The Health Food War

A recent New York Times editorial called it "The Snake Oil Protection Act." Others denounce it as a return to the nineteenth century. On the opposite side, it is being declared that we are about to lose our dietary freedoms. Here is the story behind the controversy. Read it carefully, for it vitally affects you.

It is not a controversy; it is a battle, and it is being waged between the *Food and Drug Administration (FDA)* and the Health Food Industry. The rest of us are caught in the middle.

Senator Orrin Hatch (R/Utah) has called it the *"Supplement Wars."* It all started a few years ago. Supposedly recognizing the value of proper nutrition in the area of disease prevention, Congress passed the *Nutritional Labeling and Education Act (NLEA)* in the summer of 1993, and directed the FDA to develop regulations to implement the NLEA. The objective was for the FDA to come up with regulations which would protect our health and make sure we obtained proper information about dietetic factors.

According to health food advocates, the FDA then went in exactly the opposite direction that the government originally intended,—and prepared regulations restricting important information about specific nutrients.

According to critics, one of the most shocking of the FDA's recommended regulations was the development of *Recommended Daily Intakes (RDIs)* to take the place of *Recommended Daily Allowances (RDAs).* RDIs list even lower amounts for specific nutrients than RDAs. They give the consumer the impression that he or she does not need very much of this vitamin or that mineral. After releasing its proposed regulations, many scientists, researchers, medical doctors, and other healthcare professionals have come forward to say that the scientific evidence has proven that the RDAs are not even high enough to establish optimum health. Among the long list of professionals opposed to the FDA regulations is Dr. Linus Pauling, a two-time Nobel Laureate.

Then the FDA went a step further, and announced a regulation that health food stores would no longer be able to distribute therapeutic information, even when it consisted of reprints of scientific and medical studies. For example, it would become illegal to give you a copy of Dr. Pauling's remarkable discoveries about the values of Vitamin C.

At this point, Senator Orrin Hatch (R-Utah) and Representative Bill Richardson (D-New Mexico) introduced the *Dietary Supplement Act* (the full name of which is the *Dietary Supplement Health and Education Act—DSHEA).* It is claimed by advocates for health foods that, without the enactment of DSHEA, Americans will lose their first amendment right to information and free press in regard to nutritional supplementation.

DSHEA was introduced by Hatch into the Senate as S784. It was introduced by Richardson into the House of Representatives as HR1709. The FDA says this act, if passed, will hinder its efforts to safeguard America's health. The health food industry says this act will not only prevent the FDA from overburdening the health food industry with unnecessary restrictions, but will also ensure that the consumer receives quality supplements manufactured under high standards. In addition, it will give consumers access to more information about the benefits of these supplements by allowing health claims on product labels and accompanying literature.

But the FDA says that your doctor is your best source of information on such matters, and he should make the decisions as to what is best for you. In addition, the FDA wants to have information on vitamins and minerals curtailed until those substances have undergone intensive government laboratory tests to see if there is value in them. After years of drug-like testing, the information will then be released.

Critics say that, by then, you may be dead.

As you can see, it is a battle. And you are involved. So select a side and write your senator or representative.

The FDA says it is trying to help you by letting government and physicians work together to give you more professional guidance than you are able to get from a nutritional store.

The health food industry says that many dietary supplements available today could be banned or restricted; popular dietary products would be banished from retail store shelves; and echinacea, golden seal, and other herbs would be classified as drugs and restricted accordingly.

In addition it is said that, if FDA regulations are approved, small to medium-sized dietary supplement manufacturers and retail health food stores may not survive the new regulation procedures, due to costs and loss of product lines. As if that is not enough, it will be illegal for product labels or literature to inform you about current scientific knowledge concerning dietary supplements and their health benefits.

When the FDA published their long-awaited *Dietary Supplement Task Force Report,* as well as their new proposals for regulating supplement labeling, the FDA's agenda became clear—for they had put it into print:

1—Lower the potencies of vitamins and minerals in bottles—to equal those found in food.

2—Classify higher doses of vitamins and minerals and other dietary supplements as unsafe food additives.

3—Put amino acids on prescription.

4—Classify herbs as drugs.

5—Make unavailable the presentation of truthful, non-misleading health claims based upon current scientific

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knowledge.

When, after years of testing, vitamins and minerals again become available as "approved drugs," they will be sold in drug stores and generally by prescription only. Their sale will be a bonanza for druggists and pharmaceutical companies. The FDA regulations would eliminate nine out of ten products currently available in health food stores and nutritional catalogs.

In order to stop those FDA regulations in their tracks, the Hatch/Richardson bills (DSHEA, mentioned above) were introduced into the two houses of Congress. Specifically, DSHEA would establish the following:

1—Good manufacturing practices (GMP) for dietary supplements.

2—Purity and identity standards for nutrients found in dietary supplements.

3—Disintegration and disillusion standards for vitamins and minerals to ensure their best absorption by the body.

4—An educational campaign with accurate, scientifically objective information about the safety, proper use, benefits and risks of products.

5—An Office of Dietary Supplements in Washington, D.C.

Enough support for DSHEA has come from the general public, that on January 8, 1994, a majority in the House of Representatives co-sponsored the bill. That is an important breakthrough. But sponsorship is not passage. The powerful FDA and related interests are strongly opposed to it.

On December 29, 1993, the FDA declared that they are opposed to DSHEA, and that they intend to eliminate the ability of supplement manufacturers and retailers to inform you about any health benefits of nutritional supplements or specific nutrients or herbs. Only "FDA-approved" health claims will be permitted after July 1994.

But critics say that virtually no health claims will ever be approved by the FDA regarding specific nutrients. They say that it is the very agency which has shunned the idea of dietary fiber, cancer prevention, zinc, and immune deficiency in the elderly—even though countless scientific studies have confirmed the therapeutic benefits of fiber, zinc, antioxidants, and omega-3 fatty acids, just to name a few.

It is contended that only recently has the FDA approved the health claim for folic acid and the prevention of birth defects. That is only the second nutrient health claim approved by the agency in its 88-year history, and the approval came after 11 years of petitioning the agency to approve this claim. In that 11-year period, more than 130,000 infants were born in the United States with neural tube defects that may have been prevented.

Yes, it is a battle, and it is far from over.

FDA officials have said they plan to take action if the agency feels a drug claim is being made for any nutritional product.

Nutritional advocates recommend that you contact your congressman and tell him:

1—Protect my nutritional rights.

2—Co-sponsor the *Dietary Supplement Health and Education Act (DSHEA),* which is *HR1709 in the House,* and *S784 in the Senate.*

3—Write back to me and tell me what action you are going to take.

Advocates for the other side urge you to tell your congressman:

1—Vote against DSHEA and sup-

WHAT IS THE FDA?

Congress established, what later became known as, the Food and Drug Administration in 1906 under the Pure Food and Drug Act, thanks in large part to the public outcry over Upton Sinclair's novel, *The Jungle*, which described how meat suppliers often sold rancid and tainted products. The act gave the federal government the power to regulate and check for tainted or adulterated foods and drugs.

Under the act, a separate law enforcement agency—the Food, Drug, and Insecticide Administration—was formed in 1927 to ensure the safety of the nation's food supply and other consumer products. That agency later became the FDA. In 1938, passage of the Food, Drug, and Cosmetic Act extended the jurisdiction of the agency to cosmetics and medical devices and authorized it to conduct factory inspections.

Today, the FDA is just one of several federal agencies which regulate consumer products. (The others include the U.S. Department of Agriculture; Bureau of Alcohol, Tobacco, and Firearms; Centers for Disease Control; and the Federal Trade Commission).

But the FDA is a very important agency. It is responsible for overseeing 25 percent of every consumer dollar spent in the United States. That is an immense amount of your usable income.

The FDA has a $700 million annual budget to carry on its work of testing, regulations, inspections, etc. It is responsible for ensuring the safety and wholesomeness of all foods sold across state boundaries, except meat, poultry and eggs (which are under USDA jurisdiction).

The FDA develops standards for the composition, quality, nutrition, and safety of foods, including food and color additives. It also enforces federal regulations on labeling, additives, and sanitation. In addition, it regulates medical devices, human drugs, animal drugs and feeds, vaccines, cosmetics, and dietary supplements.

The FDA, under Commissioner David Kessler, is part of the Department of Health and Human Services (HHS), under HHS secretary, Donna Shalala.

The FDA has approximately 9,000 employees scattered across the nation. These include 1,000 investigators, who are responsible for inspecting more than 90,000 stores, warehouses, manufacturing facilities, and other establishments.

The FDA does not have the authority to demand recall or closure, but it can use diplomacy or threats to accomplish this purpose. If that does not work, it can send a letter listing the violations the company needs to correct. If that does not succeed, it can have seizures, injunctions and prosecutions be done through the Justice Department or the federal courts. If police powers are necessary, the agency will call upon U.S. marshals and local law enforcement agencies.

It was the FDA that was behind the well-known raid on Dr. Jonathan Wright, at his King, Washington, office in May 1992.

So that is the story of the Food and Drug Administration.

port the FDA which is trying to protect your health rights.

Whichever side you choose to be on, there is not much time remaining to support that side! Call the Senate at 202-225-3121, and the House of Representatives at 202-224-3121. Tell them where you live and ask to speak to your senator or representative.

As of the present time (late April 1994), the House has failed to act on the Dietary Supplement Health and Education Act (DSHEA). Thus, the entire matter is stalled in the House, and DSHEA has yet to come to the floor of the Senate.

So that is where the matter stands at this time.

ACCESSIBILITY

"The public is under the erroneous impression that we are going to limit access to vitamins and minerals."—Dr. David Kessler, FDA commissioner, June 15, 1993, quoted in the Washington Post.

Federal Register, June 18, 1993, p. 33708: The FDA's proposed regulations will forbid high potency vitamin supplements as presently found in health food stores, but will make some available in drug stores. "For example, some vitamins have therapeutic effects when consumed at levels far above those that are normally characteristic of food. When the vitamins are intended to be consumed at those levels to have those therapeutic effects, they are drugs and not foods."

Federal Register, p. 33690-33749: The proposed FDA dietary supplement regulations will remove the majority of vitamins and minerals as formulated, because they contain potencies the FDA arbitrarily claims are unsafe. Instead, the FDA wants low multiples of the RDA as a maximum dose in health food stores.

Federal Register, p. 33708: The FDA's proposed dietary supplement regulations will remove almost all herbal dietary supplements even though not proven unsafe or dangerous. The FDA claims that any herb used for purposes other than flavor or aroma is a drug.

Federal Register, p. 33697: "The Task Force recommended that amino acid-containing dietary supplements be regulated as drugs." This would include any dietary supplement which contained any protein substances.

Federal Register, p. 33694: "The Task Force recommended that, to ensure the safety of products containing vitamins and minerals, the agency adopt a 'Dietary Supplement Limit' (DSL) for each vitamin and essential mineral."

Food Drug, and Cosmetic Act, section 411: The FDA's proposal is in violation of the *Proxmire Amendment* which was signed into law on April 22, 1976. That amendment prohibits the classification of vitamins and minerals as drugs because of their potency.

SAFETY PROVISIONS

"The burden is on industry to prove these products are safe and can remain on the market."—David Kessler, FDA Commissioner, quoted in the Washington Post, June 15, 1993.

"We are back at the turn of the century when snake oil salesmen were free to make claims for their products that could not be substantiated."—David Kessler, FDA Commissioner, statement made in Representative Henry Waxman's Health Subcommittee Hearing, July 29, 1993.

"The fact that some herbs and other ingredients of dietary supplements have been used for thousands of years does not necessarily justify a conclusion by the FDA that their use is safe."—Federal Register, p. 33710.

Federal Food, Drug, and Cosmetic Act (FFDCA): According to the FFDCA, the FDA only has a certain degree of authority, such as to regulate products manufactured, and inspect manufacturers and suppliers.

National Nutritional Foods Association, Testimony before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, July 29, 1993: Regarding the comparative causes of deaths (annual average): (1) Adverse drug reactions—60,000 to 140,000 persons. (2) All vitamins—0. (3) Uncontaminated amino acids—0. (4) Commercial herbal products—0.

Statistics provided by Citizens for Health: The risks of dying from vitamin, mineral, or herb supplements are: (1) greater than 1 in 30 million; (2) less than the risk of being hospitalized for a drug reaction, which is 1 in 2,500; (3) less than the risk of dying of passive smoke exposure, which is 1 in 40,000.

SAFETY OF AMINO ACIDS

"We do have some concerns about basic safety of amino acids."—Brad Stone, FDA Washington spokesman, quoted in Kansas City Star, August 14, 1993.

"The best-known [amino acid] hazard was L-tryptophan that caused a blood disorder [EMS] fatal to 38 people."—USA Today, June 15, 1993.

FDA Consumer, an FDA publication, June 1991: "Epidemiologic studies indicated that a vast majority of the EMS cases were linked to products containing *L-tryptophan* produced by Showa Denko K.K. However, it appears that the problem is not with the amino acid itself, but rather with the product becoming contaminated as a result of a change in the firm's manufacturing process."

HEALTH CLAIMS

"Consumers would be protected from poorly substantiated claims while benefiting from legitimate ones."—Bruce Silverglade, legal counsel for the Center for Science in the Public Interest, quoted in Los Angeles Times, June 15, 1993.

Nutritional Health Alliance, July 1993: "The FDA, since its inception, has only allowed one health claim for dietary supplements: Calcium to prevent osteoporosis." [It recently added folic acid as the second claim, after refusing for years to permit a health claim for that dietary supplement, even though the U.S. Public Health Service, the American Medical Association, the American College of Pediatrics, the British Health Services, and the Australian Medical Association urgently recommended that women of childbearing age take folic acid to prevent neural tube birth defects. We can be thankful

that they eventually changed on that point.]

Federal Register, p. 33708: By FDA definition, a dietary supplement is a drug if there is a health claim made for it, and therefore must go through the drug approval process.

Medical World News, January 1993: The FDA refuses to allow health claims for safe antioxidant vitamins, although extensive scientific research shows they help prevent heart disease and cancer. According to the *Surgeon General's Report on Diet and Health, 1988,* those substances offer potential for a 50 percent reduction in heart attacks, saving 250 lives and 29 billion dollars a year.

A LOOK INTO THE FUTURE

The following statement was prepared by the New Hampshire Health Freedom Coalition:

The FDA will not *directly* take supplements off the shelf, because they cannot prove those supplements are unsafe. Instead, they will do it by attrition and by enforcing the NLEA regulations.

Here is how this will be done:

The NLEA [*Nutritional Labeling and Education Act,* passed by Congress in 1993] regulations require the following label changes or the supplement can be classified as a *drug:*

No descriptive labeling: Making claims to efficacy is viewed as prescribing for a medical condition, something limited only to medical practitioners. An herbal product such as "Sleep Ease" would not to be allowed, for its name implies treatment for a medical condition. The FDA says that would be prescribing.

No dosage indications: According to the FDA, dosage (amount of tablets or capsules to take daily) recommendations translate into prescribing. As a result, no literature can be sent from the manufacturers to guide the consumer, or even the store owner, as to the proper use of a supplement. Dosages cannot even be listed on a vitamin bottle. The FDA says that would be prescribing.

No reference books: Books on herbal medicinals and preparations are already being selectively edited. Truthful scientific information about any given natural health product cannot even be placed near the product in a store. The FDA says that would be prescribing.

No one can make a suggestion: Not a store owner, clerk, not even a degreed naturopathic physician can recommend a supplement or a natural remedy for anything. We cannot "advise" the use of prunes for constipation! The FDA says that would be prescribing.

Herbs will be eliminated: Under the NLEA ruling, it will be required that the nutrients occurring in herbs be labeled, a virtually impossible task due to the cost of such research. Therefore, herbal products will disappear quickly because they cannot meet the NLEA labeling requirements.

What will happen when the "drug" classification is applied to supplements and herbs: When a consumer hears that the FDA intends to classify herbs, amino acids or other supplements as "drugs," they often think that means "prescription drugs." The truth of the matter is that a dietary supplement reclassified by the FDA as an unapproved "drug" or an unapproved "food additive"—is not to be sold at all! That product simply goes off the market. It's gone! It's not even available by prescription!

Here is an additional look into the future, compliments of the National Nutritional Foods Association. (The information is based on a summary of the FDA's Dietary Supplement Regulations (DSR):

The FDA took no action to retract the proposals in its June 18, 1993, proposed regulations to consider treating most amino acids as drugs, treating many herbs as drugs, and placing potency limits on certain vitamins and minerals.

The FDA is going to permit any health claims linking supplements to the prevention disease, except calcium/osteoporosis in white and Asian women and folic acid for childbearing age women.

The FDA is going to continue applying the same drug-efficacy standard of "significant scientific agreement" that it used to reject all of the claims to date.

The FDA still will not permit fiber/cancer, fiber/heart disease, or antioxidant/cancer claims for supplements despite having given permission to do so for fruits and vegetables.

The FDA says it may, at an unspecified time, consider antioxidant claims for vitamins, but not for any other nutrient. This would eliminate selenium, ginkgo, and other product claims.

The FDA states that most claims for supplements are not scientifically supported.

The FDA states that few if any herbs will ever be able to carry health claims.

The FDA will not accept herbs as products to be sold, unless they list calories, fat, cholesterol, protein, etc.

The FDA rejects the use of a Botanical Ingredient Review Panel (BIRP), stating that "it [the FDA] should retain the right" to decide on committees and that FDA personnel "are fully competent to evaluate" herb claims.

The FDA says no herb claims based on preliminary scientific proof may be made.

The FDA confirms that third party literature sent by a manufacturer to a retailer is "labeling."

The FDA confirms its view that dietary supplements can still be treated as food additives.

The FDA says that RDI levels of 19-20 percent will permit companies to claim "high in" in a vitamin or mineral (although 100 percent of an RDI amount is very low).

The FDA calls any level above RDI as "truly high" and therefore under "drug status."

The FDA says "high potency" will not be permitted on labels until it (the FDA) issues a new regulation.

The FDA says consumers will continue to purchase supplements, even after the changeover, because "they erroneously believe will prevent serious illnesses."

Thre are those who believe the federal government should have greater control over our health, our food, and our lives. It is said that placing professionals in charge of such matters will protect our health and improve our lives.

Then there are those who believe that each person should be able to decide for himself, and should be able to gain access to any and all literature on the subject. It is claimed that this will protect our health and improve our lives.

As to which view is correct, you will have to decide for yourself. But it would be well if you made a decision on one side or the other, and let your elected officials know where you stand.

Or soon others will be deciding for you.

For, you see, there is a war going on and, whether you like it or not, your health and your very life is in the center of the controversy.

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