BOLTON ARCHIVE

Regulating Vitamins

By Kelly Patricia O'Meara

Under proposed legislation dressed up as a public-safety concern, the standard for natural dietary supplements would be set far above that for highly profitable drugs being pushed by pharmaceutical giants.

The age-old, surefire call to regulate is being trumpeted once more in the interest of "public safety." This time it is to keep the public safe from those infamous killers — vitamin pills. Sen. Richard Durbin (D-Ill.) has introduced legislation that effectively would give the Food and Drug Administration (FDA) the authority to remove from the market any dietary supplement it chooses, including vitamins E and C. Opponents of the bill say the senator may be deficient in his understanding of natural supplements and has overestimated the daily allowable dose of federal regulatory intervention that Americans will swallow.

Durbin's Dietary Supplement Safety Act of 2003 (S 722), cosponsored by Sens. Hillary Clinton (D-N.Y.), Charles Schumer (D-N.Y.) and Dianne Feinstein (D-Calif.), is said to result from the growing number of deaths allegedly associated with the use of dietary products containing the natural supplement ephedra, including that of Baltimore Orioles pitcher Steve Bechler on Feb. 17. While fatal use by a few high-profile athletes has focused attention on dietary supplements containing natural stimulants, Durbin says it was the death of

his 16-year-old constituent Sean Riggins, who died from an ephedra-induced heart attack on Sept. 3, 2002, that pushed the senator to fight for a federal prohibition of the supplement and to get ephedra banned in Illinois, the only state in the nation to take such a step.

What Durbin says he hopes to do, in the name of public safety, is to require manufacturers of dietary supplements to prove the product is safe before marketing it. The Durbin bill would expand the FDA's authority to require exotic proof of safety from any dietary-supplement maker if the agency has received so much as a single report of an adverse reaction (AR). If the manufacturers fail during hideously expensive tests to prove that the product is safe, the commissioner of the FDA can remove it from the market.

The legislation would require manufacturers of dietary supplements to report to the FDA, within 15 days, any and all serious adverse health events by anyone using their products, something critics say is almost impossible to do as a matter of simple practicality. Even so, the Durbin claims about dangers seem nothing if not wildly exaggerated. Although the Illinois senator claims "scientific reports have linked ephedrine and similar dietary supplements to 117 deaths and more than 17,000 other health-related problems," in 2001 the Department of Health and Human Services (HHS) received just 10 adverse-event reports from manufacturers for all dietary-supplement products combined. Durbin's take on the disconnect between HHS and other alleged scientific reports is that "the voluntary-reporting system under current law is clearly not working."

What is interesting about the legislation is that, even though the senator spotlights ephedra and other "stimulant" products to excite interest in his case for added federal regulation on natural supplements, the word "ephedra" does not appear anywhere in the eight-page bill. Critics say this is because the senator wants to impose on manufacturers of natural dietary supplements the same exorbitant costs as have been imposed on drug manufacturers to make prescription medicines prohibitively expensive for so many Americans. Apparently Durbin thinks that is the only way the public can be protected.

Consider some of the drug products long regulated by the FDA — drugs that already must be "proved safe" before being brought to market. Take for example the chemical stimulant Ritalin, which is taken by tens of millions of school-age children every day. According to the FDA, between 1990 and 1997 there were 160 deaths associated with methylphenidate (Ritalin) and 569 hospitalizations, 36 of which were life-threatening. And it is widely accepted that the FDA formally receives less than 1 percent of suspected serious ARs.

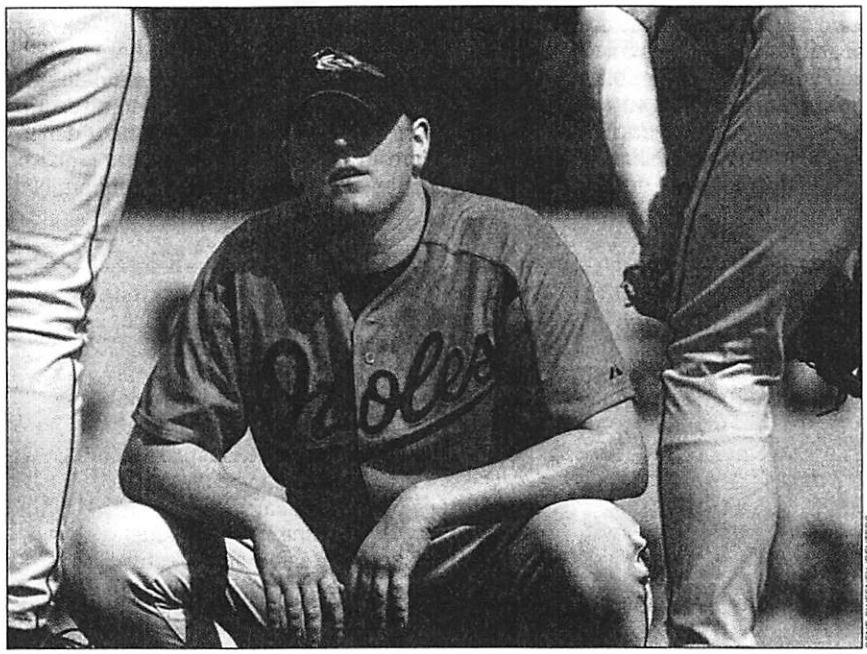
Furthermore, the adverse side effects of the natural ephedra and the pharmaceutical Ritalin, both popular stimulants, are all but identical. Yet neither Durbin nor any other federal lawmaker has called for the removal of Ritalin from the market. Consider these warnings of potential adverse reactions. **Ephedra:** nervousness, dizziness, tremor, alterations in blood pressure or heart rate, headache, gastrointestinal distress, chest pain, myocardial infarction, stroke, seizures, psychosis and death. **Ritalin:** nervousness, dizziness, irregular or fast heartbeat, chest pains, high blood pressure, severe headache, palpitations, angina, cardiac arrhythmia, abdominal pain, unusual bleeding, tics, blurred vision, insomnia, toxic psychosis, death.

Advocates of natural medicines say the antidepressant Prozac, made by pharmaceutical giant Eli Lilly, is another interesting case Durbin may want to review before putting all his "public-safety" eggs in the FDA basket. As of September 1993 there had been nearly 30,000 AR reports associated with Prozac filed with the drug agency, including side effects such as delirium, hallucinations, convulsions, violent hostility and psychosis, plus 1,885 suicide attempts and 1,734 deaths — 1,089 by suicide. And according to Thomas G. Whittle and Richard Wieland, critics who obtained documents under the Freedom of Information Act, "both Eli Lilly and officials of the FDA were aware that at least 27 deaths had been linked to the use of Prozac prior to the drug being released on the market."

These figures are 10 years old, and yet the FDA has not pulled Prozac from the market. Despite tens of thousands of AR reports detailing adverse reactions, the federal agency tasked with overseeing the public safety of drugs has not required Eli Lilly to "prove" that Prozac is safe. In fact, according to Whittle and Wieland, "a 1986 FDA safety review [of Prozac] ... discovered that Eli Lilly had failed to report information about the onset of psychotic episodes in people during Prozac's testing." And still the FDA took no action against the drugmaker.

But, when it comes to natural dietary supplements, here is Durbin doing his part to protect the public by setting a standard that critics say is far above that for pharmaceuticals. "It is impossible," Durbin says, "for anyone to calculate exactly how many people have had their lives ended or their health ruined by ephedra during the months since I first raised the issue, but whether it was 500 or five, it was too many. We can lead the country in protecting our kids by imposing reasonable safety restrictions on these dangerous drugs; this experience with ephedra should convince everyone the law should be changed in order to protect the American consumer."

Given the enormous number of AR reports filed about Ritalin and Prozac, to name just two pharmaceuticals, critics wonder aloud why, given the sena-



GENE SWEENEY/REUTERS

Tragic story: *Bechler's death focused media attention on ephedra.*

tor's concern about public safety, he has submitted no legislation to ban the use of those products, especially since Ritalin and ephedra both are stimulants and there is virtually no difference between the adverse reactions reported with their use. Apparently the guiding Durbin principle that says, "whether it was 500 or five, it was too many," doesn't apply when it comes to highly profitable drugs pushed by the pharmaceutical giants, according to holistic practitioners who prefer natural remedies.

Julian Whitaker, a medical doctor who is founder and director of the Whitaker Wellness Institute in Newport Beach, Calif., tells *INSIGHT* that "this legislation isn't about safety at all. It's about loss of control that the FDA has experienced over the last seven or eight years when it comes to regulation of the nutritional-supplement industry with passage of the 1994 Dietary Supplement Health and Education Act (DSHEA). It basically said the FDA no longer could rule arbitrarily on the nutritional-supplement industry by denying publication of truthful information on supplements. The 1994 law gave the nutritional-supplement industry a safe harbor that kept its products from being designated as drugs subject to prohibitively expensive regulation, and the industry has a safety record that reportedly is the best of any consumer-product company in the United States. This is especially important when you realize there are 5,000 deaths attributed to aspirin every year, 30,000 deaths known to be caused by over-the-counter drugs and 240,000 deaths from prescription pharmaceutical drugs used correctly."

Whitaker, the author of nine books on nutrition, is just getting warmed up. "We don't know the deaths that come from vitamins, particularly ephedra, were the result of abuse," he says. "When over-the-counter drugs are responsible for deaths no one cares even to write about it, but if a baseball player dies from a heat stroke and he's got ephedra in his system they blame the ephedra. Suppose, though, that he had Sudafed, Tylenol or alcohol in his bloodstream. Are they going to take those products off the market? Look at it this way: We have millions of people suffering from alcohol-related health problems because of alcohol abuse. Is Congress going to take alcohol off the market?"

David Seckman, executive director of the National Nutritional Foods Association, the oldest and largest trade association in the United States representing natural products, including retailers, manufacturers and wholesalers, tells *INSIGHT*, "This legislation is a bad idea and there are some provisions that we're very concerned about. It mandates that manufacturers submit adverse-reaction reports for supplements, and it defines products like stimulants that won't be allowed to be used as supplements. Naturally the bill explicitly excludes things like caffeine from the list. This is because, if you look at the definition of what a stimulant is, you learn that it is anything that increases the heart rate — which is just about anything. The commissioner of the FDA, after just one adverse-reaction report, would have the discretion to make the manufacturer of the targeted product prove it is safe before it again can be marketed."

BILL GREENBLATT/UPI

Overkill? *Durbin is pushing for tighter regulation of dietary supplements.*

Seckman says, "Our concern is that we're talking about products that have been used safely and effectively for thousands of years that now can be pulled from the market because of just one report. People will be able to call in with an adverse reaction to multivitamins and the commissioner will have the authority to make the manufacturer prove that multivitamins are safe. Under the 1994 DSHEA, supplements were classified as foods and under a totally different category than drugs. Drugs require premarket approval and are granted a patent. You're not going to be able to do that with vitamin C and other such natural products. It's just going to put the commissioner in a precarious situation to make determinations about the safety of natural products."

As Seckman notes, "Under the current law the FDA already has the ability to ban any product that it finds is not safe. Our contention is that if the FDA commissioner finds a product that is unsafe, and can prove it, then that product should be banned. We don't think the congressional intent was or is that every time there is an issue with a supplement we need Congress to decide whether vitamin C or any other natural supplement should be banned. The language is already there. Look at garlic, for instance. Should you have to prove that garlic is safe before you put it on the market? This is a possibility under the proposed legislation. And you always are going to find people who have adverse reactions to something they take, even things like vitamin C and garlic. We don't think this legislation is wise."

Len Horowitz, an internationally known public-health authority and author of more than a dozen books, including *Emerging Viruses and Death in the Air: Globalism, Terrorism and Toxic Warfare*, isn't buying the public-safety mantra. "This isn't a public-safety issue," Horowitz explains. "It may be disguised as one, but it has nothing to do with public safety. Everything is tremendously regulated to the detriment of society, and I believe that the pharmaceutical industrialists have their hand in every aspect of the regulations and legislation."

Horowitz continues, "You know, people are overdosing on coffee every day, but you don't see Congress regulating Starbucks. This argument has to be understood within the context of the fear mentality generated by the media on behalf of the pharmaceuticals who don't want to tell you that the third leading cause of death in the U.S. is drug-induced, physician-prescribed, hospital-prescribed medications. You don't see the intensity over that, but you do see it over and over again when someone overdoses on ephedra."

He asks, "Are supplements dangerous? What isn't dangerous? Water is dangerous. Try hyperventilating for five minutes and you'll pass out. That's dangerous. This is about an induction of phobia — a fear that is disproportionate to the actual size of the threat. Saying that one case or even 100 cases of people overdosing from too many vitamins, [that] amounts to trying to induce a phobia to push legislation — dreaming up justification for insane regulations."

Opponents argue that the numbers don't come anywhere near showing a need for what they regard as legislative overkill. Especially when one considers that, according to the FDA, adverse reactions to dietary supplements represent less than one-half of 1 percent of all substance-adverse events. Of course, Sens. Durbin, Clinton, Schumer and Feinstein disagree.

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