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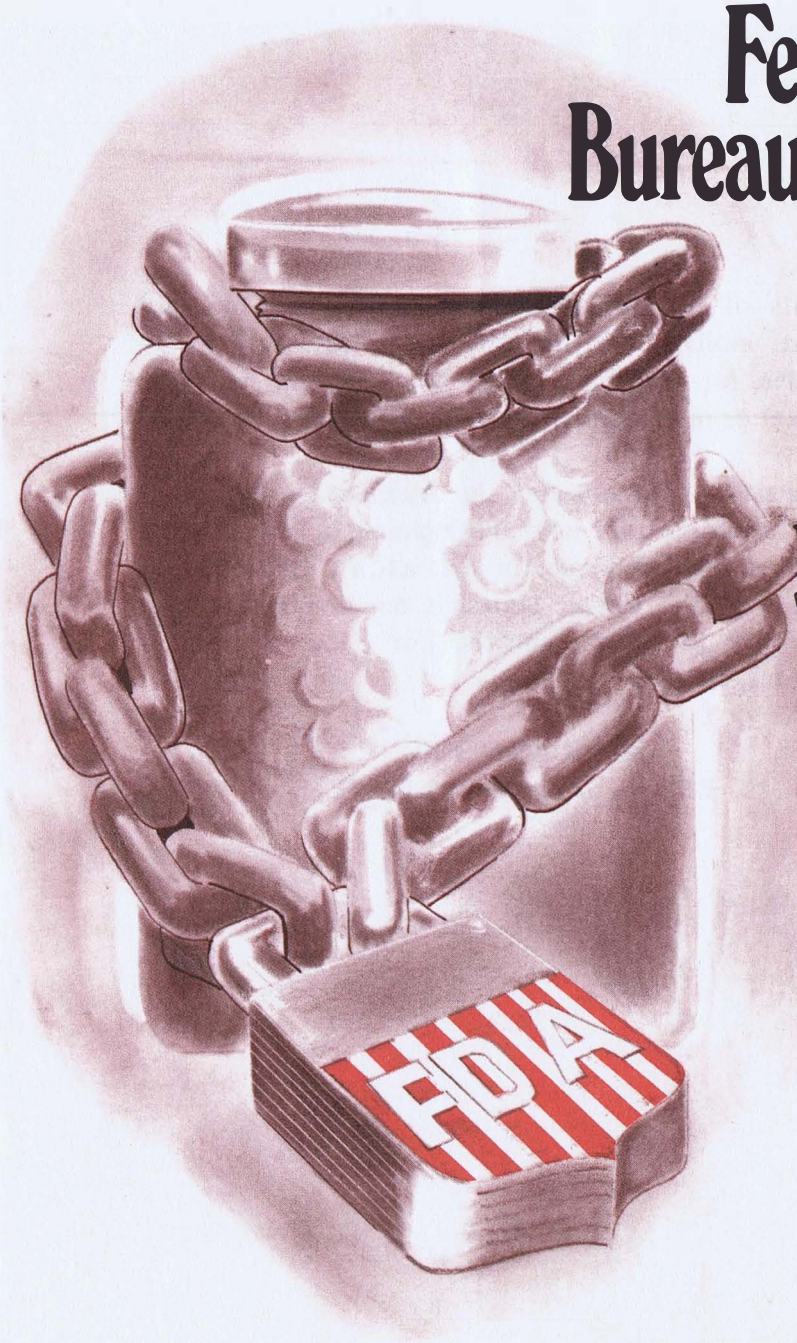
VITAMINS

Federal Bureaucrats want to take yours!



By Gary Allen

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VITAMINS

And The Food And Drug Administration

Gary **Allen**, *a graduate of Stanford University, is author of* Communist Revolution In The Streets; Richard Nixon: The Man Behind The Mask; Nixon's Palace Guard; *and,* None Dare Call It Conspiracy – *a sensational new best-seller with six million copies already in print. Mr. Allen, a former instructor of both history and English, is active in anti-Communist and other humanitarian causes. Now a film writer, author, and journalist, he is a Contributing Editor to* AMERICAN OPINION. *Gary Allen is also nationally celebrated as a lecturer.*

■ IF THE federal Food and Drug Administration has its way, Americans concerned about sound nutrition will soon be paying up to three times as much for vitamin and mineral supplements. One anticipates a clandestine organic underground in which pink-cheeked mothers meet shady characters in alleys. The ladies stealthily approach Vita-Pusher as their bright but shifty eyes peer furtively into the shadows for signs of the feds.

"How are you fixed for E?" the health-conscious mothers ask.

"They busted my E contact," grumbles Vita-Pusher, "but I can get you a fix of B-Complex or enough wheat germ to last your kids for a week."

All of this seems hyperbolic, of course, but the fact is that the faceless bureaucrats who run the Food and Drug Administration are about to make it a reality – even though the raging controversy over government restrictions on vitamin and mineral supplements has in the past four months produced nearly a million letters to Congressional offices. Consumers and retailers of health foods are discovering for themselves, as F.D.A. critic Omar Garrison observed in *The Dictocrats*, that: "When bureaucrats go on the rampage, they destroy everything in their path. They destroy human values, reputations, bank accounts, privacy, freedom of thought, freedom of speech, and freedom of belief."

Though there has long been grave concern about the excesses of the Food and Drug Administration, it took F.D.A. publication in the *Federal Register* of an outrageous set of proposed regulations on vitamins and food supplements to trigger the avalanche of mail. Consumers had discovered that the publication of the new regulations in the *Register* of January 17, 1973, was tantamount to adoption. And those proposed regulations will become administrative law unless a bill proposed by Representative Craig Hosmer is passed by the Congress to stop it.

Briefly, the new regulations drastically limit the potencies and combinations of food supplements to a narrow range which will, according to F.D.A.'s own estimates, outlaw approximately eighty percent of food supplements now being marketed. These restrictions would outlaw such products as a B-Complex formula, the combination of calcium and Vitamin D, the combination of Vitamins A and C, *etc.* Further, manufacturers would have to eliminate any and all explanations of the healthful value of their products, and they would have to publish some sort of disclaimer on their labels. They may not state on their packages that the nutrients are of any use whatsoever. It is

not even permissible to say that the nutrients can prevent or cure a deficiency state of those very nutrients.

The edict would also require that amounts of vitamins and minerals in other foods, for which nutritional claims are made, be listed on labels according to a method known as the Recommended Daily Allowance (R.D.A.). This would replace a previous labeling requirement known as the Minimum Daily Requirement (M.D.R.), and the change would further confuse consumers about the value of such over-the-counter products.

Operating on Washington's usual dictum that the public doesn't know what is best for itself, the moguls of F.D.A. don't claim that vitamins or health foods are toxic or otherwise harmful. You see, they just don't want you to waste your money. Of course the government is now the Number One waster of your money, and if Big Brother can force you to stop wasting your cash on "frivolous" vitamins and nutrition he will have established a precedent for deciding how you will spend the rest of your income which survives his tax collectors.

Nonetheless, the new administrative regulations will become operative next year, unless Representative Craig Hosmer's H.R. 643 is passed to stop the F.D.A. in its tracks. If the regulations are put into effect, millions of people who now take high-potency vitamins will be up a nutritional creek without a dietary paddle. Their only recourse will be to go to their doctors for prescriptions allowing healthful dosages larger than the paltry allowances under the ruling.

The new regulations, for example, outlaw production of capsules (or tablets) with over forty-five I.U.s of Vitamin E per capsule, and unless you want to gulp down one hundred pills or so to make up for the reduction in potency, your daily ration of Vitamin C will be limited by Big Brother to a miscroscopic ninety mg. Many top experts on nutrition, of course, recommend a daily intake of ten to twenty times the amount being promoted by the F.D.A. as desirable.

Under this arbitrary ruling, stores would be permitted to carry, for general purchase, only those supplements for which the daily intake is represented at or below the following:

Vitamin A, 5,000 I.U.	Riboflavin, 2.6 mg.
Vitamin D, 400 I.U.	Niacin, 30 mg.
Vitamin E, 45 I.U.	Calcium, 1.5 grams
Vitamin C, 90 mg.	Phosphorus, 1.5 grams
Thiamin, 2.25 mg.	Iodine, 225 mg.
Iron, 27 mg.	

The new F.D.A. ruling would remove Vitamin K, sulphur, sodium, potassium, and manganese from the non-prescription list entirely.

As Jonathan Spivak observes in the *Wall Street Journal*: "The regulations are bound to have a major impact on manufacturers, which are selling an estimated $322 million of vitamin and mineral pills a year, according to recent estimates. The minimum and maximum limitations and requirements that pills contain specified vitamins and minerals could force many companies to reformulate products. One FDA specialist predicts that 75% to 80% of the products involved may have to be reformulated."

If the F.D.A. bosses have their way under the new restrictions, sound nutrition will be officially discouraged in America. No seller of food supplements will be able to state or even imply that the nutritional adequacy of our foods can be so much as affected by heating, storing, chemically processing, or adulterating. This is as sinister as it is ludicrous. While unwilling to admit the general deterioration of ordinary foodstuffs, the F.D.A. admits in the very same *Federal Register* proposal that: "Some vitamins are susceptible to partial destruction through the effects of heat, light, oxidation and other physical and chemical reactions." As Congressman Craig Hosmer observes: "This obvious contradiction is

The Food and Drug Administration is waging war on vitamins. It has published new regulations which would limit the potencies and combinations of such food supplements to an extremely narrow range which will, according to the F.D.A.'s own estimate, outlaw 80 percent of the food supplement products now marketed. Among the features of this harassment are: Prohibition of any implication that a diet of ordinary foods cannot supply adequate nutrients; prohibition of all claims that inadequate or insufficient diet is due to the soil in which the food is grown; prohibition of all claims that transportation, storage, or cooking of foods may result in inadequate or deficient diet; prohibition of all claims that vitamins and/or minerals derived from natural sources are in any way superior to those derived from synthetic sources.

an affront to the intelligence of any man."

The Food and Drug Administration also claims that foods grown in America's soils are just as nutritious as they were in grandmother's day, and that the need for vitamin and mineral supplements is therefore minimal at best. The F.D.A. bureaucrats haven't been listening to the scientists employed by the United States Department of Agriculture, who noted in a special report in 1971:

> *The protein in feed wheat in Kansas from 1940 to 1969 declined by 44.7 percent. Recent tests per 100 grams weight showed a variation in produce grown in those two years to be as follows: Asparagus, 68 to 49 for phosphorus in California, 91 to 41 in New Jersey; snap beans for magnesium, 32 to 19 in Maryland, 39 to 22 in New York; carrots for iron, 65 to 31 in Arizona, 88 to 31 in Texas; celery for calcium, 56 to 13 in California, 74 to 41 in Michigan; sweet corn for copper, 15 to .03 in Florida, 13 to .05 in North Carolina; lettuce for sodium, 10 to 5.5 in Arizona, 1.8 to .58 in New Jersey; onions for potassium, 211 to 163 in Michigan, 188 to 144 in New York; tomatoes for phosphorus, 41 to 18 in Maryland and 39 to 16 in Texas.*

And this same Department of Agriculture report goes on to observe: "We took 4,000 samples of corn from 10 Midwest states. The old-fashioned, open pollinated corn contained, on the average, 82 percent more crude protein, 37 percent more copper, 197 percent more iron and 113 percent more manganese, as compared to the new hybrid corn. That means, the farmer must feed three times as much corn to his animals so they will get the same amount of body building protein." These experts pointed out that there had been the same sort of deterioration in the content of calcium, sodium, zinc, and magnesium.

Scientists at Rutgers verified the U.S.D.A. findings in the important Firman-Bear Report, which revealed that over a twenty-year period: "Cabbage varied in its sodium content from 94 ppm to 20 ppm. Tomatoes varied in iron from 1,928 ppm to 1 ppm. Spinach varied in its content of magnesium from 203 ppm to zero ppm." In all cases, the depreciation was highly significant, and the figures reflected a persistent downward spiral of nutrients.

Both the U.S.D.A. report and the Firman-Bear Report verify that there has been a drastic decline in all of the minor soil elements. And the Department of Agriculture concluded: "Due to the sterile condition of the soils, we are heading towards a nationwide nutritional famine." Yet the new F.D.A. regulations would prohibit any nutritional claims for supplementary rutin, other bioflavonoids, para-amino-benzoic acid, inositol, and similar substances. And it would prevent combining them with other dietary supplements in any way. To add dietary insult to nutritional injury, the F.D.A.'s ruling would also prohibit anyone from claiming that natural vitamins are nutritionally superior to synthetic ones.

Such madness would be laughable if it were not for the fact that it can only produce severe harm to American nutrition in the name of extending the authority of Big Brother over the quality of our lives. Nonetheless, the vast, arbitrary power of the F.D.A. bothered relatively few Americans until very recently. In fact, many of those who are now most vociferous in their denunciation of the outrageous rulings on vitamins and minerals were either silent or cheering the F.D.A. on to greater excess when that agency was running roughshod over other segments of the food and drug industry. Though there have been a number of well-fought campaigns against the dictatorial policies and programs of the Food

and Drug Administration over the past two decades, in almost every case the people leading them fully supported the F.D.A.'s harassment of everyone else.

For example, not long ago the F.D.A. proposed new regulations on the "unapproved uses of approved prescription drugs." The American Medical Association, in a strongly worded rebuke, denounced these F.D.A. regulations as unwarranted interference with the practice of medicine. Under the terms of those regulations, "unapproved use" means any use *not indicated on the label.* It does not even refer to an officially disapproved use. A use might not be approved on the label simply because the F.D.A. hasn't gotten around to it. The discrepancy might involve such matters as the physician's judgment about the dosage or regimen best for his patient. And it might reflect new procedures recommended by the most careful medical research.

What particularly angered the A.M.A. was another section of the F.D.A. ruling which declared that all labels for prescription drugs must declare that the prescription may not be refilled. The American Medical Association pointed out that the F.D.A. has no blanket statutory authority to prohibit refills, and that the Controlled Substances Act limits prescriptions for even Schedule III and IV substances to *five refills* without a fresh prescription from a physician.

Another section of the ruling that upset the A.M.A. required the distribution of drugs to specified channels, and limited prescribing, dispensing, or administration to physicians with specified qualifications. The American Medical Association noted that the F.D.A. was again overextending itself and that the agency had no legal authority to direct channels of distribution for previously approved drugs. "The physician is the proper person to impart needed information to patients, on an individual basis, about drugs that he provides," the A.M.A. said.

The organized proponents of health foods were silent in this controversy. Just as silent as the American Medical Association has been on the new vitamin-mineral regulations.

Few complained, and many cheered, when the F.D.A. announced on June 19, 1973, that forty thousand prescription drugs would be put to its bureaucratic test of "effectiveness." According to the Associated Press, as many as eight thousand drugs, many marketed and used successfully for as long as thirty-five years, could get the ax and be classed as worthless by the bureaucrats. Busy doctors, who had been using many of these drugs effectively for years, expressed outrage and concern. But their objections were lost in the general clamor for more and more control over just about anything and everything.

One physician who voiced indignation at the F.D.A. power-grab was Dr. William Center of San Antonio, Texas. He complained in the *American Medical News*:

> *The FDA is literally tearing to shreds the private practice of medicine in this country. The destructive process has been taking place before our very eyes and with the sympathy and votes of the people we sent to Congress. When you shake it all out, the patient ends up paying the greatest penalty. There isn't one doctor in a thousand in this country who knows and understands the* modus operandi *of the FDA to render us all robots. I offer the doctors of this country as the most eligible to receive the blue ribbon for being the biggest collective ostrich in this land.*

Even economist Milton Friedman declared in *Newsweek* for January 8, 1973, that the F.D.A.'s controls on drugs have "done more harm than good." He cited the tragic economic losses suffered by manufacturers and retailers, not to men-

tion distributors, when the F.D.A. decides to clamp down on a drug that has been used for a generation, or when it arbitrarily orders the change of one word on five million labels.

Dr. Francis A. Davis notes in *Private Practice* that the F.D.A. has caused the development of new life-saving drugs to become an "expensive, time-consuming and risky venture by imposing undue restrictions and standards." He observes that there were sixty-three important new drugs marketed in this country in 1959; but that, with the massive escalation of F.D.A. controls, only *four* new drugs were made available in 1969. In human terms, he notes, the effect of introduction of the drugs that conquered tuberculosis provides a dramatic illustration of what this means. Postponing the introduction of those drugs for just two years, Dr. Davis explains, would have meant an additional 45,000 deaths and 90,000 more cases of TB. The implication, put bluntly, is that harassment of the pharmaceutical industry by the Food and Drug Administration is resulting in the needless deaths of scores of thousands.

Still, most Americans were unaware and unconcerned about the effect of such bureaucratic harassment until that day in January of 1973 when the F.D.A. moved to choke off their vitamins and food supplements. That brought the issue home to the kitchen table. Virtually a million people wrote letters to their representatives in Washington. Enough was enough!

Much to the surprise of Representative Craig Hosmer, who had been fighting the excesses of the F.D.A. practically alone for five years, 160 Congressmen, knowing a sure vote getter when they saw one, stood in line to add their names as co-sponsors to his H.R. 643. Since he has had plenty of experience writing such bills, Hosmer's legislation is a masterpiece of simplicity. It would simply require the F.D.A. to define vitamins and minerals as foods rather than drugs. This is an important point, since it would prevent minerals and vitamins from being put into the prescription category no matter how potent. It would also prohibit the bureaucrats of F.D.A. from "their continued efforts to ban the sales of truthfully labeled vitamin and mineral food supplements for reasons other than fraud and safety."

The Hosmer bill is far from perfect, but by limiting the F.D.A.'s power in the area of food supplements it would serve notice on the bureaucracy that the Congress has had enough dictatorship by administrative ukase.

Such diverse ideological bedfellows as "Liberals" Bella Abzug and Benjamin Rosenthal joined with "Conservative" types like California's Clair Burgener and Philip Crane of Illinois in co-sponsoring Representative Hosmer's H.R. 643. It was a veritable love feast – until the *New York Times* got wind of what was happening.

On May fourteenth, the *Times* carried a hatchet job, disguised as a news feature, which blasted Hosmer and his "kooky" supporters and ridiculed "Liberals" who were co-sponsoring his bill. The *Times* reporter boasted in his story of telephoning Washington and convincing several of the terrorized "Liberals" to drop their support of the measure. Representative Morris Udall, the Arizona "Liberal," wailed that he had been "conned" into supporting H.R. 643 by "associations lobbying for the Hosmer bill who were made up of four-eyed groups." No doubt Moe, as Morris is called by his friends, prefers not to catch passes from those who wear glasses.

Also jumping backwards in the fray, an aide for Representative Howard Robinson (R.-New York), pleaded with the *Times* that the Congressman's co-sponsoring of the Hosmer bill "is all a mistake." Robinson was so frightened by the *Times* attack that he not only called Hosmer's office to complain that he had been "deceived," but went so far as to write a

letter to the Chairman of the Congressional Committee considering H.R. 643 in order to recant. Of course, Robinson knew very well that once his name was on a bill as a co-sponsor it could not be removed. It was a grandstand play by an intimidated Congressman to impress the *Times.*

The *Times* reporter demanded of Bella Abzug why she would support "such quackery legislation." Always among the first to shout her defiance in the face of opposition from the Right, Bella was so intimidated by the *New York Times* that all she could think of to say was that she had become a co-sponsor only "because Ben Rosenthal is on the bill."

As for Ben Rosenthal, he managed to be out of the country when the *Times* came calling. One of his aides, according to the *Times* reporter, turned to another and said, "Maybe you can talk your way out of this!" At which point the second aide told the *Times*: "We had an outside source telling us it was ok. I think we may look it over again."

David Ajay, an official for the National Nutritional Foods Association, is convinced that the Food and Drug Administration was responsible for the attack by the *New York Times.* He says that the objective was to "allay the fears of the public . . . in order to cause a letup in the storm of protest that has been generated in Congress."

Congressman Hosmer answered the *Times* in the House on May 24, 1973. After explaining what his bill would and would not do, Hosmer suggested that as usual big business was trying to use government to drive out the competition. He explained that the big drug lobbies are delighted to have the F.D.A. restrict high-potency vitamins to prescription, as such a move "will line their pockets as it drives the small vitamin and food supplement stores [*and producers*] out of business." He added that "the people who support HR 643 are not intellectual basket cases. They just do not believe the FDA ought to be allowed to spend taxpayers' money to take something away from people which they want and which cannot hurt them."

Clinton Miller, a spokesman for the National Health Federation, dashed off a letter to Representative Bob Wilson (R.-California), one of the key supporters of H.R. 643. Miller complained that the F.D.A. had used taxpayers' funds to print what it called an "answer to form letters adversely criticizing regulations recently published in the *Register* which relate to vitamin, mineral and food supplements." The 61-page F.D.A. "answer," said Miller, was sent to all members of the House of Representatives in an attempt to influence them to vote against H.R. 643.

In its answering tome, the F.D.A. denied "any intention of regulating any statements which are truthful and not misleading." But, as Miller pointed out, this is mere polemics. According to the F.D.A., misleading statements regarding vitamins and nutrition include those *true* statements which tend to promote the sale of nutritional supplements. The F.D.A. actually argued that there is no way in which a *true* statement attributed to individuals can be used by the "class" of people engaged in manufacturing or selling food supplements. Through regulation, the F.D.A. has thus sought to carve out a special "class" of citizens, Miller charged, who by their *occupations* cannot be permitted to tell the truth because the truth will mislead their customers.

Linus Pauling, a brilliant scientist who can hardly be called a political "Conservative," asks on Page 107 of his book, *Vitamin C And The Common Cold*:

> *Why should our government forbid anyone to learn or tell the truth about foods? Why should it be illegal to quote such information as the statement in the handbook,* Metabolism *(Altman and Dittmer, 1969), that after storage for three*

months, potatoes contain only half as much ascorbic acid as when fresh? What crime does one commit in quoting the paper of Glazebrook and Thomas (1942), who found that a ration of potatoes (12 ounces), containing 50 Mgs., contains less than one tenth as much when cooked and reheated for serving? It is well known that the vitamins in food are in part destroyed by the storage, transportation, processing and cooking of foods. Why should it be forbidden to tell the truth about the dangers of malnutrition and the possibilities of vitamin or mineral deficiencies in foods?

Why indeed? Unless the *object* is one more extension of Police State authority. If that sounds extreme, consider:

The Food, Drug and Cosmetic Act of 1962 (which the F.D.A. ruling is designed to supplement in the case of vitamins and minerals) is a criminal statute, the violation of which could result in fines and/or prolonged imprisonment. If you are a retailer or a manufacturer you can be arrested under this statute for the "misbranding" of a non-deleterious, unadulterated, and non-toxic food item, even though you are totally innocent of any intent to defraud or to harm. Further, you can be arrested and found guilty of "misbranding" a product even if you did not know the product was misbranded. And by the word "misbranding," the statute does not mean substituting peaches for pears or apples for bananas. It means that someplace on the label you have committed the crime of saying something that offends the esoteric regulations and heightened sensitivities of an F.D.A. agent somewhere. You might have a perfectly safe and non-toxic food product, but you can be sent to jail for something on the label that makes a claim the F.D.A. doesn't like – even if the claim is true.

And the F.D.A. is now trying to convince Americans that common dosages of vitamin and mineral supplements are unproved folk remedies at best and harmful quackery at worst. This is not only absurd, it is an attack on the health of millions. Discussing health problems that could be aided through nutritional prevention or nutritional therapy, the 1971 statistical report of the Special Task Force on Nutrition of the U.S. Department of Agriculture gives the following graphic examples of the *need* for widespread use of the very products that the Food and Drug Administration is harassing:

- Kidney and urinary diseases cause 55,000 deaths annually from renal failure and there are 200,000 cases of kidney stones per year. The U.S.D.A. estimates improved diet would reduce the incidence and deaths by twenty percent.
- Muscular disorders total 200,000 cases annually. Proper diet could produce an estimated reduction by ten percent.
- In 1968, there were 600,000 new cases of cancer. The report states the incidence of cancer could be reduced by twenty percent with more attention paid to nutrition.
- Eye problems were found in some 86 million Americans over the age of three in 1968, and 81,000 people went blind that year. The U.S.D.A. report claims better nutrition could have reduced incidence of blindness and severe vision disability by twenty percent.
- Digestive problems afflicted twenty million people in 1968, with fourteen million suffering duodenal ulcers. Greater attention paid to proper nutrition could have reduced the incidence of these problems by at least twenty-five percent.
- Of the sixteen million people afflicted with arthritis in 1968, 500,000 were totally disabled. It was believed around eight million could be "drastically aided" by better nutrition.
- And in the matter of one million cases of vascular disorders resulting in

death in 1967, and with five million people having definite or suspected heart disease in 1960, it was noted that twenty-five percent of those so afflicted could be "greatly aided" through better diet and a better understanding of the role of nutrition in good health.

This U.S.D.A. analysis indicates that many lives could be saved, and the health of millions of Americans could be vastly improved, by *more* concentration on proper nutrition. It seems fantastic that in the face of such evidence another government agency, the Food and Drug Administration, would devote itself to taking vitamins and nutritional supplements away from the American people.

There is certainly room for differences of opinion as to the efficacy of vitamin-mineral preparations and combinations, and there are tremendous differences of opinion among physicians and scientists as to their effectiveness or desirability. But when government becomes involved in the controversy – when the F.D.A. is permitted to charge into the arena – the differences are no longer those between individuals or between professionals in the fields of health and medicine. A difference of opinion now becomes a crime against the state, and the one with whom you disagree can use his police powers to bankrupt you, to put you out of business, to levy a large fine against you, or even to put you in jail.

There are many reasons why the F.D.A. is making this power-grab. There are obviously some within the hierarchy who favor monopolistic control over drugs and food supplements by a few large corporations, permitting easier regulation of the industry. Others are Fabian Socialists who apparently feel that Big Brother should regulate and control every facet of man's life, right down to the consumption of his vitamin pill. A third factor is that the bureaucrat mentality is always bent on fitting us all in Procrustes' bed.

Critics charge that the F.D.A. hierarchy refuses even to consider varying levels of individual tolerance and need for vitamins and minerals. The powers at F.D.A. simply will not recognize the obvious fact that everybody's body is not the same, nor will they take into consideration varying nutrient requirements for individuals engaged in varied occupations. Linus Pauling and other Vitamin C researchers claim that an individual under stress requires up to 10,000 units of the "anti-stress agent" in Vitamin C, whereas a phlegmatic and sedentary type could undoubtedly get along on very much less. According to the F.D.A., however, a 250-pound weight lifter and a 97-pound weakling each require the same dosage of vitamins.

Someone has apparently kicked sand in the F.D.A.'s face, for it has resolved to become the Charles Atlas of the bureaucracy. The Food and Drug Administration started life as a rather weak enforcement arm of the federal government, checking for toxic substances and impurities in foods and drugs in interstate commerce. It has now become a pervasive, arbitrary force with Police State clout that threatens countless retailers, distributors, and manufacturers. The F.D.A. has simply gone the way of all federal agencies. Federal power feeds on itself while parasitically feeding on the people. It is the nature of federal agencies to grow and grow. Starting as tiger cubs, they mature into beasts of prey that turn on their own masters, the people. James Kilpatrick, writing in *Human Events* of July 16, 1966, describes this phenomenon as "an arrogance of power." And he says that "nowhere is it less restrained and more abused than in the FDA. Here is the pietistic face of Big Brother, solicitous but firm, looking after our waistlines. How did the FDA get control of the icebox?" The situation became so absurd, Kilpatrick points out, that the F.D.A. proposed by administrative edict that the following label would have to appear on all vitamins and minerals:

Vitamins and minerals are supplied in abundant amounts by the foods we eat. The Food and Nutrition Board of the National Research Council recommends that dietary needs be satisfied by foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements.

"If a man feels good by reason of a multi-vitamin tablet, or thinks he can get energy from a fortified cereal, what business is this of Big Brother?" asks Kilpatrick.

The typical Big Brotherism of the F.D.A. was pointed up again on July 13, 1973, when a law suit was filed against that agency by the East Coast Healthfood Organization (E.C.H.O.) on behalf of a nutrition store in Elizabeth, New Jersey, called The Diet Shop. The plaintiffs complained about a section of the F.D.A.'s *Compliance Manual* called "Program Circular Number PC 7318.01A," which prohibits the sale of sea-weed kelp in capsules, or any mixture of sea-weed kelp and widely recognized food supplements. The F.D.A. bureaucrats stubbornly and wrongfully declare kelp to be valueless in human nutrition.

The suit was filed in the U.S. District Court for the District of Columbia by attorney John Matonis, who said: "The FDA feels American consumers are stupid or need FDA protection. American consumers, particularly the healthfood consumers, are not only smarter than Big Brother FDA thinks, but they *don't want* protection against sea weed."

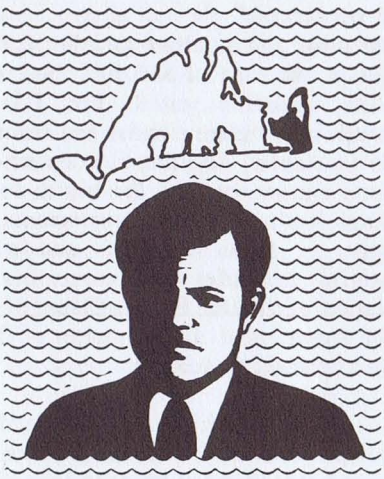
The regulations on the sale of sea kelp assumes consumers will think kelp in capsule form is medicine – even though the manufacturer and the retailer make no such claim. Further, the F.D.A. alleges that adding it to established nutrients will "mislead" the consumer into thinking kelp is also an "established" nutrient. "This is thought control and an invasion of the constitutional rights of retailers and consumers," the suit alleges, seeking mandamus and punitive and declarative relief to the tune of $10,000 plus costs.

The plaintiffs claim the F.D.A., through its program circular and enforcement measures, discriminates against retailers, consumers, and the health food, natural foods, and food supplements industry, in favor of larger and more powerful industries and companies in violation of the Due Process Clause of the Fifth Amendment. In the matter of freedom of choice, they state:

Defendant [F.D.A.], *by said program circular and its enforcement, has dictated thought control and has forced the ideology, viewpoints and economic philosophy of a federal government agency on consumers and the industry in violation of the First, Fourth, Fifth, Eighth, Ninth and Tenth Amendments. Consumers generally, and consumers of sea kelp and kelp mixtures in particular, do not want nor do they need protection of government in buying and consuming sea kelp.*

As in most cases of this kind, the arrogance of the F.D.A. was shown in the fact that no public Hearings of any kind were held regarding the efficacy or the lack of efficacy of the use of sea kelp as a nutrient or even as a simple food seasoning. The F.D.A. did not bother to spell out what methods were used in reaching its "determination" that sea kelp has, in fact, no nutritional value. Since it is well known that sea kelp contains a sizeable amount of iodine, along with other valuable trace minerals, the F.D.A.'s cavalier dismissal of sea kelp as a nutritional aid is highly suspect if not downright fraud.

The failure of the Food and Drug Administration to hold public Hearings in the sea-kelp matter comes as no surprise to F.D.A. watchers, but perhaps no Hear-



TEDDY BARE

The Last Of The Kennedy Clan

by Zad Rust

Esquire in February, reported that this explosive study of Senator Edward Moore Kennedy "heaps up mounds of evidence to prove that 1) Teddy lied about Chappaquiddick; 2) Teddy was guilty of manslaughter; 3) 'all the efforts of the police and judiciary authorities were directed . . . not toward discovery of its truth but toward its burial.' "

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ing at all is better than the farcical Hearings that were held on potency regulations for vitamin-mineral supplements. According to Robert Bahr, writing in *Prevention* magazine, the Hearings began in 1968 and concluded in 1972. They were the "longest, most expensive and most emotional in FDA history." As Mr. Bahr observes:

> *The "defendants" in this bizarre case were nutritional supplements – vitamins, minerals and other concentrated foodstuffs. They stood accused of being worthless. Claims that they could provide health and well-being were branded fraudulent. People who sold them were accused of being quacks. Those who took them were called "faddists." To those who followed the long case, the verdict was shocking for the simple reason that there was very little in the testimony to suggest the FDA has proved its case against dietary supplements. In fact, there had been a tremendous amount of evidence by experts which suggested the opposite of what the FDA set out to prove . . . .*
>
> *. . . but what made the verdict not so surprising after all is the fact that the FDA, besides prosecuting the case, was also the jury. They and they alone decided the merits of the testimony and decided the sentence.*

Robert Bahr notes that the Hearings cost the taxpayers over one million dollars, "yet they [*F.D.A.*] paid no attention to the testimony." As he says, "They only mounted the hearings as a sop to public opinion when a cry of outrage greeted their proposals back in 1962." After public opinion forced the issue out into the open, the Food and Drug Administration attempted to stage a Show Trial. "The FDA seemed to prejudge the verdict," Bahr said, "why else would they pay 90 witnesses to testify in their behalf?"

During these Hearings the F.D.A. claimed that the Food and Nutrition Board of the National Research Council believed all "dietary needs can be satisfied by foods." Dr. Leroy Voris, executive secretary of the Board, said the F.D.A. had an "overactive imagination," since at no time had his organization made any such claim nor had the F.D.A. communicated with the Food and Nutrition Board concerning the matter. "Nor has the Board reviewed or approved the labeling requirements" for vitamins and minerals, said Voris.

Shortly before the Hearings opened, a nutrition survey in New York City showed that of 642 children examined, seventy-three percent had poor diets based on the National Research Council's Recommended Daily Allowances. The Bureau of Nutrition of the New York Department of Health found that the children had low blood levels of Vitamin C, niacin, and Vitamin B_{12}. Dr. George Christakis, the survey director, urged that they be given vitamin supplements – a ringing rebuke to the F.D.A.

At the Hearings, the F.D.A.'s own witnesses repeatedly exposed its proposals as outrageous. The first F.D.A. witness was Dr. Lloyd Filer of the American Academy of Pediatrics' Committee on Nutrition. The F.D.A. hustlers all but turned purple when he declared: "I think it is in restraint of trade that the manufacturer can't make a product claim on the basis of demonstrated effect." He noted that it would be preposterous to prohibit a producer of iron supplements from claiming that his product will prevent iron deficiency "since this is the basis for the inclusion of iron in these products. Clinical studies can be cited to support productive effectiveness."

Asked about F.D.A.-proposed requirements that labels warn consumers to avoid excessive intake of Vitamin D, Dr. Filer declared that deficiency of the

nutrient was the real danger. He said that he knew of no death in the United States from a Vitamin D overdose, and suggested that too many warnings might frighten people into avoiding Vitamin D supplements, leading to Vitamin D deficiencies – from which people *do* become ill and die.

And so it went, witness after witness. The F.D.A. had egg on its face, but then it was judge and jury. Disregarding the evidence, it elected to forge ahead with its restrictions.

What it all means is that the Food and Drug Administration is determined to regulate everything you rub on your skin, put into your mouth, dump in your bath, or inhale through your nostrils. As John Matonis, attorney for E.C.H.O., reasons:

> *Certainly this was not the intention in forming the FDA. They had a clearly defined role in its original structure, but like all government agencies, it has expanded that role and its powers into regions where it does not belong and it is causing untold grief and suffering to an awful lot of people, both retailers and consumers, with its meddling ways. American consumers are not stupid.*

But the bureaucrats making their own laws and laying down administrative edicts can, indeed, be stupid with impunity. The recent cyclamates furor is a case in point. In that affair the F.D.A. declared that cyclamates produce cancer and banned their sale and distribution as dietary sweeteners. All of which cost producers millions of dollars and promptly set back a million dieters by several million unhealthful pounds. Now, according to the *Wall Street Journal* of July 2, 1973, evidence is stacking up in research laboratories all over the world that cyclamates pose no hazard after all.

The *Journal* explains that the F.D.A. used a very small number of test rats in reaching its sweeping conclusion that cyclamates are carcinogenic. Only eighty rats were used, with eight of them developing cancer of the bladder. But to produce the cancer they had to be given such huge portions of cyclamates that to approximate it a man would have to drink some four hundred bottles of diet soda a day. Under new tests using many more test animals, and even larger doses, only one rat came down with cancer – and that was an animal that received but a small amount of the sweetener.

This is a classic F.D.A. blunder, but whoever hears a retraction? Do you remember the cranberry scare of a few years ago? How many cranberry growers were driven to bankruptcy by that F.D.A. action? As the *Santa Ana Register* of July 17, 1973, points out:

> *Like the great cranberry scare of the 1960's, the fuss over DDT that helped to raise grocery prices, the furor over nitrous oxides that have now been downgraded as a smog cause, the ban on cyclamates falls into the category of undue haste on the part of the FDA.*

Was it haste or was it something else? Was it, in fact, a determination made in advance that cyclamates were unhealthy, with the research rigged to prove that assumption? Some people think so. One large manufacturer of cyclamates told your correspondent that the sugar industry had pulled the necessary strings to get cyclamates banned. That manufacturer is now sadder but wiser about the F.D.A., and has a warehouse full of currently unsaleable non-caloric sweetener to prove it. Meanwhile, cyclamates have never been proved to have caused a single case of cancer in human beings, though sugar has been established as contributing to a plethora of ailments and diseases.

The F.D.A.'s little "error" over cyclamates, in addition to the havoc wreaked

on diabetics and weight watchers trying to save their health, cost the dietary food industry and bottlers of soft drinks many, many millions of dollars.

The same kind of dictator mentality banned swordfish because of alleged mercury contamination – only to discover later that the mercury content of swordfish hadn't changed in a hundred years. But that discovery didn't save countless fishermen and sea-food distributors from being crippled by the precipitous ban. Their stocks were simply seized and destroyed by the government with no compensation. The famed Crab Cooker restaurant in Newport Beach, California, for instance, lost $75,000 worth of swordfish stored in its lockers. With no insurance to cover the loss, and no compensation from the F.D.A., it nearly foundered in bankruptcy. You can multiply the experience of the Crab Cooker by the hundreds.

This same F.D.A. attitude has resulted in the banning in America of many medications and therapies that are freely available throughout the rest of the Western world.

Syndicated columnist Allen C. Brownfeld recently blasted the F.D.A. for its refusal to allow use of the drug dimethyl sulfoxide (DMSO), first synthesized in 1866. It remained a laboratory curiosity for seventy-five years until chemist Robert Herschler, of the Crown Zellerbach Corporation, and Dr. Stanley Jacob, of the University of Oregon Medical School, teamed up to use the drug in controlled experiments. In short, they learned that it could penetrate human membranes, carrying other substances along with it.

It developed that this drug could reduce inflammation, could block nerve conduction (and thus serve as a painkiller), and was almost one hundred percent successful in treating bursitis. It was discovered the drug was highly effective in treating some kinds of arthritis and in scleroderma, a usually fatal skin disorder. It was also good for the common cold since it promptly relieved congestion when rubbed on the skin of the nose. This miracle medicine was even found to speed the healing of sprains, cure headaches, and relieve ulcers.

Dimethyl sulfoxide was sanctioned as a prescription drug in Germany and Austria on September 1, 1965, but in 1970 it was banned by the F.D.A. for use in the United States because "certain species of animals treated with DMSO had developed changes in the lens of the eye." What they didn't tell the American people was that they had used the DMSO on dogs to the tune of *one percent of the body weight* of the animals – the equivalent of two pounds for a two hundred pound man. Shades of the cyclamates experiment, with its dose equivalent to four hundred bottles of dietetic Dr. Pepper per day! Even so, only a small number of the dogs contracted the eye disorder, and it had no bad effect whatsoever when used on primates in even large amounts. Of course, when DMSO is used by man, it is applied on the afflicted area in a miniscule amount.

Senator Mark Hatfield of Oregon was among those who took exception to the DMSO ban, declaring:

> *There is no proof that DMSO has any deleterious effect on the eyes of a single human being. The FDA was premature. Dr. James Goddard, the then chief administrator for the FDA, is a very dogmatic and aggressive man, and he was determined to rule in all areas of medical drugs – they got overly cautious without at all being scientific. It was a political reaction.*

But now, if your doctor wants you to use this non-toxic medicine, which is derived from wood, he must send you to a veterinarian with a weepy tale about your horse having arthritis.

Another drug therapy denied the American people by the F.D.A. is the

so-called U Series developed by Dr. Henry Turkel. Columnist Brownfeld reports that it "can effectively remove accumulations in such diverse genetic disorders as Downs' syndrome, arteriosclerosis, the adult form of diabetes, ataxia telangectasia, certain forms of arthritis, various allergies, angioneurotic edema and certain forms of leukemia." He points out that the U Series is now used effectively in major hospitals throughout West Germany, England, Israel, Switzerland, and in South America – but not in the United States where it was developed. Brownfeld observes:

> *Part of the problem is bureaucratic regulations demanding proof of the safety and efficacy, not only of the drug, but of every ingredient in it. Dr. Turkel declares very few substances can be declared safe for all individuals because of individual idiosyncracies and allergies. Very few medicines, he notes, can be guaranteed effective for all patients for the same reasons. Congress opened a Pandora's box when it permitted bureaucrats to determine safety and efficacy of substances for purposes of interstate shipment. Turkel has concluded that Congress added to the abuse by not demanding new guidelines for new drug applications, so the FDA can now always respond with the word "incomplete" or "incorrect" regardless of the scientific data.*

With their power and authority at stake, the F.D.A. dictocrats aren't taking all of this criticism lying down. Raymond Houser, writing in *Health Foods Business* for June 1973, outlines the counterattack by the Food and Drug Administration. He observes that first the F.D.A. accused nutritionists of "making a mountain out of a molehill by misinterpreting the rulings." It then declared that its new rules would allow dietary supplements to contain potency in excess of its arbitrary declaration of daily need by fifty percent. And, finally, the F.D.A. emphasized that products providing higher potencies than permitted in dietary supplements may still be sold, but they will "merely be technically classified as drugs."

This last bit of business is very cute indeed. What the F.D.A. doesn't tell the public is that it is those two words, "technically" and "drugs," that make all the difference. As Raymond Houser notes, F.D.A. claims supplements in larger dosages than the Recommended Daily Allowance can be obtained, but they are now to be classified as "drugs," so a prescription will be needed, automatically boosting the cost and limiting general availability. One key to effective nutrition is *availability* – reduce the ready availability of nutrients and you reduce the likelihood of good nutrition.

The F.D.A. would have the public believe the so-called "technical" change in classification as "drugs" of high-potency vitamins makes no difference to the consumer. But it makes a big difference not only because of availability but because that little "technical" change brings into play a whole new group of F.D.A. regulations to be applied to anything labeled as a "drug." For instance, the higher-potency vitamins and minerals to be relabeled as drugs would now have to state on the label the symptom or the disease for which the product is effective. This sounds simple enough. But effectiveness and safety would have to be established for the record in special, very expensive, and lengthy F.D.A. tests. Small concerns, unable to afford F.D.A. tests under the new regulations, will have to drop such products from their line, and many may be forced to close their doors. As Houser points out:

> *After the effective date of the new rulings, all vitamin-mineral products with potencies higher than*

those permitted for dietary supplements will then presumably be considered as new drugs, requiring new drug applications before marketing. The cost of fulfilling the required pre-marketing studies could easily run from $200,000 to $1 million – a very heavy cost for a product that cannot be patented. Not only that, there is no guarantee the FDA would accept the new "drug" after it had been tested.

Consider some of the problems. It might be shown, for instance, that high-potency Vitamin B_1 is needed for the treatment of beri-beri, or that high-potency Vitamin C is therapeutic for scurvy, or that high-potency Vitamin B_3 (niacin) is a valuable treatment for pellagra. But, in those cases the F.D.A. would assume the patients should be under the care of a physician, so the admittedly harmless higher potencies would still be available only through a prescription.

And since the F.D.A. insists Vitamin E has no value in dosages above thirty to forty-five International Units, how would you label a high-potency Vitamin E capsule? Remember that the product must be labeled with an indication for use which is acceptable to the F.D.A. review panel. It is obvious that no Vitamin E product in potencies greater than forty-five Units per capsule would be approved for marketing, despite the tremendous amount of positive evidence, developed by such physicians as Dr. Wilfred Shute, establishing the effectiveness of massive Vitamin E dosages in certain cardiovascular disorders.

Not only does the F.D.A. plan to be judge and jury, it means viciously to attack those who dissent. The Food and Drug Administration now teams with the American Medical Association, through the A.M.A.'s Council on Food and Nutrition, to hold taxpayer-financed symposia for the purpose of attacking the food supplements industry and defaming groups and individuals who advocate freedom of choice in health matters. In his lively and authoritative book, *The Dictocrats*, Omar Garrison charges that these forums are "nothing more than one-sided propaganda ploys." He notes that to have vitamin and health food advocates participate in the A.M.A.-F.D.A. forums is apparently "as unthinkable as . . . proposing to the Kremlin hierarchy the idea of having a speaker address a meeting of a Communist politburo on the advantages of capitalism."

These so-called anti-quackery shows are replete with confiscated gadgetry, much of it dating back to the 1920s, which the F.D.A. parades in horror as current examples of why the Food and Drug Administration must act as watchdog for the American people. Film slides, motion pictures, books, tracts, pamphlets, and lectures are used to convince the public that all healing practices other than consensus medicine mandated by the A.M.A. amount to quackery. It is unlikely that these roadshows deter the real quacks, since F.D.A. is now using them primarily to defame those who advocate better nutrition.

Trying to crash your way through the mad, mad world of the Food and Drug Administration is like attempting to hack your way through the Brazilian jungle with an old razor blade. As with all federal agencies, there are regulations to regulate the regulations which regulate other regulations. But perhaps no other agency is so gifted at turning an essentially simple problem into a nightmare of paper work, red tape, and bureaucratese.

Washington attorney H. Thomas Austern remarked in the December 1967 issue of *Food, Drug And Cosmetic Journal* about a startling solicitation that had recently come across his desk. The circular offered samples from what it called the F.D.A. *Hot Line.* For a fee, the subscriber could dial a telephone number and listen to a taped transcript of a current interview with an F.D.A. official.

Austern said he was amazed at "the contrast between how the law was administered and enforced three decades ago, when the basic 1938 Act was passed, and the FDA world of today, with its official speeches, almost daily press releases, two-colored FDA paper, pink, blue, gray and gold sheets, newsletters, multiple Congressional investigations and hearings and the Annual Education Conferences."

Far from authorizing this enormous output by the Food and Drug Administration, the Congress originally granted the F.D.A. very limited authority – permitting it to issue public pronouncements "when there is imminent danger to health or of gross deception to the consumer." Today the F.D.A. issues routine press releases in which individuals, products, and manufacturers are indicted, tried, convicted, and hanged. Almost daily mass mailings go to the media, bearing the official F.D.A. seal and reporting on raids and seizures of products; testimony given at informal Hearings; indictments, past and present, of individuals and firms; hearsay information elicited in trials; and guilty verdicts, along with the sentences imposed.

As Omar Garrison notes, acquittals are never "considered worthy of a press release." Though it apparently doesn't believe in publicizing verdicts of innocence, the F.D.A. frequently continues harassment of those it finds "guilty" for as long as twenty-five years after the "crime" has been expiated by payment of a fine. And as we have seen, the F.D.A. is not beyond distorting and embroidering facts to intimidate businessmen and customers alike.

A favorite ploy is to lift statements made by a manufacturer out of context in order to make it sound as if the man is guilty of making absurd claims for his product. Or consider the incredible case of the man who was charged with misrepresenting the therapeutic qualities of honey. The F.D.A. claimed he alleged that generous application of honey on the skin would "raise the dead" . . . as if the American public needs the F.D.A.'s protection against such a claim.

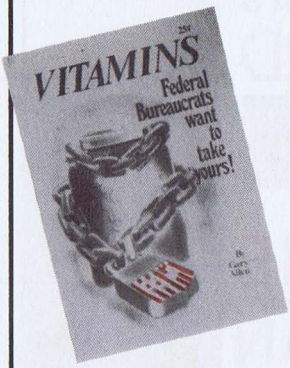
Another trick is to seize a product and then misrepresent its ingredients. For instance, a vitamin product might use starch as a binder and talcum powder as a lubricating agent in the process of manufacturing. Both of these practices are perfectly legitimate and routine. But the F.D.A. is fond of stating, upon seizing such a product, that it "was found to contain talcum powder and starch," as if those were the sole ingredients and the manufacturer was therefore defrauding the public.

And these boys play rough. Robert Bahr notes that "The FDA warmed up for its assault by making a number of raids and seizures without benefit of any regulations whatsoever to support its actions. In 1963, they seized 568 cases of Dextra sugar on charges of misbranding and ordered the manufacturer, in effect, out of existence. In court, the FDA argued that Dextra labels stating the sugar contained minerals and B vitamins – which was true – were *misleading* because people would think Dextra was better than other sugars."

The manufacturer of Dextra refused to roll over and play dead. He fought. When the case was heard in court, after considerable time and expense, U.S. District Judge Emmett C. Choate found that the F.D.A. had brought the charges because "it is not in sympathy with its [*Dextra's*] use. The provisions of the Federal Food, Drug, and Cosmetic Act did not vest in the Food and Drug Administration or any other Federal agency power to determine what foods should be included in the American diet. This is the function of the marketplace." And Judge Choate added: "Plainly, only Congress can or should regulate the use of vitamins, and then only to prevent public injury."

When the court was upheld on appeal, the F.D.A. simply ignored the ruling and continued harassment as usual.

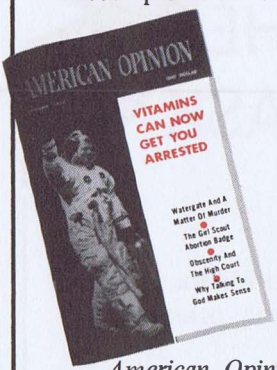
What You Can Do



Now that you have read *Vitamins: Federal Bureaucrats Want To Take Yours*, you know that the Food and Drug Administration wants to make it *illegal* for you to buy high-potency vitamins without a prescription. What can you do to prevent this latest government assault on your right to choose?

First, use the coupon below to buy as many copies of this article as you can afford, and distribute them to friends, neighbors, business associates, and local druggists. Then, write your Congressman (and urge others to do the same), demanding that this federal power-grab be stopped.

Additional copies of this article are available at the following prices: One to 99 copies, five for one dollar; 100 to 999 copies, sixteen cents each; 1,000 or more copies, fourteen cents each. Postage is prepaid when payment accompanies the order.



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The Food and Drug Administration is quite sophisticated in intimidating consumers and the public. In 1963, F.D.A. boss James Goddard testified before the Senate Subcommittee on Aging, remarking that his agency was distributing, through a trade union news agency, "news articles" supporting the F.D.A.'s views on cosmetics and drugs. It was shortly discovered that the writer in question was under contract to the F.D.A. and was not a legitimate member of the media. The *Wall Street Journal* remarked that "the question is whether it is proper for any governmental agency to feed its propaganda in disguise to a segment of the press gullible enough to accept it." Judging from the recent attack on the Hosmer bill by the *New York Times*, the *Times* is among the "gullible."

As a result of F.D.A.'s use of the press to support its power-grabs, Congressman Hosmer has submitted his bill to Committee at least five times, and each time it has been bottled up effectively by the ten men on the Committee who are opposed to curbing F.D.A. excesses. And, despite the fact that the current Hosmer bill has 160 co-sponsors, there is still a good chance the Committee will again consign it to limbo. The key will be public reaction. A million letters have already reached the Congress in support of curbing the Food and Drug Administration. It may take two million, or ten million, such letters. But Congress must be made to know that the people have had enough.

And the people must recognize that far more important than the F.D.A.'s vitamin-mineral ruling itself is the onerous and stupefying power the Food and Drug bureaucrats have assumed over manufacturers, retailers, and consumers at all levels. Justice Brandeis once said: "The most precious of all rights is the right to be left alone." Congress ought to have that motto chiseled in stone on the portals above the Food and Drug Administration. And while it is at it, Congress might add those words from the Hippocratic Oath which emphasize that the principal duty of a physician is *to do his patient no harm.* ■ ■

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