National Health Federation BULLETIN

APRIL, 1975

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37 SENATORS ON NEW VITAMIN BILL

JUDGE VOIDS BAN ON LAETRILE

NHF'S 20th ANNUAL NOW ON TAPES

CONSUMERS UNITED WON IN UTAH

Big Brother Would Control Health Food Ads Via FTC

Fluoride and Cancer Deaths

A LINK?

PRELIMINARY STUDY BY NHF SCIENCE DIRECTOR YIAMOUYIANNIS SHOWS FLUORIDATED CITIES' CANCER DEATH RATE 24% ABOVE U.S. AVERAGE

John Yiamouyiannis, Ph.D., is an intense, dedicated scientist whose refusal to be muzzled on the fluoride issue cost him a job with Chemical Abstracts

More Fluoride 'Scoops' Inside!

Dedicated to the Protection of Health Freedoms

THE
NATIONAL HEALTH FEDERATION
BULLETIN

Protection of Health Freedoms — Published Monthly

Volume XXI — Number 4 — April 1975

CONTENTS

The Bulletin serves its readers as a forum for the presentation and discussion of important health issues including the presentation of minority or conflicting points of view, rather than by publishing only material on which a consensus has been reached. All articles published in the NHF Bulletin — including news, comments and book reviews — reflect the individual views of the authors and not necessarily official points of view adopted by the Federation.

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NHF Victory in Utah

Near-Disaster for Food Supplements Avoided by United Consumer Action

The "fast footwork" of NHF Legislative Advocate Clinton R. Miller, supported by thousands of concerned consumers, turned potential disaster into victory for those opposing giving control of food supplements to a State Department of Public Health.

The scene was Utah, the time — early February. Adroitly concealed in a bill separating control of drugs used by humans from the Agriculture to the Health Department in Utah was a clause which included food supplements. Buried within the wording of the bill, the consequences of the proposed change were not discovered until the legislation had passed the Senate 26-1, and had been approved by the Health Committee in the lower chamber, undergone two readings on the House floor and was ready for final reading and vote.

At that point, the Utah Chapter of National Health Federation put in an S.O.S., to Mr. Miller, agreed to finance the trip to Salt Lake City, and he flew west. The action was underway. For 10 days NHF leaders and others with a mutual concern visited offices of State Representatives to win support for an amendment, modeled after the federal Proxmire-Schweiker Bill, which would return responsibility for regulation of food supplements to the Department of Agriculture. Among those sponsoring the amendment were House Majority Leader Roger F. Rawson and Minority Leader Lorin Pace. When the amendment was offered on the House Floor, it was adopted 72-1. The amended bill was sent back to the Senate for approval.

Mr. Miller said he learned from House members that the telephone calls and mail in behalf of the amendment "far surpassed anything they've experienced this session. There were literally thousands of concerned consumers united behind the effort to prevent the Health Department from taking control of regulating food supplements. With that kind of unity and support, we won a decisive victory."

NHF Board Chairman Kurt W. Donsbach observed that "The Utah experience makes us acutely aware that this could happen elsewhere. Each of us, in every state in the Union, must be alert to this possibility. The forces desirous of placing food supplements under regulation as drugs have not been successful in Washington, yet, and it is conceivable the effort may be made at the state level. We must, indeed, be increasingly alert."

At NHF Board Meeting

Proposed FTC Health Food Ad Regulation Opposed

A decision to oppose a proposed Federal Trade Commission regulation to regulate advertising in the health foods field; amendment of by-laws to provide for election by State Chapters of at-large-members of the Board of Governors; a resolution in support of the work of Legislative Advocate Clinton R. Miller; and commendation for the contribution to NHF growth by Founder and former Board Chairman Fred J. Hart are among actions taken by the Board of Governors of National Health Federation during sessions on the eve of the twentieth annual Convention in January in Anaheim.

The Board of Governors serving during 1974 met first, with 14 members in attendance. That session was followed by a meeting of the Board chosen to serve during 1975, attended by 17, including newly-elected members W. E. "Slim" Taylor of Williams, Ariz., who fills the vacancy left by the death of Charles Pratt; Harold Stueve of Altadena, Ca., who fills the vacancy left by the resignation of Fred J. Hart; Dr. William A. Ellis of Tarentum, Pa.; and Mary Lou Martin of Bronx, N. Y.

The credentials committee reported election of nine members to serve through 1977: Norman W. Bassett, Kirkpatrick Dilling, Kurt W. Donsbach, Dr. Ellis, Dorothy B. Hart, Bruce Helvie, Mrs. Martin, Betty Lee Morales, and John W. Noble.

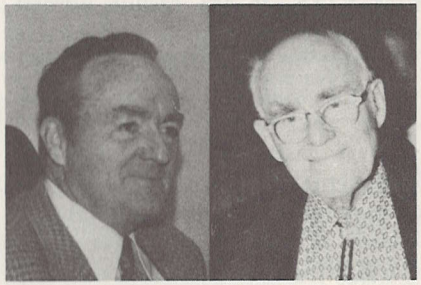
Officers to serve also as members of the Executive Committee this year were elected: Charles I. Crecelius, President; Mrs. Hart, Vice President; Dr. Donsbach, chairman

NHF Officers Who Attended 1975 Convention*

**Missing is Mary Lou Martin of New York, ed. regrets!*

DR. KURT DONSBACH
Board Chairman

V. EARL IRONS
Vice-Chairman



CHARLES CRECELIUS
President

DR. EMORY THURSTON
Treasurer

BETTY LEE MORALES
Secretary

KIRKPATRICK DILLING
Legal Counsel, Member

BOB HOFFMAN
Member

BRUCE HELVIE
Member

of the Board of Governors; V. Earl Irons, Vice Chairman, Board of Governors; Betty Lee Morales, Secretary; and Dr. Emory W. Thurston, Treasurer.

During the meeting of the 1974 Board, by-laws were amended to provide that instead of being appointed, Board members-at-large shall be elected at large by State Chapter members. A further change in by-laws provides that in event of a vacancy on the Board of Governors, with exception of the Board's State Chapter members, the vacancy may be filled by an appointee selected by the President with approval of the Executive Committee, then filled at the time of the next general election.

It also was decided that the agenda for the Board's annual meetings be prepared and mailed to members at least two weeks in advance.

The Board heard a report from Legislative Advocate Clinton R. Miller on the Federal Trade Commission proposal to control advertising—a proposal which would outlaw use of such words as "health," "health foods," "natural," "organic," "organically-grown." Mr. Miller and Attorney Dilling reiterated the importance of stopping implementation of these regulations, and a motion was adopted instructing Mr. Dilling to contact Max Huberman of the National Nutritional Foods Association and their attorney, Milton Bass, to coordinate filing of objections to the proposed FTC regulation.

Harald J. Taub of Los Angeles lauded Mr. Miller's work in Washington and observed that he enjoys the "undivided support" of the National Health Federation's Executive Committee, "with whom he is in constant touch, sometimes almost daily. There are those in Washington," he continues, "who should be made aware of the organization's wholehearted approval of Mr. Miller's legislative efforts."

At the suggestion of Board Member Ajay of Sacramento, board members will be polled to determine whether a consensus exists when major policy matters are involved, and this motion was approved.

In other action the Board: Agreed to consider a proposal that

(Please turn the page)

HARALD J. TAUB
Member

LORRAINE ROSENTHAL
Member

WILLIAM ELLIS, M.D.
Member

DAVID T. AJAY
Member

NHF membership have access to a prepaid health plan; that the possibility of retaining a Sacramento lobbyist be studied; and that after receipt of a written application outlining details of the case, consideration will be given the possibility of financially aiding members of the Long Island, N.Y. Chapter of International Association of Cancer Victims and Friends, arrested by state authorities.

Resolutions commending the Executive Committee for its work last year, supporting Mr. Miller, "for the vigorous and productive handling of his assignment in Washington," and commending the work of Founder and Past Board Chairman Fred J. Hart were approved.

The 1975 budget was adopted, and President Crecelius commented that activities will "necessarily have to parallel the amount of funds received – much depends upon successes of conventions and other fund-raising efforts."

The meeting was closed with these comments from Chairman Donsbach: "I would hope that we have reflected the consensus of this Board and of the Executive Committee concerning the business of the Federation. Personally, it is not an easy task to sit as a member of the Executive Committee and be asked to make decisions for which you know you will be criticized. However, each of us serves without remuneration, content with the knowledge that we serve the total membership in the cause of freedom for each individual and for our country."

The 1976 Board meeting has been set for January 15, the day before the twenty-first annual convention opens in Anaheim Convention Center.

JOHN J. MATONIS
Member

A. I. MALSTROM
Member

HAROLD STUEVE
Member

California Court Rules Ban On Laetrile Unconstitutional

For the first time in the 30-year struggle to legalize use of Laetrile (amygdalin, B-17), a California court has ruled as unconstitutional a regulation of the State Health and Safety Code banning its use.

James R. Privitera, M.D., Covina, and Carroll Leslie, West Covina, were cleared of charges of illegally administering or selling it when the case was dismissed by Judge Sam Cianchetti who said if the law were strictly observed, "it would be illegal to prescribe aspirin."

A charge of conspiracy, brought by the U.S. Customs Service against Dr. Privitera and Mrs. Leslie and three others in a San Diego court are pending, with an appearance before a Superior Court judge set for April 7.

The Bulletin **expects to publish full details of the dismissed case in an early issue.**

Southeast Regional NHF Convention Set May 3-4

"Water quality" will be emphasized during the Southeast Regional NHF convention set for May 3 and 4 in Braniff Place, New Orleans, according to Dr. John Yiamouyiannis. Dr. Robert Harris, director of the toxic substances program, Environmental Denfense Fund, Dr. Jay Lehr, executive director of the National Well Water Association, and Dr. Aly Mohamed are among the eight program speakers. Dr. Harris conducted the study of the New Orleans water supply revealing the presence of herbicides, pesticides and chlorine in the New Orleans water supply – chemicals suspected of causing the high cancer death rate in New Orleans. Dr. Mohamed, University of Missouri, will speak on chromosome damage due to fluoride.

Honolulu Convention Is Canceled

The Pacific Islands convention initially scheduled in Honolulu April 26-27 has been canceled, NHF Convention Director John Yiamouyiannis, Ph.D., announced.

With the Editor . . .

We've Got to Win This One!

Zealots within the Public Health Service and the Los Angeles Chapter of the American Dental Association seeking to infuse the Los Angeles water system with fluoride, and the scheme's equally-determined opponents are locked in a contest which truly can be termed "battle of the century."

It is vital to plans of the U.S. Department of Health, Education and Welfare to win this one – it would be a prestigious victory, invaluable in its campaign to fluoridate the rest of the country.

By the same token, it is just as vital for advocates of an unadulterated water supply to stop HEW-ADA in their tracks!

Fluoride zealots thought they had it in a bag when Los Angeles City Council voted to treat the water with the substance, also a deadly air pollutant. That position was softened when National Health Federation and People's Lobby through a petition campaign let the Council know that just a lot of people don't want to have to drink fluoride-treated water. And the issue was put to a referendum – the vote set for May 27.

A successful campaign costs money. HEW can use your tax dollars to pay the salaries of people who will campaign for the proposition. And with its prestige on the line, so to speak, trusting members of the Dental Association will come up with substantial donations to finance advertising on the air, on billboards, and in newpapers.

While providing leadership and making speakers available, the National Health Federation is not financially able to underwrite costs of the campaign to educate residents of the City of Angels on the fluoridation issue. So funds are being solicited for this specific purpose – and as Science Director John Yiamouyiannis puts it, ". . . contributions of from $1 to $10,000 from each and every one of you will assure the overwhelming victory over fluoridation that is so essential at this time. It is the duty of everyone from coast to coast to rally in support of Los Angeles to stop fluoridation by giving as much as possible, right now. The mayor of Houston has already said of the issue, as goes Los Angeles, so goes Houston."

And so will go other metropolitan centers! It's a crucial fight – and we can't let the misguided pro-fluoridationists get their way on May 27. Mail contributions to NHF Fluoridation Fund, Box 688, Monrovia, Calif. 91016. Let your conscience be your guide!

Hats Off to Dr. Thalenberg!

Elsewhere in this issue is the story of a remarkable decision by a remarkable man – the announcement that after 30 years of supporting fluoridation of water supplies, Dr. Marvin Thalenberg of Rockland County, N.Y., now feels conscience-bound to oppose it.

Dr. Thalenberg's change-of-mind is typical of what is happening to many other professional people in the sciences. For years they believed the original reports and positions of early-day proponents. Lacking the time to make an in-depth study of the issue, they accepted in good faith, conclusions of those favoring fluoridation.

But now a new factor has emerged: The issue of *total fluoride ingestion.* How much of this toxic substance is in fact entering the human body from air, in the food chain, in addition to what man may be placing in the water?

These questions trouble the good doctor in New York State – and he possesses the integrity to "stop, look, and listen" – to take a new look as it were. And he finds too many unanswered questions.

"I have not been able to find reliable estimates of how much fluoride has been added in non-water sources. I have not been able to find studies of fluoride levels and surveys of the effects of added fluoride on populations such as the elderly with impaired renal excretion.

"For these reasons, to my own surprise, I cannot support universal fluoridation of our water supply . . ."

Thus speaketh the good doctor, bless his heart! He searched and he found. Then he was morally strong enough to acknowledge publicly his revised conclusions as to fluoridation of public drinking water. This takes courage, and we salute Dr. Thalenberg! We might add – the same kind of integrity is leading others in the professional field toward the same conclusions – and this is the hopeful sign on the horizon: More and more professionals, as they take the time to examine, and to face the issue of *total fluoride ingestion* – an unanswered question ignored by HEW and the Dental Association – are doing exactly what Dr. Thalenberg has done, they're saying "No thanks" to fluoridation "until we get answers to these crucial questions."

Thanks, *Let's Live!*

Kudos to the folks at *Let's Live* for the striking cover on the February issue. Imagination and skillful artwork were involved in depiction of the commercial-political combine which has grown up at the federal and state levels to restrict the rights of the individual to seek help from any branches, not just one, of the healing art. The cover dramatizes existing repression of "unorthodox healing," and leads the reader into the article by a prominent San Francisco attorney who suggests some changes in the law. Publisher Carolyn Bassett, Editor Mike Spencer, and Art Director Al Fortune are to be commended for their separate roles in focusing public attention on this issue.

Edwards' 5-Year Plan

HEW Seeks $8 Million As Starter To Finish Fluoridating Entire U.S.A.

It may not have made headlines throughout the country, but a story in *The Washington Post* dated Jan. 2 revealed that the White House has been told by Dr. Charles C. Edwards, assistant secretary for health, HEW, that fluoridation of the remaining water supplies in our country "could cut billions of dollars in dental bills."

This signals an all-out attempt by pro-fluoridationist forces to "finish the job."

By the same token, it becomes the rallying cry for those who want to keep water free of that toxin to accept the challenge, head-on!

In case you haven't seen the quotes from Dr. Edwards – who by the way headed the Food and Drug Administration before being kicked upstairs – here's what the man proposed in the plan presented along with budget requests for the 1976 fiscal year which starts July 1:

In the next five years he wants the federal government to inaugurate two programs: One would reduce occupational health hazards in industry – which he believes might result in eliminating 30,000 cases of cancer a year; the other program is fluoridation of the still-nonfluoridated water systems in the nation.

Eliminating cancer-inducing hazards in industry certainly is an objective with which few will quarrel. But to ask the President to endorse HEW's longtime effort to force the entire country to drink fluoridated water – that's a horse of another color – and we trust the White House will be so advised in a blizzard of protesting mail.

Dr. Edwards seeks to persuade the White House that it should support total fluoridation on the thesis it will prevent dental decay, and that this will save the population "billions of dollars in dental bills." A massive fluoridation program, he contends, would be "a key element toward prevention of dental cavities." Half the nation's water systems already are fluoridated he points out, and "experts" estimate that an $8 million budget in 1976 could start a program to fluoridate them in the rest of the country.

This of course has been a goal of HEW for some years. Had it not been for the opposition of NHF and other opponents, it would have been implemented in the Children's Dental Health Act of 1973. HEW was defeated in that attempt, and it's up to us to stop the bureaucrats again!

Why can't they listen to reason? Why can't they do as many non-government professionals are doing – reassess the position on fluoridation when confronted by the new element of total ingestion arising from fluoride contamination in the air and processed food – possibly in amounts well in excess of what even HEW considers "safe?"

Unless or until HEW takes a new look at the issue and is willing to concede that it's a different ballgame, due to this compelling new factor, we, the people, must "stay in there," letting 'em know this is something we simply won't buy!

Fluoride *and* Cancer

Preliminary Study by Dr. Yiamouyiannis Shows Fluoridated Cities With Cancer Rate 24% Higher Than National Average

Are you drinking fluoridated water?

Now we don't want to raise a red flag to terrorize anyone – and we make it plain at the outset that the findings are "tentative," based on a preliminary study which should be followed by further studies – but the facts of this initial study by Dr. John Yiamouyiannis, National Health Federation Science Director, reveal:

- In U.S. cities with a population of one million or more the cancer death rate in the six cities with fluoridated water is substantially higher (plus 24%) than the national average.
- In one of the two cities with nonfluoridated water (Los Angeles), the cancer death rate is identical with the national average, and in the other city (Houston), the cancer death rate is 27% below the national average.

Sort of a block-buster, isn't it?

Now you ask, where did the figures come from, how authentic is the information?

Answer: Statistics are from the United States government – "Fluoridation Census, 1969," HEW, Division of Dental Health, Bethesda, Md.; and "U.S. Cancer Mortality by County: 1950-1969," Department of HEW Publication, National Cancer Institute, Bethesda.

These sources have to be "the horse's mouth," right?

Startling? That's putting it mildly. Stunning is a more descriptive adjective for this one.

How did Dr. Yiamouyiannis happen onto this gem? Interviewed by *The Bulletin*, he explains: "While watching a CBS Special on water quality, I was disturbed to find that in discussing carcinogens in drinking water, no mention was made of radioactive compounds or fluoride, each of which has been reported to be carcinogenic – cancer-stimulating, cancer-producing. Since I have been working in the area of fluoride research, I was particularly disturbed that fluoride was not mentioned. Three studies already in my possession indicated that fluoride is carcinogenic.

"The first paper was published

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in 1963 in the Japanese journal, *Nippon Sakumotsu Gakkai Kiji* (vol. 32, pp. 132-8). The authors, T. Okamura and T. Matsuhisa, found a definite relationship with the amount of fluoride consumed and gastric cancer.

"The second paper, also published in 1963, appeared in the journal *Genetics* (Vol. 48, pp. 307-10). Authored by I. H. Herskowitz and I. L. Norton, it showed a drastic increase in tumor growth with increasing fluoride concentrations in the culture medium.

"The third paper by A. C. Taylor and N. C. Taylor appeared in 1965 in *Proceedings of the Society for Experimental Biology and Medicine* (Vol. 119, pp. 252-5). This study showed a 15% increase in the rate of tumor-growth observed in mice receiving water with 1 part per million (1 ppm) fluoride.

"With this information at hand, I then acquired some of the cancer data used by Dr. Robert Harris, one of the principals in the CBS Special, and decided to see if there was any correlation between Cancer death rates and fluoridation.

"'Fluoridation Census, 1969,' (Page 12), published by the Department of HEW, Division of Dental Health, boasted that six cities, each having a population of one million and over, already were fluoridated. So I took those cities as well as the two remaining cities with populations of more than one million, and compared their cancer death rates. Results of this preliminary study appear in the following table:

CITY	WATER[1]	CANCER DEATH RATE[2]
1. Baltimore	FLUORIDATED	34% HIGHER*
2. Philadelphia	FLUORIDATED	27% HIGHER
3. New York	FLUORIDATED	24% HIGHER
4. Cleveland	FLUORIDATED	22% HIGHER
5. Detroit	FLUORIDATED	20% HIGHER
6. Chicago	FLUORIDATED	18% HIGHER
7. Los Angeles	NONFLUORIDATED	0% AVERAGE
8. Houston	NONFLUORIDATED	27% LOWER

[1]from "Fluoridation Census, 1969", U.S. Government Printing Office 1970 0-380-791, Division of Dental Health, Bethesda, Md., 1970.

[2]from "U.S. Cancer Mortality by County: 1950-1969", DHEW Publication No. (NIH) 74-615. National Cancer Institute, Bethesda, Md., 1974. Dates cities were fluoridated are 1952, 1954, 1965, 1956, 1967 and 1956, respectively. 1960 census figures used.

*as compared with national average

NOTE: San Francisco, which was fluoridated in 1952, has a cancer death rate 22% higher than the national average. It was the only major California city fluoridated so long, and the only major California city on the high cancer list.

Dr. Yiamouyiannis cautions that "It must be borne in mind that fluoride is not the only cause of cancer. Many other variables come into play. Thus, living in a low fluoride area would not assure one of not getting cancer. However, results of this study, while preliminary, are dramatic. These cities comprise somewhere between 10% and 20% of the population of the United States, so the sample size is much larger than the number of cities (eight) would indicate."

The National Health Federation has made an appeal to the Department of Health, Education and Welfare for funds to continue this study, Dr. Yiamouyiannis concluded.

Dr. Thalenberg Changes His Mind

Health Chief Recommends Against Fluoridating County Water Supply

Another influential voice has joined the ranks of those who believe fluoride should not be added to drinking water: Marvin Thalenberg, M.D., chairman of the Rockland County (N.Y.) Board of Health, after 30 years' support of fluoridation, on January 8 came out unequivocally against fluoridation of the county's water supply.

While expressing belief, on the basis of the literature over the past 30 years, that fluoridation "has proved to be safe and effective in reducing dental decay," Dr. Thalenberg based his changed position on these points:

". . . the increasing presence of fluoridated water throughout the country has increased the amount of available fluoride in processed foods.

"There has been a continuing increase in fluoride in the atmosphere, as a byproduct of industrial gases and its use as a component of spray-can propellants.

"I have not been able to find reliable estimates of how much fluoride this has added in non-water sources.

"The fluoridation of water itself presents a problem to a physician accustomed to precise dosage of medication. Fluoride is added at the source, and its actual concentration at the supply end is variable – in Nyack County for example it is 0.1 parts per million, while some Spring Valley sources have .45 parts per million.

"And, of course, ingestion of fluoride is widely variable. I have not been able to find studies of fluoride levels, nor surveys of the effects of added fluoride on populations such as the elderly with impaired kidney excretion."

The chairman of the Rockland County Board of Health then told his Board:

"To my own surprise, I find I cannot support universal fluoridation of our water supply. I therefore recommend to the Board . . . that we explore such alternates as free available fluoridated vitamins,

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tablets, and topical application."

Dr. Thalenberg concluded his recommendations with this clincher — a proposal too often overlooked, but a must in dental health care:

"I would also urge that the Board of Health support education programs to cut down the use of sucrose in children's foods, and that it work with consumer groups already working toward this end."

(Ed. note: Beautiful, isn't it? If you like what the doctor has said and done, drop him a line saying "Thank you, Sir!")

Commenting on Dr. Thalenberg's recommendations that the the Board consider issuing fluoridated vitamins, tablets and topical application to children whose parents desire them, and that the Board launch an educational campaign to help reduce the use of sugar in children's foods, the *Rockland County Journal-News* observed editorially last January 14:

"This, of course, represents fluoridation by individual consent and not through the blanket program recommended last summer by the Rockland County Dental Association. The point should receive the utmost consideration by the Board of Health, which is composed of both professional and lay representatives, and the County Legislature. In the broadest sense, Thalenberg is saying that while fluoridation seems to have proved effective in prevention of dental caries, the effects of its long-term ingestion, particularly through non-water sources, is still open to question. Perhaps the next step is an absolute determination of the control factor, and the effects of added fluoride on all the population."

(Ed. note: This is precisely what anti-fluoridation people, including Ralph Nader, have been urging for some time — a determination through bonafide studies on a national level.)

Fluoride Removal Bills Introduced

Legislation banning use of fluoride in public drinking water has been introduced in two state legislatures, is being considered in three more, and "this is just the beginning," according to NHF Science Director John Yiamouyiannis, Ph.D.

Dr. Yiamouyiannis prepared an amendment to a fluoridation law in Ohio, designed to "maintain the amount of fluoride in public water supplies and waterworks systems at a safe level."

If a water supply contains more than .8 ppm of natural fluoride, the bill would require removal to a fluoride content of not more than .5 ppm, and not less than .1 ppm.

If fluoride is being artificially added, the proposed legislation requires that "such addition shall be terminated within 30 days after passage" of the bill.

Similar legislation is being considered in California, Kansas, and Oregon where mandatory statewide fluoridation legislation has been introduced.

Dr. Yiamouyiannis would like to hear from individuals interested in lining up legislators to introduce antifluoridation measures in states where mandatory fluoridation already exists, as well as states where it has been proposed or might be proposed. He can be reached by writing NHF headquarters in Monrovia, Calif., 91016.

Is Fluoridation Legal?

By LEE HARDY

(No. 19 in a Series)

Governments are established to protect the citizenry and to guarantee their rights and freedoms as individuals. The Constitution of the United States of America was adopted for that purpose, and laws have been enacted setting up the machinery to accomplish that end. A Bill of Rights was attached to the Constitution to define certain inalienable rights. Amendment Four states: "The right of the people to be secure in their persons . . . shall not be violated." Amendment Fourteen prohibits abridgement of "the privileges and immunities of citizens."

In matters of public concern, communities establish policies for their government by the vote of a majority. Still, in matters of private concern the right of the individual is guaranteed by the Constitution, and is inviolable. In the words of Chief Justice Hamley, of the Washington State Supreme Court, "Constitutional guarantees are to protect the rights of the minority — not the majority. The majority does not need protection, because it does not do anything it does not want to do."[1]

Matters of public health are of public concern. Matters of private health are not. The freedoms of individuals may be abridged to protect the public from the spread of a contagious disease. Quarantine may be imposed upon a household whose member has smallpox, scarlet fever or the plague. However, tooth decay is not communicable, even from one tooth to another in the same mouth, and there is no threat of harm to any person by reason of another's having decayed teeth. Tooth decay is not a matter of public health, but strictly a private health matter, with which no public agency has any legal right to be concerned.

Even if fluoridation were beneficial and desired by some, still it could not be justified, since it is possible for any who wish to treat their children's teeth with fluoride to do so without fluoridation. Continuing the remarks of Chief Justice Hamley, "Even if it were to be assumed that the majority of the citizens . . . approve of this move (fluoridation), that would not con-

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done the impairment of constitutional rights."[1]

Some contend that the phrase, "to promote the general welfare," in the Preamble of our Constitution is authority for the government to take any measure it chooses in providing for public welfare or individual welfare. It must be remembered, however, that a preamble is merely a general statement of purpose, and does not authorize anyone to do anything. That purpose is implemented only by express authorization contained in the articles of a constitution or in amendments to it.

A number of suits have been initiated asking injunction against fluoridation. Some have been decided in favor of the plaintiffs, others have not. In the case of Dagmar Ready et al. v Saint Louis (Missouri) Water Company et al., the court declared the fluoridation ordinance to be "void and of no effect" (1960). Judge Douglas C. Jones handed down an opinion stating, in part: "The rights of the police power are correlative with inherent individual rights or, as stated by the Fourteenth Amendment, the right secured to each individual, the right to life and liberty that neither State nor County Council . . . may infringe upon or deprive an individual of these rights."[2]

Also in 1960, in a suit filed by citizens of Council Bluffs, Iowa, Judge R. Kent Martin, of the Fifteenth Judicial District of the State of Iowa, restrained the City of Council Bluffs from fluoridating the water supply on grounds the charter granted the city by the State of Iowa gave the city no such authority.[3] Circuit Judge Wallace Sample granted citizens of Fort Pierce, Fla., permanent injunction against fluoridation on the same grounds, April 13, 1961.

Notable among the suits decided against plaintiffs are Dowell v City of Tulsa which, upon appeal to the Oklahoma Supreme Court, was denied on the ground "the plaintiffs introduced no evidence;" Kaul v City of Chehalis, Wash., by a five-to-four decision after review by the State Supreme Court; Schuringa et al. v City of Chicago, in which an appeal to the U. S. Supreme Court eventually was dropped, presumably because of lack of funds to continue the case, and after the death of some plaintiffs.

In the Kaul case, the majority denied the injunction on grounds no evidence of harm was presented and no claim was made that fluoridation would affect the wholesomeness of the water supply, and it was assumed without argument that addition of fluoride actually would prevent tooth decay. Justice Matthew W. Hill in a dissenting opinion pointed out that the appellant was deprived of his liberty by being compelled to drink fluoridated water because there was no other practical source of supply.[1]

Justice Charles T. Donworth, in stating his own dissent, said: "The issue in this case is whether the individual citizen is to be allowed to decide for himself what medicine he will or will not take, or whether the city council (or commissioners)

HARDNESS OF WATER UNRELATED TO DEATHS

The hardness of drinking water in three Los Angeles communities appears to have no effect on death rates from heart disease or on infant mortality, a UCLA School of Public Health study by four researchers indicates. In recent years there have been conflicting reports on whether lower death rates from heart disease and lower infant mortality rates are associated with hard water. No such relationship could be found in a study of water in Reseda with the softest water – 82 parts per million of calcium carbonate; Burbank, using Colorado River water averaging 189 ppm of calcium carbonate; and Downey's well-water with 327 ppm of calcium carbonate.

Recently I had to go into a hospital. I paid $200 a day for a private room, and so did the other five patients in it.

– Lucille Gould in *Parade*

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and the state board of health are to decide this question for him and force the dosage down his throat by mixing it with the municipal water supply."[1]

In the case of Alice Schuringa and other citizens against the City of Chicago, Superior Court Master in Chancery, Mayer Goldberg, ruled against the plaintiffs even though he admitted (1) that the individual dose would vary ("There is no question, the more water you drink the more fluoride you take in.");[4] (2) that the concentrations delivered by the water system could not be governed ("All the units in the water will vary from time to time. I don't see where this could be constant . . . It's obvious there are extreme variations.");[5] (3) that the amount of harm would vary ("It is obvious everybody is going to be different in their retention and absorption of fluoride.");[6] (4) and that the higher incidence of ailments causing death in Colorado Springs, with 2.5 parts per million of fluoride in the water, was among those who had lived there longest.[7]

Among the Chicago plaintiffs was Walter Olson, a member of the Christian Science Church. Here again we find in fluoridation a violation of the Constitution. The First Amendment expressly states that there shall be no law prohibiting free exercise of religion. Since Christian Science doctrine denies the beneficial effect of material remedies, including drugs, it is obvious that by fluoridation Mr. Olson or any person of similar religious belief is denied free exercise of religion.

1. Kaul v City of Chehalis (Washington), 2d 616, 277 p. 2d 352.
2. Jones, D. L. C., Circuit Court, County of St. Louis (Missouri)), Cause No. 230189.
3. Martin, R. K., District Court, Pottawattamie County (Iowa), Cause No. 37349 in Equity.
4. "Final Summary Submitted in the Fluoridation Injunction Suit Against the City of Chicago," 1960, Citizens Against Fluoridation, P.O. Box 14, Chicago, Ill., p. 10.
5. Ibid., pp. 19-20.
6. Ibid., p. 60.
7. Ibid., p. 98.

37 Senators on New Vitamin Bill

FDA Efforts to Regulate Vitamins As Drugs Hit By Proxmire, Schweiker

(Ed. note: This is perhaps the best-organized and most complete explanation of what the "vitamin legislation" is all about to be published to date. It answers the questions raised by Congressman Paul Rogers whose subcommittee annihilated a similar bill in the House last December. It responds concisely and directly to FDA objections to a bill which would prevent that agency from defining and thus regulating vitamins as drugs. If there is sufficient demand, reprints may be made for use in the offices of "wavering" Congressmen as the issue develops in each branch of Congress this year).

February 3 was a red-letter day in the history of National Health Federation—and a significant one for the American consumer: As of that "point in time," 37 United States Senators had agreed to cosponsor S.548, the Proxmire-Schweiker Bill which stipulates that vitamins are foods, not drugs, and thus not subject to treatment as drugs as sought by the Food and Drug Administration.

The news was relayed by Legislative Advocate Clinton R. Miller by telephone to NHF's Monrovia headquarters where President Charles I. Crecelius, who took the message, exclaimed, "This puts us where we left off when the 93rd Congress ended. It is a significant development demonstrating there has been no change of mind in the Senate, and we are naturally elated."

Listed on the bill in addition to the author, Senator William Proxmire of Wisconsin and cosponsor Richard S. Schweiker of Pennsylvania, are Senators Hugh Scott of Pennsylvania; James Abourezk and George McGovern of South Dakota; James Allen and John Sparkman of Alabama; Frank Church and James McClure of Idaho; Lawton Chiles of Florida; Alan Cranston of California; Pete Domenici of New Mexico; James Eastland of Mississpp; Paul Fannin and Barry Goldwater of Arizona; Mike Gravel of Alaska; Orval Hansen and Gale McGee of Wyoming; Vance Hartke of Indiana; Daniel K. Inouye of Hawaii; J. Bennett Johnston of Louisiana; Patrick Leahy and Robert Stafford of Vermont; Mike Mansfield of Montana; John McClellan of Arkansas; John Moss of Utah; Sam Nunn of Georgia; Bob Packwood of Oregon; Claiborne Pell of Rhode Island; Jennings Randolph of West Virginia; Adlai Stevenson III of Illinois; Strom Thurmond and Ernest F. Hollings of South Carolina; Robert Dole of Kansas; James Buckley of New York; and Hubert Humphrey of Minnesota.

(In the House, similar legislation has been introduced by Representatives de la Garza and Patman of Texas, Broomfield and Cederberg of Michigan, Annunzio of Illinois, Delaney of New York, Randall of Missouri, McKinney of Connecticut, Matsunaga of Hawaii, and Quillen of Tennessee.)

Although requiring considerable space, the issue is so important to the future of each of us that the statements, as published in the *Congressional Record*, of Senator Proxmire and Schweiker on the Senate floor last Feb. 3, are reproduced herewith:

S. 548

A bill to amend the Federal Food, Drug, and Cosmetic Act to include a definition of food supplements, and for other purposes. Referred to the Committee on Labor and Public Welfare.

VITAMIN BILL — FOOD SUPPLEMENT AMENDMENT OF 1975

MR. PROXMIRE: Mr. President, on behalf of myself and Mr. Schweiker and (the other cosponsors), I introduce a bill to amend the Federal Food, Drug and Cosmetic Act to include a definition of food supplements and for other purposes.

The purpose of the Proxmire-Schweiker bill is to prevent the Food and Drug Administration from regulating safe vitamins as dangerous drugs. The bill is similar to the measure which passed the Senate by an 81 to 10 vote on September 24, 1974, but which died as part of the Health Manpower Act when that bill died in Conference the last day of the Congress.

The Senator from Pennsylvania and I have issued the following joint statement which I shall now read upon introduction of our new vitamin bill.

FDA WOULD REGULATE VITAMINS AS DRUGS

The Food and Drug Administration is proposing that vitamins sold in amounts greater than 150% of the so-called U.S. Recommended Daily Allowance — RDA — be regulated as drugs.

But vitamins are not drugs. They are foods. For years they have been regulated as foods. The fundamental thing the Proxmire-Schweiker bill does is to tell the FDA that vitamins are foods and should continue to be regulated as foods.

The Proxmire-Schweiker bill does not diminish in any way the existing protection to the consumer against toxic, adulterated, or mislabeled vitamins and foods. Under present law, FDA has ample authority to regulate any of the few vitamins which are toxic or which might be mislabeled.

Furthermore, the bill specifically states it does not reduce in any way the existing authority FDA has over cyclamates, carcinogenic substances, or food additives.

Under the FDA's proposed regulations, relatively small amounts of very common vitamins would have to be sold either as over-the-counter — OTC — or prescription drugs. Vitamin C is a good example of

(Please turn the page)

what could happen: The new recommended daily allowance for vitamin C is 45 milligrams. But vitamin C is routinely sold in 100, 250, or 500 milligram tablets. Since it is nontoxic and harmless there is no reason why that should not continue.

If the FDA has its way, any vitamin C tablet sold in excess of 150% of the RDA, or 67.5 milligrams, would be regulated as a drug and would be required to go through the long, tortuous, and expensive FDA drug proceedings. That is both ridiculous and irresponsible.

The Proxmire-Schweiker bill is clear. Provided a vitamin or mineral is safe and not mislabeled, the consumer should have the same freedom of choice to buy it, just as he may buy thousands of other foods and beverages.

Since FDA first proposed the regulations in June 1966, a Damoclean sword has been hanging over the heads of the vitamin consumer, the small health food stores, and the vitamin producers, in the form of these unnecessary and arbitrary requirements. Without our bill, they could finally go into effect next July.

We believe that with the wide support there is in both Senate and House for the basic principles in the Proxmire-Schweiker Bill, either it or an acceptable compromise to achieve the same purpose can be passed this year.

Mr. President, I ask unanimous consent that the language of the bill be printed at this point in the *Record.*

There being no objection, the bill was ordered printed in the *Record,* as follows:

S. 548

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, that this Act may be cited as the "Food Supplement Amendment of 1975."

Sec. 2. Subsection (f) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 (f)) is amended by (1) redesignating clauses "(1)", "(2)", and "(3)" as clauses "(A)", "(B)", and "(C)", respectively, (2) inserting "(1)" immediately after "(f)", and (3) adding at the end thereof the following:

"(2) The term 'food supplement' means food for special dietary uses.

"(3) The term 'special dietary uses', as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

"(A) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological, or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

"(B) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

"(C) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use."

Sec. 3. Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341-348) is amended by adding at the end thereof the following new section:

"*Sec. 410* (a) In administering this Act the Secretary shall not limit the potency, number, combination, amount, or variety of any synthetic or natural vitamin, mineral, or other nutritional component of any food for special dietary uses if the amount recommended to be consumed does not ordinarily render it injurious to health.

"(b) Nothing in this section shall be construed to limit the Secretary's exercise of authority concerning food additives pursuant to subsection 409 (a) of the Act, or to prescribe the steps to be taken to establish their safety, pursuant to subsections 409 (b) and 409 (c), including compliance of food additives with the anti-carcinogenic provisions of said subsection 409 (c)."

Mr. Proxmire: Mr. President, in the past the Food and Drug Administration has charged that the language of our bill would radically change the FDA rules, regulations, and procedures. But the language in our bill comes in large part from the Food, Drug, and Cosmetic Act and the FDA regulations themselves. To show this clearly I ask unanimous consent that the language from chapter I, section 1.11 of the Special Dietary Uses section of the Code of Federal Regulations, Title 21, be printed at this point in the *Record.*

There being no objection, the material was ordered printed in the *Record,* as follows:

1.11 Special dietary uses.

(a) The term "special dietary uses," as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

(1) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

(2) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

(3) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

(b) No provision of any regulation under section 403 (j) of the Act shall be construed as exempting any food from any other provision of the Act or regulations thereunder, including sections 403 (a) and (g) and, when applicable, provisions of Chapter V of the Act.

(Please turn the page)

20 F.R. 9529, Dec. 20, 1955

MR. PROXMIRE: One will note that the language here is identical to that in our bill. What we have done is to put into the law the regulations under which the FDA has regulated vitamins as foods for many, many years.

I ask unanimous consent that the provisions of section 402 (a) (1) of chapter IV — Food — of the Federal Food, Drug and Cosmetic Act, as amended, be printed at this point in the *Record.*

There being no objection, the material was ordered printed as follows:

CHAPTER IV — FOOD

* * *

ADULTERATED FOOD

SEC. 402 (342). A food shall be deemed to be adulterated —

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or

MR. PROXMIRE: One will note that the phrase, "* * * if the quantity of such substance in such food does not ordinarily render it injurious to health," the latter part of which is a key phrase in our bill, comes directly from the law itself.

Finally, Mr. President, I ask unanimous consent that excerpts from the statement I made in the debate on September 24, 1974, be printed at this point in the *Record.*

There being no objection, the material was ordered to be printed, as follows:

EXCERPTS FROM SEPTEMBER 24, 1974 STATEMENT OF SENATOR WILLIAM PROXMIRE

This is an amendment to prevent the Food and Drug Administration from regulating safe vitamins as dangerous drugs.

WHAT THE AMENDMENT DOES

The Food and Drug Administration, for several years now, has been attempting to regulate safe vitamins and minerals — which are foods — as dangerous drugs. They have tried to do this through FDA regulations and orders rather than through legislation.

What this amendment does — and all it does — is to stop that action. It restores the status quo. It says to the FDA that they shall continue to regulate vitamins and minerals as foods.

FDA ATTEMPTS TO DISTORT MEANING

Time and again throughout the debate over this amendment, the FDA has attempted to distort its meaning by claiming it would limit their jurisdiction and shift the burden of proof for safety to the FDA rather than the vitamin manufacturer or retailer.

Nothing could be further from the truth. The key language in the amendment is taken either directly from part 1.11, 21 Code of Federal Regulations, which have been in effect since 1955 — or two decades — or taken directly from the law itself — namely, from section 402 (a) (1), which states the FDA cannot limit the potency, number, combination, amount, et cetera, of a vitamin or mineral "if the amount recommended does not ordinarily render it injurious to health." That is our phrase, and it is already in the law. The amendment restores that phrase and would supersede the FDA's intended regulations.

BUSINESSES AT STAKE

Why is this amendment so urgent? The health food industry — not the big drug manufacturers, but the health food industry and the small health food stores — the Mom and Pop health food stores found all over the country — are in grave danger of being out of business.

The FDA's regulations say that when they go into effect, any vitamin sold in quantities in excess of 150% of the so-called U.S. Recommended Daily Allowance — U.S. RDA — will become a drug and be regulated as a drug. These regulations were to have gone into effect next January. Now they have been postponed by court order until next July 1. But then they can go into effect.

The health food stores have this Damoclean sword hanging over their heads. It has been there since 1966, when the FDA first put out its regulations. It is time we settled this matter, and settled it for good.

We are proposing this amendment on this bill to save those businesses. We are also doing it to save the consumer from being ripped off, because if vitamins cannot be bought in amounts greater than 150% of the U.S. RDA, the consumer will have to pay through the nose for quantities of vitamins he now uses routinely.

The time has come to deal with this matter and to deal with it decisively. What this amendment does therefore, is to restore the matter as it was before the FDA came forward with its regulations. It tells the FDA that instead of acting by executive fiat or through regulations, if it is going to make drastic changes affecting the livelihood of millions of people, then do it through legislation and not by administrative regulation.

U.S. RDA'S AN ARBITRARY, SUBJECTIVE, CAPRICIOUS STANDARD

One of the reasons for this is that the RDAs are questionable standards. The FDA's U.S. RDAs, which are based on the Food and Nutrition Board's so-called recommended daily dietary allowance, are an arbitrary, subjective, and capricious standard.

First, they are, more often than not, too low. And the reason for that is so that the orthodox food industry can put on the side of its breakfast food containers that the breakfast food contains a very high proportion of the recommended daily allowances. The lower the RDAs, the better the nutritional value of the breakfast food industry, and other food industry products look.

Second, the Food and Nutrition Board's RDAs, upon which

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the FDA's U.S. RDAs are based, have had major changes in values almost every time they are issued. For example, the 1968 RDAs had 55 changes in values over the 1964 RDAs, which varied from 20 to 700%.

Take vitamin E, for example. In 1964 there was no RDA. In 1968, the RDA for pregnant women was 30 international units. In 1974, the RDA for vitamin E for pregnant women was 15 RDAs.

If the FDA's regulations had been in effect for each of these years, this would have been the situation.

In 1964, since vitamin E was not even on the list, it could have been purchased in unlimited quantities.

In 1968, with an RDA of 30 international units, one could have purchased vitamin E in 45 international unit capsules.

But in 1974, vitamin E in excess of 22.5 international units would become a drug and would be regulated either as an over-the-counter-drug or put on prescription.

Even the experts differ on RDAs. I ask unanimous consent to have printed in the *Record* a table indicating the difference between the RDAs recommended in 1970 by Dr. W. H. Sebrell, Jr., chairman of the committee which established the 1968 RDAs, and the 1974 RDAs.

There being no objection, the table was ordered printed, as follows:

	Dr. Sebrell	1973-74 RDA's	Percent Sebrell Above RDA's
Pregnant women:			
Vitamin A (IU)	8,000	5,000.0	160
Vitamin E (IU)	30	15.0	200
Vitamin B12 (Mcg.)	8	4.0	200
Child under 4: Vitamin B12 (Mcg.)	4	1.5	333

MR. PROXMIRE: That table indicates that the experts differ, and differ very much, on the proper amounts that should be proposed as recommended daily dietary allowances. If these amounts were simply advisory, there would be no complaint. But the FDA has taken those amounts and put them into regulations. And that means that if some manufacturer or some health food store makes vitamins or sells them in greater quantities, they are subject to the "criminal law." That is too harsh a penalty to hand out when the basis for the regulations is so controversial.

The Second Circuit Court of Appeals, which delayed the date when the regulations go into effect, stated:

"Our examination of the record (of the FDA vitamin hearings) has turned up not a single instance in which the scientific processes by which the RDA figures were developed were subject to searching examination."

Other experts differ as well. Among them are Dr. Paul Gyorgy, discoverer of vitamin B-6, who recommended in 1971 that the RDA for vitamin B-6 should be set at 25 milligrams a day, or 12.5 times the 2 milligram level the Food and Nutrition Board established for 23-50-year-old females.

Dr. Linus Pauling recommended daily levels of vitamin C which are over 100 times the 45 milligrams recommended by the Food and Nutrition Board.

The RDAs, about which there is so much controversy even among the scientific community, is no standard on which to base criminal law.

AMENDMENT DOES NOT TOUCH EXISTING FDA POWER TO REGULATE TOXIC, UNSAFE, OR MISLABELED FOODS

This amendment does not change the vast power the FDA has to regulate foods. All it states is that the FDA shall regulate vitamins as foods and not as drugs.

If a vitamin or mineral is toxic, the FDA has adequate authority to regulate it. It has done so in the case of vitamins A and D and vitamin K.

If a vitamin or mineral is mislabeled, there is more than adequate authority to deal with it under existing law. In fact, many people believe the FDA already has gone too far, as for example when it banned sale of a book on the favorable effects of vinegar and honey when it was displayed and sold in a store which sold vinegar and honey. Since vinegar and honey also are proposed in the Old Testament as nutritious foods, there are many who believe that if the FDA had gotten its way on that one – and fortunately it did not – then Macy's or Gimbel's would be barred from selling vinegar and honey if they also sold the Old Testament in their stores.

Finally, there are a great many food substances which are highly toxic – far more than vitamins – but which are regulated as foods – because they are foods – and not drugs.

If the FDA is to retain any logic in its point of view, it should regulate sugar, salt, coffee, tea, and even water as dangerous drugs, because they are toxic if used in large or excessive quantities.

CONCLUSION

The amendment does nothing more than restore the status quo. Its language is that of the law and of the regulations which have been in effect for two decades.

It does not take away from the FDA any power over toxic foods or mislabeled foods or foods made in unsafe surroundings.

But it does tell the FDA it is not to place the business of thousands of small health food stores in jeopardy through executive fiat and administrative regulations.

And the amendment would do that now, because these small businesses and millions of consumers have had the FDA regulations hanging over their heads for years and will shortly experience the final coup de grace if the FDA has its way.

Mr. President, the argument has

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been made that the vitamin amendment is an "irresponsible" amendment because it diminishes the FDA's power over food additives, not just vitamins. There is no way under our amendment the FDA could not regulate cyclamates.

This is an outright misrepresentation of our amendment.

First, our amendment provides – as the present existing laws provide – chapter IV, food, section 402 (a) (1) – the FDA with every existing authority to regulate adulterated foods. The language comes directly from the "adulterated food" section of the law.

Second, our amendment does not limit or take away any power the FDA now has over "food additives" such as cyclamates, the reason being that a food additive by definition is "a chemical ingredient not generally recognized as safe."

What the FDA wants to do – and which we object to and which our amendment would prevent – is to treat safe vitamins and minerals, which by definition are special dietary foods, as "unsafe food additives."

Vitamins are special dietary foods. Vitamins are not food additives. The entire fight is whether or not the FDA is going to treat vitamins—which are foods—in the same way they treat unsafe chemical additives or drugs, like cyclamates.

But our amendment does not prevent the FDA, in any way, from acting under existing food laws to regulate vitamins if they are toxic, if they are misbranded, or if they are made in unsafe or unclean surroundings. FDA has that authority now. We reinforce it by saying that vitamins shall be regulated under that authority. And our amendment does not prevent – in any way – the FDA from acting against "food additives"—which are by definition "unsafe chemical." We do not touch that authority. We do not limit that authority.

HISTORY OF FDA ENFORCEMENT

The FDA also argues that it needs the new drug regulations in order to get needed enforcement powers for abuses. FDA officials say it is too difficult to bring cases one by one, and hence need blanket authority. Here is the answer to that: Under our amendment as under existing food laws—FDA has every needed authority to regulate "toxic" or unsafe foods. Under the present laws – which our amendment merely restores – the FDA has regulated vitamins A and D, and K because of apparent toxicity. This authority remains under our amendment. We do not touch it.

There is no evidence that there has been any more fraud or misrepresentation in the food supplement industry than in any other industry or business. The FDA's own figures bear this out. There has been only a "mild" incidence of violations of the FDA regulations in this area, and the FDA has had no difficulty controlling them. Here are the facts:

First, the nature of the cases: 90 percent of the regulatory actions begin with seizures under section 502 (a) – which has to do with misbranding because of false or misleading labeling.

In 28 years, the total number of cases was 1,028, or 36 a year.

of these, 649 – or 23 a year – involved supplements of vitamins or minerals.

Of the 649 – 70 involved products containing iodine or sea water preparations, 41 involved reducing aids, and 283 concerned miscellaneous health foods.

Second, disposal of the cases indicates existing authority is adequate.

Of the 1,028 cases, 883 were civil seizure cases of which 99% were disposed of either by default – 638 – or consent decree – 234.

That took no great enforcement effort, nor does it show that laws are inadequate as FDA claims.

One hundred twenty-two were criminal cases – of which 85% were disposed of by guilty pleas – 102.

In the last 28 years the FDA has had to try only about 20 cases. Of these, 15 went for the government, and 5 for the defendants.

The FDA's legal branch has not been overworked and needs no new authority.

Finally, the Food, Drug and Cosmetic Act is an unusual criminal statute because courts have regularly held that the FDA does not have the usual burden of proving that perpetrators of alleged felonies intended to misbrand the food, or even knew it was misbranded.

Thus, the FDA now has great authority under the food laws.

Our amendment does not diminish that authority. What it does is continue to allow the FDA to act under the food laws, but prevents it from acting under the "drug" laws by calling vitamins – which are foods – dangerous drugs.

All the factual information I have cited was presented to U.S. Court of Appeals for the Second Circuit.

DOES NOT SAY ONE WORD ABOUT SO-CALLED MEDICAL CURES

Opponents of the amendment charge that the amendment authorizes the sale of vitamins for unproven medical cures.

There is not one line in the bill doing any such thing.

If the vitamin is toxic, it can be regulated under the amendment.

If the vitamin is mislabeled – it can be seized under our amendment and the present law.

If it is made in unclean surroundings, the FDA can act as well.

The amendment does not authorize the sale of vitamins for any purpose such as an unproven medical cure.

If that is illegal now, then it is equally illegal, under our amendment.

The Proxmire amendment does not "retreat" to 1938 and put the burden of proof on the government. Under the food laws, the burden of proof is now on the government with respect to foods.

And there is a very good reason for that.

The FDA exercises criminal statutes.

The Food, Drug and Cosmetic Act is unique in that the criminal

act requires no intent. People can be sent to jail for what are essentially innocent actions.

When a government agency exercises criminal laws – and very stringent criminal laws – the burden of proof should be on the government. People should be innocent until proven guilty.

That fact has not prevented the FDA from acting against any toxic, unsafe or mislabeled vitamin or mineral in the past.

FDA has put vitamin A and D in large quantities on prescriptions, and under this amendment that would and could continue.

FDA has seized mislabeled and misbranded foods. That authority continues.

All the amendment does is to prevent the FDA from treating safe vitamins as drugs, which is what it is determined to do if not stopped, either by legislation or by the courts.

VITAMINS AS OTC AND PRESCRIPTION DRUGS

The FDA charges that proponents of the amendment falsely state that the FDA would put vitamin pills on prescription, rather than treating them as over-the-counter drugs.

Here is the answer:

First: It is true that what the FDA would do, mainly, is treat vitamins as over-the-counter drugs – OTC – if they exceed 150% of the so-called U.S. recommended daily allowance.

Second: However, if treated as an over-the-counter drug, the manufacturer or retailer must prove to FDA that vitamins are not only safe – which is no problem and already provided under the food laws – but that they are "efficacious."

Third: But the FDA already has said that such vitamins as Vitamin C and Vitamin B-6 and other vitamins are not needed in quantities more than 150% of the RDA, and are not effective or useful in such amounts.

In fact, in its vitamin regulations – which the courts have stopped temporarily – the FDA stated that a food shall be misbranded if its labeling represents, suggests, or implies six items including item 1 which states:

"(1) That the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom."

It is now illegal to claim that. Yet to become an over-the-counter drug, a manufacturer would now have to make such a specific, illegal claim for the vitamin.

That is impossible.

What it means is that the FDA Over-the-Counter Committee, if it follows the proposed FDA regulations, would have to reject such a claim for "effectiveness" out of hand.

Fourth: In those circumstances, the vitamin could then only be sold under prescription in amounts greater than 150% of the RDAs.

That is why there is very great chance vitamins in amounts greater than 150% of the RDAs will have to be gotten under prescription. That is a genuine possibility. It is no idle threat.

SENATOR SCHWEIKER SPEAKS

MR. SCHWEIKER: Mr. President, I am pleased to join my distinguished colleagues in introducing this bill to prevent the Food and Drug Administration from carrying out its determination to classify safe vitamin and mineral supplements as drugs, and regulate them under the drug provisions of the law rather than as foods or food supplements.

As ranking Republican on the Senate Health Subcommittee and as a member of the Select Committee on Nutrition and Human needs, I have been closely involved with the study and improvement of our Nation's health care system. I have introduced legislation to provide funding for teaching applied nutritional education in medical schools and dental schools. Furthermore, I sponsored a bill to require mandatory nutritional labeling of all food commodities months prior to FDA's initial issuance of voluntary nutritional labeling regulations.

Testimony before my committees has centered a great deal on the lack of sound nutritional knowledge in the medical profession. Regardless of this inability of many doctors to provide us with consistent and sound nutritional advice, the FDA wants to make all vitamins, whose potencies exceed 150% of the questionable RDA, over-the-counter drugs.

For example, vitamin C tablets in excess of 67.5 milligrams would be considered an over-the-counter drug. Thus, this relatively weak dose of Vitamin C would be subjected to the lengthy and expensive procedure required by the Food and Drug Administration for approval of all OTC products.

The FDA argues it is acting in the best interests of the general public. Is limiting the availability of a nontoxic, safe Vitamin C tablet in the public interest? Is forcing up the cost of this tablet in the public interest? I say no, and again I am strongly supporting a bill to prevent the FDA from taking this restrictive action.

Mr. President, it is no secret there exist merchants who are trying to sell unsuspecting consumers vitamin products which they do not need. Likewise, there are merchants trying to sell consumers options for their automobiles which they do not need. But is the government trying to restrict the sale of automobile options, even though they may decrease gasoline mileage and not be in the best interest of our country?

With the exception of Vitamins A and D, I am not aware of any conclusive medical evidence which would indicate that vitamin and mineral consumption will damage one's health. I have personally met with FDA Commissioner Schmidt to discuss the proposed vitamin and mineral restrictions. I am convinced the public has the right to purchase such vitamins and minerals as they choose, unless they are shown to endanger a person's health. I agree in principle with

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20th Annual Convention Another 'Bell-Ringer'

A roster of knowledgeable speakers, supported by appreciative audiences – judging from the response, not only oral but financial! – marked the four-day Twentieth Annual Convention of National Health Federation in Anaheim in January.

Space in *The Bulletin* is too limited to report the 35 lectures. Tapes of most presentations except those of "workshop" nature, are available from the Monrovia office of NHF. (For listing and prices please turn to pages 31-32).

The days started with 7 o'clock workshop sessions conducted by the fluent and tireless Clinton R. Miller for a small but dedicated group (you've got to be dedicated to start a convention day off at that hour, right?).

He told his listeners, "We have built up momentum for the Proxmire-Hosmer-type bills, and we must hang onto that momentum." With the 37 sponsors of a newly-introduced Proxmire-Schweiker Bill in the Senate, NHF efforts now will be focused in the House where it is essential that 218 Congressmen be persuaded to sign a discharge petition to force the desired bill out of the subcommittee, he said. Eleven members of the House introduced bills similar to the Hosmer Bill after the new session opened Dec. 16. H. R. 920, introduced by Congressman Randall of Missouri replaces the Hosmer Bill.

Mr. Miller told his NHF audience that "the power of persuasion," coupled with "perseverance," are the ingredients for changing solons' minds. "Letters, letters, letters – that does it," he continued, "and don't let anyone tell you form letters are worthless." A new letter now is available at NHF headquarters for use in persuading Congressmen that a bill similar to the old Hosmer Bill be moved through the House.

Declaring that "one person can change a Congressman's mind," Mr. Miller described the work of Mr. and Mrs. Bruce Helvie of Cincinnati who have been responsible for changing the minds of six Congressmen, through the patient use of *letters*.

"When you have a Congressman who hasn't budged on the issue, write letters, one for each day of the week, sign them and drop one into the mail each day. Eventually that Congressman will decide to take a position on the side of the consumer – our side," continued Mr. Miller. "Another good rule is TCK – treat your Congressman kindly. They are good people – they will see things our way if we persevere!"

President Charles I. Crecelius told the audience that "we fight a desperate struggle – monopoly is trying to take away from us our freedom of choice. They have a service to sell, and they don't want the money they'll make interfered with. I don't hesitate to use the word conspiracy when considering the issues before us and those who insist on controlling decision-makers. Whenever great companies become so powerful they can recommend and put into authority people in government who will see that their interests are taken care of, that is conspiracy!

"To do this, they must mount a tremendous publicity campaign, making people think that taking vitamins is dangerous. But neither they nor their friends in government make any effort to remove tobacco or alcohol from store shelves – and we all know these things are injurious."

Mr. Crecelius introduced Mr. Helvie, a member of NHF's Board of Governors who attends national conventions regularly. He told how he and Mrs. Helvie learned about nutrition 35 years ago, "then started sharing what we had learned. I gave up a good job to go into the food supplement business, and we heard how the Food and Drug Administration planned to seize our products claiming they were worthless. We felt awfully alone 20 years ago, then we heard about National Health Federation and we joined, felt the support of numbers. We became life members, and finally, though money didn't come that easy, we became perpetual members, sending in a monthly check until the thousand dollars was paid. We also have a routine we call 'TT co me.' Tithe of a tithe, count on me. Don't be stingy with yourself – NHF stands for principles that are important to you, whether you realize it or not."

Dr. Walter Hodson, who with Dr. John Yiamouyiannis emceed the meetings, summed it up thus on the last program the final day: "If you're not a member, you're letting someone else do your work!"

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the FDA's action with Vitamins A and D.

But I do not agree that the FDA should have the authority to place, on some future date, additional vitamins and mineral supplements, at a particular potency, on a prescription-only basis. This will greatly increase their price and limit their availability.

Mr. President, S. 2801, last year's version of this bill, passed the Senate as an amendment to the Health Manpower Act by an 81-10 margin. Subsequently, the Conference Committee did not complete its work on the bill, and it died with the adjournment of the 93rd Congress.

This year's bill is, for the most part, identical to S. 2801. Although controversial, I feel its basic philosophy is acceptable to most members of both chambers. With this in mind, I am optimistic an acceptable compromise can be obtained prior to the end of this year.

NEW LIFE AND PERPETUAL MEMBERS

Perpetual

Alfred Coles Barney
Howard M. Hofmann

Life

Cora G. Chase
Katherine Keppel
Mr. and Mrs. Wayne Reber
Mr. and Mrs. Harold P. Leland
Edward Palecek
Juana Carreras
Jim Loukopoulos
W. H. and Vernis A. Haines
Wilbur E. Wheeler
Otto O. and Maxine A. Jeanes
Laren W. Smith, D.C.
Mrs. Nellie Gherkin
Mr. and Mrs. C. M. Hittinger
Mrs. J. C. Shelton
Ursa Parkhurst
Florence M. Gomez
Dr. William J. Woolbright
R. C. and Gertrude Lockhart
Elliot S. Graham
Esther A. Hansen
L. W. Townsend
Mervyn G. Shippey
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Mr. and Mrs. John H. Cagle
Virginia M. Griswold
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Nadine Kirkendall
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Helen I. Spence
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Deanna Bohn
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Mrs. Millicent Hines
Mrs. James L. Rodgers
Dr. Kermit G. Clemans
Chris Hoekstra
Carmela LasPina
Susan W. Nelson
Dorothy L. Frederick
Henry and Lillian Esparza
Ann Hardy
Edward C. Butler
Helen B. Gilfillan
Donald and Luella Kook
Pat and Al Kass
Meryl H. Smith
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Mr. and Mrs. Fred H. King
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Sharon A. Jull
Mrs. John H. Klopp
Lorena Hurst
Marguerite A. Knott
Attilio J. Bombelli
Marvin L. Brown
Gertrude McNeil

(Received mid-January thru mid-February)

Another Nuclear Shutdown

WASHINGTON — Twenty-three nuclear power reactors were ordered shut down by the Nuclear Regulatory Commission to search for cracks in emergency safety system pipes. It is the second time in five months that nuclear reactors have been ordered to cease operations for inspection of emergency systems for pipe cracks that might lead to pipe failures if the emergency systems must be used.

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"New Developments in Cancer Therapy," Dean Burk, Ph.D. — $3.50		
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"Continuing Legal Battles for Health Freedom," Kirkpatrick Dilling (NHF Counsel) — $3.00		
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"Food And Drug Activity As Related to the American Scene," Carlton Fredericks, Ph.D. — $3.50		
"Preventive Nutrition vs. Crisis Medicine, Part I," Carlton Fredericks, Ph.D. — $3.50		
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"Viewpoint On Nutrition," Arnold Pike, D.C. — $2.50		
"Nutrition for All But the Cancer Patient," James R. Privitera, M.D. (Courageous doctor specializing in preventive health care). Plus: "An Encounter With the Goon Squad," (a case history), Carroll Leslie, B.Sc. — $3.50		
Dr. Robert Harold Schuller, internationally-known lecturer and author of *You Can Be the Person You Want to Be* — $3.50		
"Medical Treatment of Mental Retardation In the United States and Abroad, Part I," Henry Turkel, M.D. — $3.50		
"Medical Treatment of Mental Retardation In the United States and Abroad, Part II," Henry Turkel, M.D. — $3.00		
"Fluoridation . . . a New Horizon for NHF," John Yiamouyiannis, Ph.D. (NHF Science Director) — $2.50		

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THIS IS THE NATIONAL HEALTH FEDERATION

The National Health Federation is America's largest, organized, noncommercial health consumer group. It is a nonprofit corporation founded in 1955. Its membership is comprised of men and women in all walks of life, belonging to a variety of religious faiths and political persuasions, and engaged in nearly every profession and trade.

Its members believe that health freedoms are inherently guaranteed to us as human beings, and our right to them as Americans is implied in the words, "life, liberty and the pursuit of happiness." Yet, frequently, these freedoms and rights have been and continue to be violated. Too often, as a result of the unopposed pressures from organized medicine, the chemical industry, pharmaceutical manufacturers, and others, laws and regulations have been imposed which better serve these special-interest groups than the public at large. We see and hear of new instances daily. To name a few: spiraling health-care costs, consumer exploitation by leading industries, excessive devitalization and adulteration of our foods, restriction of certain types of treatment, banning of certain health books from the mails, the harassment of those who advocate natural methods of healing and natural foods, the poisoning of our air, water and soil through greed and carelessness, and many other health-related issues.

The NHF opposes monopoly and compulsion in things related to health where the safety and welfare of others are not concerned. NHF does not oppose nor approve any specific healing profession or their methods, but it does oppose the efforts of one group to restrict the freedom of practice of qualified members of another profession, thus attempting to create a monopoly.

The public needs a strong voice, such as the NHF provides, to speak and act in their behalf in these health-related matters. Legislators need your support to balance the pressures exerted upon them by the special interests. The National Health Federation, through a special legal and legislative staff in Washington, keeps its members apprised of all health legislation, opposes inadequate or undemocratic health legislation, while supporting or drafting bills to protect the individual's health freedom.

Will you join us in this worthy effort?

ELECTED FEDERATION OFFICERS

Charles I. Crecelius — President and Executive Head of the Federation. Address: P.O Box 688, Monrovia, California 91016.

Betty Lee Morales — Secretary

Dorothy B. Hart — Vice-President

Kurt W. Donsbach — Chairman of the Board of Governors and Executive Assistant to the President. Address: P.O. Box 688, Monrovia, California 91016

V. Earl Irons — Vice Chairman of the Board of Governors

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Don C. Matchan — Editor of **NHF Bulletin.**

Opinions expressed in The **Bulletin** are those of the writers of the articles and are not necessarily the opinion of the National Health Federation.

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Every family in America should belong to the National Health Federation to —

1. Support the principle of freedom of choice and liberty in health matters.
2. Be a part of a strong and united consumer's voice in all health matters.
3. Work for beneficial and needed health legislation and, at the same time, oppose proposals which are detrimental to the health interests of the people or which do not provide for equality of recognition of all legally established health professions.
4. Support a united effort to reduce the cost of health care.
5. Oppose insults upon our ecology which have an impact on health
6. Oppose the use of chemical food additives which have not been proved absolutely safe or which are not needed.
7. Secure fair and impartial enforcement of food and drug laws and regulations.
8. Insist that all monies raised for health research and care be used exclusively for these purposes.
9. Compel all health fund-raising organizations to disclose in an annual report, the amount of funds collected and how the funds were expended.

THESE ARE THE THINGS THE NATIONAL HEALTH FEDERATION IS ORGANIZED TO DO — JOIN ITS RANKS AND TAKE PART IN THIS VITAL EFFORT ON BEHALF OF YOURSELF AND OF ALL AMERICA.

UPCOMING NHF CONVENTIONS

Southeast — May 3-4
Braniff Place — New Orleans

Southern California — May 17-18
El Cortez Hotel — San Diego

Rocky Mountain — May 31-June 1
Downtown Holiday Inn — Denver

HELP SAVE OUR HEALTH FREEDOMS