC Title 18, Chapter 93, Section 1912 stipulates that 'No part of money appropriated by any enactment of Congress shall, in the absence of express authorization by Congress, be used directly or indirectly to pay for any personal service, advertisement, telegram, telephone, letter, printed or written matter, or other device, intended or designed to influence in any manner a Member of Congress ... to favor, adopt, or oppose, by vote or otherwise, any legislation, ... whether before or after the introduction of any bill, measure, or resolution proposing such legislation ...' This raises eyebrows about USADA's lobbying efforts."

In addition to directly supporting the Supplement Safety Now, there are direct or indirect references to the organization's support of S.3002, sponsored by Senator John McCain. It is unclear as to whether the USADA, or a company it may employ, has registered with Congress, as is required under the Lobbying Disclosure Act (P.L. 104-65, 31 USC § 1352).

In March, the National Health Federation sent USADA a demand letter reminding it of its obligations under Federal regulations and demanding a response to the above question as to whether USADA is using any of its Federal funds in support of the McCain bill. As of this writing, it is too soon for any response to this recent demand, and compliance is possible. But we would like to know. Both this letter and any response will be posted on the NHF Web site at *www.thenhf.com/government_affairs_federal.html.*

Serious and Sustained Opposition

All of the health-freedom and industry trade organizations are united in opposition to this senseless and dangerous legislation. The number of press releases issued by them in opposition to this bill is astounding (see *e.g.*, *www.thenhf.com/press_releases/pr_19_feb_2010.html*, *www.crnusa.org/CRNPR10ResponsetoNewDietarySupplementLeg020310.html*, and *http://salsa.democracyinaction.org/o/850/p/dia/action/public/?action_KEY=2230*). Talk-show hosts throughout the country are speaking out against the bill, while the Federation has an on-line petition (go to *www.thenhf.com/press_releases/dietary2010_petition.htm*) opposing the bill that all are urged to sign. And the Washington, D.C. law firm of Venable LLP has organized a strong coalition of industry and other opponents for a combined effort against the legislation. Early on, Venable asked NHF to join this coalition.

Reports, though, are coming back that the politicians supporting this bill are completely out of touch with reality. One NHF member called McCain's office about S.3002 only to be asked if she herself had read the bill. When she replied yes, the McCain staffer ignorantly told her that McCain just wants all ingredients to be labeled on the bottle! Obviously, McCain and his staff are the ones that need to read their own bill and then make a field trip into any health-food store so that they can see with their own eyes that ingredients are already on supplement labels.

Probably written by the same staff members, McCain's Senate Floor Statement of February 22nd repeats the same ignorance, even illiteracy: "If you go to a grocery store and pick up a box of cereal, bread, yogurt or any product off the shelf, you can read the product's label to clearly know the ingredients and be sure you aren't eating something that you find concerning, hazardous or unhealthy. Those who take dietary supplements should have the same option. Simply put, this legislation is about truth in labeling."

Senator Jack Reed (D-RI) is another of the great unwashed and misinformed. In an e-mail, dated February 23, 2010, that he must also be sending to all other persons contacting him about his support for this bill, he responded in part, "While I recognize the potential health benefits of dietary supplements, I strongly believe that consumers need to have accurate information about these substances... As you may know, S.3002 would create new regulations for dietary supplement manufacturers to ensure patient safety and health." Unfortunately, Jack Reed is a member of the Senate Committee on Health, Education, Labor, and Pensions, to which S.3002 was referred. And, equally unfortunate, Senator Reed has not a clue about either current law or this bill.

Fortunately, those organizations, individuals and constituents arguing against S.3002 have been addressing this kind of nonsense being pushed out to the public. If politicians cannot read, or will not, then we must make them. After all, politicians do not see the light, they feel the heat.

And John McCain has most definitely felt the scorching heat – not only from American citizens but also from a fellow Senator. Senator Orrin Hatch (R-UT) had a private meeting with McCain on behalf of the industry and his constituents this month and, and as he has so often done for this industry in the past, he saved the day by convincing McCain to withdraw his support from S.3002.

Kill the Bill

Even before Senator McCain agreed to drop his support for S.3002, trade organizations such as the Council for Responsible Nutrition had not believed that the McCain bill has any legs, while lawyers at Venable thought that perhaps the registration part would have legs and that the mandatory-recall provision could only pass if the language were modified to apply only to those products actually constituting a dangerous health risk. In any event, no House companion bill was introduced; and perhaps never will be with McCain knocking out the props from his own bill. But even with the Hatch-McCain "stake through the heart" of S.3002, the beast is not yet four legs stiff in the air. Pressure must still be brought to bear on its other sponsors and supporters since we cannot afford the luxury of sitting back when this Congress has a sneaky habit of trying to pass anti-freedom bills like this one while the citizens doze.

Moreover, regardless of the impending or actual demise of S.3002, McCain and Hatch have now joined together with Senators Harkins and Dorgan to fold certain "McCain provisions" into existing legislation such as Senator Durbin's S.510 Food Safety bill with some but not all of the ham-fisted bureaucracy of S.3002. Whether this actually occurs or not remains to be seen, but we should be done compromising on any legislation such as this. The FDA already has ample power to deal with the illegal steroid issue. If you keep compromising freedom with slavery, salami slice by salami slice, eventually you end up a slave. This bill, and any successor bill, must be killed – deader than a doornail. Only that will send a message to those who would take away our health freedoms and to those who cannot read.

> Reason and Ignorance, the opposites of each other, influence the great bulk of mankind. If either of these can be rendered sufficiently extensive in a country, the machinery of Government goes easily on. Reason obeys itself; and Ignorance submits to whatever is dictated to it.
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> —*Thomas Paine, Rights of Man (1791-1792)*