National Health Federation BULLETIN

JANUARY, 1974

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THE NHF
LEGAL DEFENSE FUND
IN ACTION
— A REPORT —

House Subcommittee Holds Hearing On Hosmer Bill

The President's Annual Message

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Annual Report of Activities
By NHF's Legislative Advocate

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The Fluoride Controversy

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Senator Nelson Introduces Bill To Outlaw
Trade Names On Prescription Drugs

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Medical Device Bills Seen As Safety 'Over-Kill'

Dedicated to the Protection of Health Freedoms

THE
NATIONAL HEALTH FEDERATION BULLETIN

Protection of Health Freedoms — *Published Monthly*

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The Bulletin serves its readers as a forum for the presentations 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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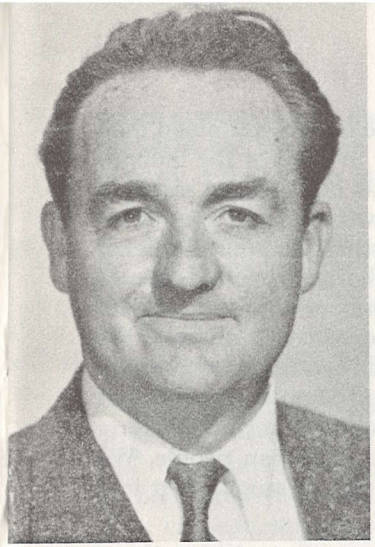

The President's Message

CHARLES I. CRECELIUS
President, National Health Federation

This has been a year filled with heavy obligations. More and more the NHF has been playing the leading role among organizations interested in health education and health freedom. It has been the most exciting and rewarding year of NHF's nineteen year history. Based on necessity, FDA's food supplement regulations and related issues have been our number one priority action. It started in 1962 when the Food and Drug Administration attempted to impose their restrictive food supplement regulations. At that time we activated our members and friends to join in a postcard drive that we felt was our best effort. 70,000 of these communications prepared by NHF were sent to members of Congress and then forwarded to Commissioner Larrick of the Food and Drug Administration. This stopped the regulations.

The current regulations were introduced and promoted with much greater determination. When a national FDA survey indicated that over half of the adult population believed in vitamins and it became obvious that a health monopolistic crisis had arrived. Those turning to more natural methods to maintain or restore health were not likely prospects as drug customers. It was clear that this time a much greater effort on our part, perhaps a million or more communications, would be required if this denial of health freedom was to be prevented. This, our greatest effort to date, has resulted in well over a million communications to the Congress, with the effort still under way.

The nutrition revolution, that had been quietly growing for several years, hit Washington with explosive force. Hearings by the health subcommittee that officials said could not be scheduled, were held. Support began to come from unexpected quarters and still there was much dis-

tance to travel. Fighters for health freedom became more determined than the monopolies and their friends who were trying to prevent the individual's free choice on health matters. It has served as our greatest example of what can be accomplished by sincere people who believe in a cause and don't become weary in well doing. Since lasting victories involving all of the many issues we deal with must rest on the secure foundation of an informed, educated populous, it is difficult to know whether the impact of our letter campaign on members of Congress or the education of the thousands that were spoken to about the issue and then followed through with signing letters in support of the Hosmer Food Supplement bill was of greatest value. Those projects are most effective that not only inform our legislators but help to inform and awaken the American people. We are indebted to each member and friend who has put so much effort into this and other freedom projects.

Developments in the fluoridation field have been as significant if not quite as dramatic. In March 1972 our *Bulletin* carried the information "Sweden Bans Fluoridation." The action was taken by Sweden after a thorough investigation which revealed that the oft-quoted studies, reporting benefits, have not been made, and hence the statistics are without basis.

We have received reports that the highest court in the Netherlands declared fluoridation illegal on June 22, 1973. Recent articles in the General Practitioner, London, England, have pointed out that Britains may be over-fluoridated from the food they eat and the fluoride pollution in their environment. More information pointing out the possible dangers in fluoridating water supplies comes with each passing month. How long it will take for the American people to support our right to drink water free from fluoride pollution may depend upon how soon we can reach them with the facts and information now becoming available to us.

As Europe proceeds to free itself from the fluoride promotion, Canada, the United States, Australia, and New Zealand are being urged to endorse fluoridation without examining the facts that an honest investigation could uncover. For much too long we have permitted those who view health issues with closed minds to pose as the experts. We are now seeing the beginning stages of an accelerated awakening.

A few months ago, NHF initiated a new and different attack in the fluoridation matter. Arthur Koch, as attorney for the National Health Federation filed a petition before the Food and Drug Administration to have fluoridated water classified as a drug and thereby meet the rules and regulations that apply to all other drugs. This would require that fluoridated water would have to be subjected to the same critical and exhaustive tests for both safety and effectiveness that are required for all new drugs and, in addition, presumably would have to observe certain labeling regulations including a warning concerning potential hazards. How to label

water coming out of the faucet might be an unsolvable problem. As yet, the FDA has not acted on the petition but on this issue, we are prepared to carry it through as many courts as necessary.

During the past year, we have staged many conventions throughout the United States. They have been well attended and well received. We are especially pleased with the very favorable treatment of our conventions by the news media and particularly the TV coverage where many of our speakers have been interviewed. We consider our conventions as a very important phase of our educational program.

Members of the National Health Federation are fortunate to be sitting on the fifty yard line. It is our firm conviction that the nutrition revolution and the general awakening that is taking place regarding health matters in the United States will not be stopped. We rededicate ourselves to continue our educational programs through conventions, projects, and programs which will secure needed legislation and further educate the American people. With your continued help, victory is assured.

Senator Nelson Introduces Bill To Outlaw Trade Names On Prescription Drugs

Senator Gaylord Nelson (D-Wis.) has introduced legislation to outlaw trade names on prescription drugs.

Nelson charged that drug manufacturers are making profits because of confusion caused by multiple names for the same drug. He cited Food and Drug Administration figures showing there are about 20,000 prescription drug products on the market, but only 700 different drug compounds. He said. "In other words, each drug in the country has, on the average, 30 different names, selling in an unbelievably wide price range."

As examples of the wide price range, Nelson said there are 24 different brand names for the antibiotic, tetracycline. "Achromycin," manufactured by Lederle sells to the pharmacist for $5.35 per 100 tablets of 250 milligrams each. On the other hand, "Tetracyn," an identical product, manufactured by Roerig, sells for $3.95.

Nelson contends that if a drug were prescribed by its generic name, pharmacists would be able to purchase from any number of competing manufacturers and a patient would get a substantial price break.

The Senator disputed the assertion by some drug manufacturers that one brand is better than another. "In this country, every batch of antibiotics is tested by the FDA, and all these drugs, no matter who markets them, must meet the same government standards," he said.

House Subcommittee Holds Hearings On Hosmer Bill

A summarized report of the statements of opponents and supporters of HR 643, and related bills, presented before the House Subcommittee on Public Health and the Environment

In spite of the predictions of our detractors and opponents of the Hosmer bill who said we would never get hearings on the bill, *the hearings were held on October 29, 30 and 31.* Furthermore, support for the bill continues to grow in the House. As this report is being prepared, a *majority* of the House members have now cosponsored the bill with Representative Hosmer or have introduced identical or similar bills on their own. Though some of the bills vary in minor details, they all are similar in that they would restrict FDA's authority to limit the potency and combinations of vitamins and minerals in dietary supplements except when proved to be harmful to health.

The hearings were held by the House subcommittee on Public Health and Environment under the chairmanship of Representative Paul Rogers (D-Fla.). The subcommittee is under the House Interstate Commerce Committee. An overflow audience was present throughout the hearings, mostly made up of those opposed to FDA's current pending dietary supplement regulations.

Representative Hosmer Says Regulations Violate Constitutional Freedoms

As the chief sponsor of bills being considered by the subcommittee, Representative Craig Hosmer was given the privilege of making the initial remarks. His statement was brief but pointed. He stated that although he, himself, does not take vitamins or mineral supplements, he strongly believed that those who do use such products, which no one has ever shown to be harmful in whatever quantities, should be freely allowed to continue doing so.

In commenting on the FDA dietary supplement regulations, which would classify as drugs all products supplying more than 150% of the recommended daily allowance, he said, ". . . there is absolutely no justification for defining them as drugs which then can be made subject to a prescription. In answer to this," he said, "FDA will tell you that it has no intention of requiring prescriptions for non-harmful food supplements. But I ask you: Have you ever heard of giving a bureaucrat power he did not eventually use? Of course not. The FDA should not ask for power it does not need for the protection of the public and all that the bills before us propose to do is to put out of FDA's reach the power for which it is grasping, but does not need."

Representative Hosmer continued saying, "Those people on whose behalf I plead aren't kooks or nuts or food faddists or loonies. They are just plain people. They are my constituents, and millions of other people throughout the country, like them, who find benefit from using these harmless products.

"Obviously they would not go to the trouble and expense of taking them if they did not believe that their well-being is thereby enhanced. And, in these areas where the interconnection of mind and body are the determinents of well-being, no one but the individual himself is qualified to make a subjective judgment on whether or not some harmless substance actually does improve him in some intangible way. A physician cannot make this judgment. Nor can you or me or an agent of the Food and Drug Administration make this judgment.

"Thus to deny an American citizen the right to make this judgment for himself is a downright violation of the freedom Constitutionally guaranteed our people for the pusuit of their happiness."

Opposing the Hosmer and related bills were the Food and Drug Administration, the American Medical Association, the American Association of Retired Persons, Miles Laboratories (makers of One-A-Day brand vitamins), and Harvard nutritionist Stanley Gershoff.

FDA Commissioner Schmidt Strongly Opposes Bill

FDA Commissioner Schmidt, when he appeared before the subcommitee to defend the pending dietary supplement regulations, was making his first appearance on Capitol Hill before a congressional committee since his appointment a few months ago. Schmidt made it clear that FDA is "strongly opposed" to the Hosmer bill and all similar bills "which would diminish our statutory authority to protect the consumer." He stresed that the aims of the new regulations are "truthful labeling, rational combinations of ingredients" and control by prescription only upon evidence of toxicity. In alluding to "irrational" combinations, he did not, however, explain why FDA considered as irrational, to the point of forbidding, certain combinations found abundantly in natural foods—for example vitamin C in combinations with bioflavonoids. Schmidt said, "Most of the objection to our new regulations reflects a gross misunderstanding and unwarranted suspicion of their purpose." The agency's "sole purpose" is to protect the public against "fraudulent claims" and to make it clear that beyond specified potencies, vitamins and minerals should be "used only for medicinal purposes."

Commissioner Schmidt emphasized, "The new regulations do not remove one nutrient or other food component from the marketplace;

(Continued on next page)

every nutrient or other food component that has been available to consumers up to now will remain available in the future." He failed to explain, however, that the new regulations strictly prohibit combining what FDA considers to be "nonessential" vitamins and other food factors in the same formula with the "essential" vitamins and minerals. He emphasized also that with the exception of vitamins A and D, products containing other vitamins and minerals at levels higher than 150% of the recommended daily allowance would not be subject to prescription. Later, he did admit that these higher potency products would be classified as 'drugs" and thus they would be subject to review by the Over-the-Counter Vitamin-Mineral Advisory Panel which could recommend that certain vitamin or mineral products, because of their potency or combinations, should be available, if at all, only on prescription. Schmidt faced stiff questioning from subcommittee chairman Rogers and others concerning FDA's justification for placing vitamins in a drug category for dosages greater than 150% of the RDA.

AMA Echos FDA

AMA's team of witnesses was led by C. E. Butterworth, Jr., M.D., chairman of the AMA Council on Foods and Nutrition, joined by Philip L. White, M.D., AMA nutrition council's secretary, and Roy S. Bredder, a member of AMA's legislative staff.

Dr. Butterworth's testimony fully supported FDA's new regulations and, in general, voiced the supportive arguments which have been given by the FDA throughout the past year . . . that the new FDA regulations are needed to protect the public from irrational combinations and from supplements containing ingredients with no recognized nutritional value such as rutin, bioflavonoids, inositol, etc. Butterworth further stated there is no valid evidence to demonstrate that the taking of vitamins in quantities greater than the recommended daily allowance is beneficial under ordinary physiological conditions.

It was at this point that Subcommittee Chairman Rogers observed that FDA seemed most interested in stopping misleading or fraudulent claims for vitamin products and suggested that perhaps a new law is needed to give FDA concurrent jurisdiction with the Federal Trade Commission over ads in this area. He added, "It seems you can get at dangerous, unsafe quantities under the food laws; I'm not sure I see the advantage [of the regulations] as long as you can protect the public safety and protect also against any fraudulent claims through an extension of the advertising law."

Brickfield Charges Flood Of Misleading Information

NRTA-AARP (National Retired Teachers Association-American Association of Retired Persons) was represented by its Legislative Counsel, Cyril Brickfield, who also defended the FDA regulations and

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Our Thanks and An Apology To Representative Hosmer

THE NATIONAL HEALTH FEDERATION
212 West Foothill Boulevard
Monrovia, California

November 27, 1973

The Honorable Craig Hosmer
Rayburn House Office Building
Washington, D.C. 20515
Dear Congressman:

As Chairman of the Board of Governors of the National Health Federation, and on behalf of all its officials, members, and friends, I hereby thank you for your skillful preparation and drafting of the Hosmer bill which you courageously introduced and supported in the U.S. House of Representatives for many years and during a number of sessions of Congress. Your skill and foresight is supported now by more than two hundred other members of Congress who desire also to protect the nutritional health and welfare of all Americans.

With the highest respect and a humble heart, I hereby express my sincere regret for having inadvertently and erroneously implied that NHF wrote the Hosmer Bill. On page 20 of the November, 1973 issue of the National Health Federation Bulletin under the title "The Family Circle" appear the statement: "Consequently, it was NHF which wrote the bill introduced by Representative Hosmer during the past several sesions."

The representatives of NHF prepared only a rough tentative draft of said proposal Bill for consideration, study, and revision by you and your Legislative Counsel. You incorporated some of the salient ideas or suggested provisions presented by NHF into the now famous Hosmer Bill.

Of course, I realize that NHF presented only its ideas and reasons for its ideas in draft form in the same manner as the Department of Health, Education and Welfare and other trade, medical, labor, food, drug, and charitable associations present their ideas to Members of Congress for consideration.

This apology to you is made without any mental reservation or hesitation, because it was only you who wrote the Hosmer Bill to protect the nutritional health and welfare of Americans and to preserve their right of freedom of choice in health care so long as the exercise of that right does not infringe on the rights and welfare of others.

This is to assure you, also, of the Federation's wholehearted and enthusiastic support of the Hosmer Bill.

With sincere appreciation for your service to America, and with a fervent prayer for your good health and happiness and that of your family, I remain,

Respectfully yours,

Fred J. Hart
Chairman of the NHF Board of Governors

Annual Report Of Activities By NHF's Legislative Advocate

By CLINTON R. MILLER

There is no question about 1973 being our busiest year but also, in many other ways, it has been our greatest year to date. The National Health Federation has taken some giant strides forward during 1973. The Federation has moved into a position of prominence and has become the spokesman for the health freedom movement. This has been borne out by the increasing times the news media has contacted us to determine NHF's position on certain health-related matters.

We are mindful that our accomplishments in Washington, D.C. have been made possible by the active support of NHF members and their friends all over the United States and thus, I should like to take this opportunity to thank each one of you who have helped make 1973 a year of significant achievement.

I should like also to enumerate the areas of major concern during this past year.

1. The Hosmer and Related Bills

Working for the passage of the Hosmer bill (or one of the similar bills) has been our No. 1 priority. As a result of your letters and a great deal of hard work here, we have been able to get 218 cosponsors to this bill which would, in effect, nullify FDA's pending dietary supplement regulations. This is the first time in our 18-year history we have been able to get the majority of the 435 members of the House of Representatives to cosponsor a bill backed by NHF and opposed by FDA, AMA, and the food and drug industries which control over $200 million in sales annually.

As a result of this overwhelming support, hearings were held on the Hosmer and related bills on October 29, 30 and 31 by the House Subcommittee on Public Health and Environment.

Our efforts in behalf of the Hosmer bill has attracted the cooperation of many other groups and organizations interested in nutritional freedoms. We are especially appreciative of the cooperation with the National Nutritional Foods Association. Max Huberman, NNFA president, deserves unlimited thanks and credit.

Immediately after FDA issued their tentative final dietary supplement order last January, NHF initiated a massive letter writing campaign urging members of the House of Representatives to cosponsor the Hosmer bill which would nullify the FDA order. Scores of other organizations and individuals picked up this campaign and gave it their active support. As a result, over one million letters reached Congress.

History reflects a sustained and continuing increase in our ability to influence legislation in Congress. In 1962, then U.S. Representative David King, told NHF, "I can count up to about 6 or 8 congressmen who are friendly to you (NHF) to the extent that they would cast an unpopular vote to support your program. You need at least 100-150 good friends before you can expect to enact any significant legislation."

Taking the Hosmer bill, which has been in Congress since 1967, as an example, we can note the steady, though sometimes small, increase in the number of cosponsors. In the 90th Congress (1967 and 1968), we were able to get 71 cosponsors. In the 91st Congress (1969 and 1970), 85 cosponsors. In the 92nd Congress (1791 and 1972), 87 cosponsors. Finally, in the 93rd Congress, during 1973 only, 218 cosponsors.

Our long term strategy has been to get the Hosmer bill passed first in the House where we were the weakest, and then to focus on the Senate. We do not have the bill through the House yet, but we will keep things moving on the bill in the House while we concentrate on the Senate during 1974.

2. Fluoridation Bills

The Children's Dental Health Act of 1973, with a clause to provide federal funds for fluoridation, is still pending in the Senate and House with no action scheduled. We have not been able to devote the time we would like on this issue, but seemingly action has been temporarily checked on the bills in this Congressional session by our strong mobilization of anti-fluoridation forces in the United States through our form letter drive in January, 1973. While we have, of necessity, put our efforts to defeat this bill on the back burner, we stand ready at any time to put it a top priority position if it appears as if the House or the Senate will take action. (The bill passed the Senate in the last Congress with only one opposing vote but we were able to discourage action in the House.)

Our position in the House needs much work when we consider that HR 2728 has been introduced by Rep. Paul Rogers (D-Fla.), Chairman of the Subcommittee on Public Health and Environment, who has been joined by 7 of the 11 members of the subcommittee as cosponsors. They are Representatives Kyros, Preyer, Symington, Roy, Nelson, Carter and Hastings. The NHF form letter, *Fluoridation-20*, was sent to almost every member of the House and Senate and we believe this helped delay action in both the House and Senate during the current session.

3. NHF's Famous Guinea Pig Amendment

The loophole AMA was able to tack onto NHF's "Human Guinea Pig Amendment of 1962" may soon be removed if we can get enactment of Rep. James Symington's excellent bill, HR 11339, just introduced November 7, 1973. This bill would require that *all* patients and volunteers in experimental drug

(Continued on next page)

programs give written "informed consent" before the investigation, instead of leaving it to the discretion of the experimenter's judgment as AMA's loophole allows.

In contrast to the Senate-passed biomedical research bill, which contained an informed consent definition and a proposed 11-member commission, Symington has tried to avoid a single commission because he says, "a single profession should not have total responsibility and power to set medical, scientific, and moral principles for human experimentation."

4. Label Legislation

Bills to require full disclosure of ingredients on *all* processed or manufactured foods including those for which a standard of identity has been set have been introduced by Rep. Rosenthal of N.Y. NHF has not been able to give these the support we would like because of preoccupation with the Hosmer bill. They may soon be front burner.

5. Conventions

During the first eleven months of 1973, I appeared on the program as a speaker at 22 conventions—this averages more than a convention every other week end. The convention appearances are, of course, in addition to our regular work week schedule.

6. Cyclamates

The cyclamate issue is raising its head again and NHF will be working with other consumer groups to beat back any attempt by FDA to lift the ban on cyclamates.

7. Medical Device Bills

Medical device bills have moved through the Senate and are now under consideration in the House. All these bills (and there have been several similar bills introduced) require premarket testing and clearance before any medical device is placed on the market for sale and use. NHF believes these bills to contain objectionable flaws which should be removed or corrected before passage. It is anticipated, however, that a medical device bill will be enacted sometime during 1974. We regret that we have not had the time and the staff to give these bills the attention they require.

8. Chiropractic

Chiropractic is in Medicare because of the last two years successful joint activity of NHF with chiropractic groups. Chiropractic lobbies are fighting hard to prevent unreasonable regulation of this bill. They seem able to handle the present difficulties and have not enlisted NHF's aid. However, they have been so busy with their own problems they have not been able to help us with the Hosmer bill which affects them almost as much as it does health stores.

9. FDA's Invitation To Nominate Members For Vitamin-Mineral Review Panel

FDA extended to NHF an invitation to nominate qualified persons for possible appointment to a Vitamin, Mineral and Hemotinic Review Panel charged with the responsibility of reviewing the safety, claims and efficacy of vitamin and mineral products classified as over-the-counter drugs. We refused to acknowledge the legitimacy of ever classifying vitamins as drugs merely on the basis of their potency and thus declined the invitation feeling that, in the end, it could work as a trap. Our refusal received wide comment in the trade press.

10. Meeting With FDA Commissioner Schmidt

We had the opportunity to meet personally with the new FDA Commissioner, Alexander Schmidt, in a 2-hour interview. It is our impression that he may be the most anti-health freedom and anti-nutritional freedom Commissioner since Mr. Larrick.

11. The Delaney Amendment

The Delaney amendment to the Food, Drug and Cosmetic Act, enacted about 15 years ago with the help of NHF, bans the use in foods of any chemical found capable of producing cancer in man or animals. There is currently a growing move to weaken this clause of the Act. NHF will continue to defend the Delaney amendment as enacted at every opportunity.

12. Conference of the International Society for Fluoride Research

We were extended an invitation to attend the Fifth Annual Conference of the International Society for Fluoride Research held at Oxford, England. We were privileged to accept the invitation and there met with, and evaluated the work of, the world's leading fluoride researchers who we will need when NHF makes anti-fluoridation a top priority. At such time, we may need to bring to America some of these key scientists to supplement our excellent U.S. scientists who oppose fluoridation.

13. The Fluoride Petition

During 1973, NHF petitioned the FDA to classify the fluoride compounds used in fluoridating public water supplies as "drugs" which they are by definition, and to require that the compounds be subjected to the same safety and efficacy tests required of all other drugs. The FDA has not yet acted on the petition. Arthur Koch has been retained to continue work on this case.

14. Cancer Legislation

Legislation to legalize the use of non-toxic remedies in the treatment of cancer has not been reintroduced in either the House or the Senate during this session. We tried unsuccessfully to get Senator Metcalf to introduce such a bill early in 1973. We have worked closely with Dr. Dean Burk and two national cancer societies in areas of mutual interest.

LOYALTY(?)

A mayor who was very proud of his city, was asked how the recession had affected it. He answered, "We don't have a recession here, but I will admit we are having the worst boom in many years."

More Suits Filed Against FDA's Dietary Supplement Regulations

In addition to the court actions (10 so far, we understand) which have been filed against FDA's pending dietary supplement regulations and reported previously in these pages, still more suits have been, or soon will be filed.

On October 25, Dr. Linus Pauling, joined by Dr. Roger Williams, filed an action in the District of Columbia Circuit Court. It is anticipated their suit will be consolidated with the other previously filed actions which will be heard in the 9th Circuit Court of Appeals at San Francisco. NHF's suit, filed earlier in New York, has already been moved to San Francisco and consolidated with the other similar suits.

On October 31, the East Coast Healthfood Organization, a trade organization, joined by Citizens for Truth in Nutrition, filed a petition, through their attorney John Matonis, in the U.S. Court of Appeals for the District of Columbia Circuit asking the Court to order FDA to reopen its hearing on the dietary supplement order. The hearing on the then proposed order was held 1968-1970 (the longest administrative hearing in history) and the current, pending dietary supplement order is based, purportedly, on the facts revealed during the hearings. The petition filed by Matonis argues that the regulations are based on consumer attitude caused by advertising and labels, and that this attitude has changed substantially since evidence on consumer attitude was presented at the FDA hearing.

Matonis submitted a consumer survey and report prepared by two marketing experts and business administration professors from George Mason University (Fairfax, Virginia), Drs. James H. Sood and Richard L. Seely who completed a survey of health food customers in Washington, Maryland and Virginia last April. The survey showed overwhelming objections to the FDA vitamin regulations among health food consumers, a high level of nutritional understanding and consumer demand for high potency vitamins and outlawed combinations of vitamins. The survey revealed also that almost one-half of today's health food consumers did not shop in health food stores three years ago.

In addition to the two new cases just described, we understand also that still another action is being prepared for filing. We are informed that this case will differ from all others inasmuch as it will dwell on the scores of procedural errors and other illegalities in connection with the hearing held in 1968-1970 upon which the present regulations are based. The petition to the court undoubtedly will charge that the hearing examiner was selected in an illegal manner, that the hearing transcript is replete with instances showing bias on the part of the hearing examiner, that he often prevented full and complete cross examination of witnesses and that other decisions of the examiner prevented the introduction of vital evidence. If the court agrees, it could stay the implementation of the current regulations and order a new hearing on the basis that the current regulations are based on conclusions drawn from incomplete or faulty evidence presented during the 1968 - 1970 hearing.

Rep. Symington Introduces Bill To Require Written Informed Consent In Experimental Drug Use

In 1962, Congress enacted a law which frequently has been referred to as NHF's Guinea Pig Amendment which was intended to require the informed consent of patients to whom experimental drugs were to be given. Shortly before the passage of the bill, however, the bill was amended under pressure from the AMA to permit physicians to use experimental drugs without the consent of the patient involved when, in the opinion of the physician, it would be better not to inform the patient. This loophole, of course, severely weakened the intent of the original bill.

Rep. James W. Symington (D-Mo.) has introduced a bill (HR 11339) which will close the loophole left open in the 1962 law. Under the amendment of the Food, Drug and Cosmetic Act proposed in the Symington bill, patients or legal representatives and volunteers in experimental drug programs would be required to give written informed consent before the investigation begins which would have to include the following basic elements:

— "a fair explanation of the procedures to be followed in the administration of such drug (or controls), including an identification of any which are experimental;

— "a drug description of any attendant discomforts and risks to be expected from such drug (or controls);

— "a fair explanation of the likely results should the drug (or controls) fail;

— "a description of any benefits reasonably to be expected from such drug (or controls);

— "a disclosure of any appropriate alternative drugs or procedures that might be advantageous for the individual;

— "an offer to answer any inquiries concerning the drugs or procedures; and

— "an instruction that the subject is free to either decline administration of such drug (or controls) without prejudicing his future care."

Further, the bill provides that the consent must be given "without the intervention of any element of force, fraud, deceit, duress, or other form of constraint or coercion."

M.D. Congressman Apologizes For Attack On Dr. Carlton Fredericks

By CLINTON R. MILLER
NHF Legislative Advocate

The National Health Federation was victor in the first crucial credibility confrontation of the House vitamin hearings October 29, 30, and 31. When the smoke cleared away, our invited witness, Dr. Carlton Fredericks was vindicated and his attacker and detractor, was apologetic for his mistaken sources.

In the rudest and most unjustified attack I have witnesed during my 12 years working with the U.S. Congress, Tim Lee Carter, M.D., a Republican Representative from Kentucky, attempted unsuccesfully to discredit Dr. Carlton Fredericks during his testimony before the House Health Subcommittee, October 30, 1973.

The National Health Federation immediately demanded and received an apology and correction in the record and in the press.

The story has many undercurrents and overtones. The low profile role of Dr. Tim Lee Carter in pushing through medically oriented legislation and in blocking or suppressing non-medically sanctioned bills and viewpoints cannot be overemphasized. He is serving his 5th term (10th year) in Congress. By voting together with the health subcommittee's other medical doctor, William R. Roy (D-Kan.), the medical viewpoint is able to start with nearly 20% of the subcommittee vote on any vital health issue. Dr. Carter is second ranking minority (Republican) member on the 11 man House Subcommittee on Public Health and Environment. Until now, Drs. Carter and Roy have been able to keep ultra-low visibility in their role which has been to see that all health legislation gets a medical slant.

Dr. Roy's office claims he has received no direct American Medical Association financial support for either of his two elections. I believe this. However, on the issue of FDA's restrictive vitamin regulations, one cannot see daylight between the views of AMA and those of Drs. Carter and Roy.

Such was the situation Dr. Carlton Fredericks confronted when his excellent testimony was abruptly interrupted midway by Dr. Tim Lee Carter with his uncalled-for personal attacks on the academic credentials held by Dr. Fredericks.

After showing much visible agitation and disapproval, and without asking permission of Chairman Paul Rogers to speak—which is the first rule of courtesy meticulously observed at all congressional hearings—Dr. Carter blurted out. "I can't agree with all the stuff this man is putting out!"

Dr. Fredericks calmly replied, "The figures I quoted came from FDA."

Immediately before the unbridled Carter outburst Dr. Fredericks had stated, "FDA sets the requirement of adult women at 18 milligrams a day for iron—if a woman selects her food intelligently, which is a rare commodity in women. I have said, if you want a course in nutrition, follow the housewife through the supermarket, buy what she rejects and reject what she buys, and you are on the path of good nutrition. It takes 1,000 calories of well-selected food to yield 18 milligrams of iron per day."

Mr. Carter: I followed your testimony all the way through and I know your record quite well and I hesitate to expose it at this time, but what you are saying is just absolutely incorrect.

Mr. Fredericks: May I ask a question, sir? Has the requirement been set for 18 milligrams for iron for women?

Mr. Carter: I am sure that is quite correct, but I don't think it is that difficult to get iron.

Mr. Fredericks: Would you explain why the FDA has moved to double the iron . . . ?

Mr. Carter: You are the witness, sir.

Mr. Fredericks: You said you don't believe what I say and I am trying to find what sources you do believe.

Mr. Carter: For anyone who has read this and gone over it, it is just absolutely incredible that you would try to put this down and present this as truthful testimony before all these people.

From the floor: I object to that.

Mr. Carter: You do this in such a manner that you will hypnotize some people and bring them around to your way of thinking. I must say what you are saying is just not credible to one who has studied these things.

At this point Chairman Paul Rogers stepped in with, "May I suggest that you finish the testimony? Dr. Carter has expressed his viewpoint."

Carton Fredericks and the rest of the first half of our panel then finished their testimonies. Attorneys David King, Milton Bass and Kirkpatrick Dilling were followed by Max Huberman, President of the National Nutritional Foods Association.

The chairman then opened the panel to questioning by members of the Subcommittee and Dr. Carter reopened his attack on Dr. Fredericks.

Mr. Carter: I want to direct my questions now to Mr. Fredericks, with your permision, Mr. Chairman.

Mr. Satterfield (D-Va.) who was temporarily presiding in place of Rep. Paul Rogers: Yes sir.

Mr. Carter: Doctor, where did you get your Ph.D.?

Mr. Fredericks: New York University.

(Continued on next page)

Mr. Carter: You have a Ph.D. at the present time from New York University?

Mr. Fredericks: Yes.

Mr. Carter: I would like to see that made a part of the record, if such a degree exists, which is in doubt,

Mr. Fredericks: I don't know where it is in doubt. It is in my biography in Who's Who.

Mr. Carter: You can make it a part of the record.

After some other equally flimsy issues were raised by Dr. Carter he attempted to justify his attack at personalities rather than the issues before the subcommittee.

Mr. Carter: You see, the thing about it is it makes it very difficult for us to make a decision if you bring people to this committee who have such records.

Mr. Fredericks: What does the Congressman mean by 'such records'?

Mr. Carter: I think it is my duty to bring out such things because people can be taken advantage of and I don't think that should be done.

Mr. Satterfield to Dr. Fredericks: I think in the interest of the committee, in the interest of fair play, if you have any evidence you wish to make against the allegation made, we will be happy to receive it.

Immediately following this unfair, unjustified attack, NHF phoned New York University and received verification by phone and telegram of the existence of the degree. The telegram read, "A doctor of philosophy degree was awarded to Carlton Fredericks on February 28, 1955 through our school of education." It was signed Mrs. Stell D. Kaisted. We then immediately prepared the following letter demanding an apology and delivered it by hand to Rep. Carter.

Oct. 31, 1973

Dear Mr. Carter:

The National Health Federation hereby respectfully demands a public apology to the Federation, to its invited witness Carlton Fredericks, Ph.D. and to the Congress for the unprofessional discourtesy and rudeness exhibited by you in implying at the Public Hearing, Oct. 30, 1973, of the House Subcommittee on Public Health and Environment that Dr. Carlton Fredericks is claiming a Ph.D. degree he does not have.

A simple phone call to the office of the Recorder, New York University, School of Education, Washington Square, New York City, New York, telephone: 212-598-3782, to Ms. Kaisted will verify Dr. Fredericks was awarded his Ph.D. Feb. 28, 1955.

Your apology for the act above should be made publicly today, at the third and final day of the Subcommittee hearings before the same committee and press.

Sincerely,
Clinton R. Miller
Legislative Advocate

We delivered the letter to Rep. Carter at 2:00 p.m. on Wednesday, October 31 as he was going to the hearings for the third and final day. We also passed out press releases with copies of our letter to the press. At about 3:00 p.m. Dr. Carter made the following public apology to the press, the public, Dr. Carlton Fredericks, and the Congress :

Mr. Carter: I want to say something in fairnes to Dr. Fredericks who testified here yesterday. He is a Ph.D. according to information that I received. I regret that the information I received previously didn't show that. In all fairness, I think I should state that that is true.

United Press International sent out the following as part of their story on the hearings to the thousands of newspapers and radio stations who subscribe to their services: "On the second day of testimony Rep. Tim Lee Carter (R-Ky.) who is a medical doctor, challenged the academic credentials of Dr. Carlton Fredericks, author and radio broadcaster. Later that same afternoon, New York University School of Education confirmed that Fredericks had been awarded a Ph.D. in philosophy, a fact Rep. Carter duly corrected in the record."

Food Chemical News, a $200.00 a year weekly Washington publication for food and drug executives, reported it this way:

"Dr. Carlton Fredericks, Visiting Professor of Nutrition, Farleigh Dickinson College, called for a law to protect consumers from FDA's double standard against vitamins. He said the FDA has had a long-standing obsession reflected in a 25 year effort 'to discourage the public's consumption of health foods and the use of dietary supplements. He said FDA had enough manpower to raid health food stores, but not enough to deal adequately with botulism.

Rep. Carter (R-Ky.), a physician member of the Health subcommittee, questioned Fredericks' Ph.D. and called his testimony 'absolutely incredible.' The National Health Federation called the Carter charges rude and discourteous and demanded a public apology. Carter made a public apology for questioning Fredericks degree."

As soon as Dr. Fredericks read of Dr. Carter's apology he wrote him thanking him for it and suggested they have lunch together, with Fredericks' choosing the menu, to discuss the possibility that whereas Dr. Carter had now found his early sources in error about Dr. Frederick's Ph.D. degree, it might be possible that they were equally in error about the role of nutrition in health. FDA's vitamin regulations and other related matters.

Dr. Carter had not accepted Dr. Frederick's invitation at the time this article went to press.

To their everlasting credit, Chairman Paul Rogers and Representative David Satterfield, who alternately chaired the subcommittee during the Carter-Fredericks episode, handled the confrontation with fairness and firmness. Their statesmanlike control of the situation set the stage for our invited witness to have the record promptly cleared in the manner reported above.

No words of praise can describe NHF's appreciation to Dr. Fredericks who remained cool and unruffled throughout the incident.

SMILE AWHILE

The dream of the older generation was to pay off the mortgage. The forlorn hope of the young families of today is to get one.

By David Gunderson

Labeling Ingredients

Reprinted from 'Letter to the Editor' in
THE WASHINGTON POST

The announcement that complete listing of ingredients will be required for all alcoholic beverages sold in America puts to an end the Food and Drug Administration's excuse for "lack of authority" for not requiring full ingredient listing on all food labels despite persistent consumer requests.

It has long been recognized the FDA does not want to force food processors to give full information on labels as to all the contents including chemical additives, preservatives and artificial coloring and has used the ridiculous excuse of lacking authority to avoid alienating the processed food industry.

Additional, back-up excuses for not requiring full content revelation have included such vagaries as: "The purchaser wouldn't under stand the names of the additives," "it would require too much label space" and "the ingredients are safe, anyway." These can be resolved quickly by allowing the buyer to decide if he understands the complex terminology, by using labels similar to those currently affixed to our foods exported to Israel where full labeling is required and, again, allowing the buyer to decide if he is confident of the safety of all the ingredients since many hidden additives deemed safe for the "average" consumer impart serious, sometimes deadly, allergic reactions to sensitive individuals.

The buyer has the right to full revelation of every product he contemplates purchasing, be it food, beverage or material goods.

It is an obvious, incontrovertible fact: If full labeling can be required for "booze" it can certainly be required for food essential to life.

—*Bettie Huyett Mustard*
Moorestown, New Jersey

The NHF Legal Defense Fund In Action — A Report

When the 1973 annual NHF Liberty Stamp drive was launched last summer, it was announced that all monies received in the drive would be deposited in a "Legal Defense Fund" which had just been established. The Legal Defense Fund had just been established by NHF in order to assure the availability of funds to provide financial assistance and to assure a proper legal defense in certain health-related cases.

It must be made clear, however, that the fund is not intended primarily to defend persons but rather to defend principles, to provide assistance in cases where constitutional issues prevail, where liberties and freedoms guaranteed by the constitution are in danger of being ignored or trampled, and in cases where freedom - restricting legal precedents may be established in the event of a decision adverse to the defendant.

During the past six months, the generous contributions to the fund by members and friends of NHF has made it possible for NHF to intercede or otherwise assist in a number of cases. By way of a report to the contributors to the fund, it is now possible to comment briefly on the following cases in which NHF has been involved. In addition, there are other cases still pending on which we may report later.

Dr. Emory Thurston: Dr. Thurston is a fine scientist, a young "octogenarian," nutritionist and health care advocate of many years standing. For merely making available Laetrille to one who pleaded for it, *at no profit to himself,* Dr. Thurston was prosecuted by the California authorities, criminally. The National Health Federation legal defense procedures were brought into play to assist Dr. Thurston's attorney. Thus, numerous conferences were had, background material on Laetrile was presented, and suggestions for pretrial procedures were relayed to Dr. Thurston's counsel. Due to the technicalities of the statute involved, a complete avoidance of liability was not possible, but happily the jail sentence sought by he State was avoided, and Dr. Thurston continues to be a free man.

Ruth Goerling: This lady, possessor of a degree from a German university, and student of one of the leading U.S. nutritionists, has engaged in practice as a nutrition consultant, in Northern California. Miss Goerling became involved in a criminal prosecution for "practicing medicine without a license," in effect, due to dietary recommendations of which she had made for a young lady with a chronic condition, which had not yielded to the best of medical care, and in fact

(Continued on next page)

this young lady was faced with removal of the major portion of her large intestine, due to medical recommendations. Large doses of "cortisone" had created enormous health problems for this young lady, and as she came to Miss Goerling for dietary recommendations, she was very ill indeed. Due to the fact that she did not respond nutritionally, in a short period of time, during which she was consulting others, the State moved in with its prosecution. Kirkpatrick W. Dilling, on behalf of NHF, appeared for Miss Goerling at the preliminary hearing, cross-examining the witnesses against her, a circumstance which undoubtedly helped Miss Goerling later in the case, as her California counsel proceeded with the matter. Miss Goerling's counsel negotiated a reduced plea for her, and Miss Goerling was not jailed or deprived of her liberty. In Miss Goerling's case, the National Health Federation was able to provide a significant "back-up," undoubtedly having a considerable effect on the outcome of this case.

George Parsons: This gentleman, a resident of Texas, is a strong advocate of Laetrile, and its non-toxic favorable results achieved in many, many cancer cases. He and a partner have operated the Southwest Arthritis Center at El Paso, Texas, and Parsons has been a lecturer on the subject of cancer and arthritis treatments considered unorthodox by the "establishment." Recently, as Parsons departed from an appearance on a TV show in Arizona, he was served a subpoena, very broad in scope, purporting to require him to produce numerous records kept not in Arizona, but in Texas, including the film strip "World Without Cancer." The Federation considers that this film strip is wholly non-partisan in character, having been evolved by a not-for-profit organization in California, not connected with the Federation, and thoroughly and objectively describing Laetrile and its effects. The film strip advocates no particular practitioner or organizations. As this is written, the Arizona Attorney General is proceeding to attempt enforcement of the subpoena, but the Federation, working through Kirkpatrick W. Dilling and Arizona counsel just retained, is assisting Parsons in resisting the public import aspects of this case, as they relate to the film strip in question. Clearly, the issue of "freedom of expression" is involved here, and will be pursued by the Federation because of its implications as to the case in question.

Dr. Andrew Ivy: Dr. Ivy is one of the medical giants of all time. He was chosen by American medicine to be present at the Nurenberg trials, he has authored or co-authored several thousand scientific articles, many of the greatest doctors of the United States studied under Dr. Ivy when he was Vice-President of the University of Illinois, and indeed he may be termed one of the most honored men in medicine. Dr. Ivy incurred the enmity of the "establishment" by performing research as to a non-toxic substance known as "Krebiozen" (he now calls that substance "Carcalon"), and by noting, truthfully, its favorable results for cancer treatments. FDA put Dr. Ivy and several others through an 8-months criminal trial some years ago, in an effort to jail him for his forthright views. Dr. Ivy was acquitted, and his work continues, successfully. Recently, an amendment to the Illinois Food and Drug statutes was made, proclaimed as "closing a loophole" whereby Dr. Ivy's research work with his patients has been conducted, Happily, NHF counsel has researched the law concerning this subject, has consulted with Dr. Ivy and others, being of the opinion that his work shall continue. Procedures are in readiness to combat any efforts by the authorities to blunt his research.

FDA-Apricot Kernels: Hundreds of tons of apricot kernels are sold and distributed throughout the United State each year. One nutritional writer stated that probably the original "apple of the garden of Eden" was in truth an apricot. Numerous persons purchase apricot kernels to insure a reasonably high level of "amygdalin" or" nitriloside" factors, believed by certain scientists to have a cancer preventative effect, among other things. Hundreds of commonly consumed foods contain nitriloside factors. However, FDA does not desire that the consumer shall have "freedom of choice" in this respect, and is taking preliminary steps to outlaw apricot kernels, under the guise of banning the hydrocyanic acid content level usually found in this product. Mr. Dilling has cooperated thus far with a retailer of these kernels, as well as a grower, and it is likely that the Federation will take an active part in defending this item of food for its availability to the consumer.

The above are representative instances of how the National Health Federation, through its legal defense procedures, is aiding in its efforts to preserve the "freedom of choice" of the consumer in health matters.

NEW LIFE MEMBERS

Dr. James H. Laubach
Leona F. Carothers
Dr. Donald R. Scott
Elizabeth Sweeten
Concord Health Food
Fern Farris
Nicolas Gregory Miatelin
Kenneth Rhoda
Gosta Oscarsson
George Hinson-Rider
Joey Hinson-Rider
William Burks
Capt. and Mrs. Charles R. Hoeft, Jr.
Martha Belle MacAuley
Thomas J. Soisson
Cdr. and Mrs. O. G. Urquhart
J. Wolfe Goldstein, D.C.
Helen M. French
Mrs. Clara Graham
Mr. and Mrs. S. S. Eldridge
J. D. and Dorothy Corder
Alma Ploeger
Mr. and Mrs. R. A. Laurye

Received mid-October to mid-November

Medical Device Bills Seen As Safety 'Over-Kill'

Legislation seeking to regulate the safety and efficacy of medical devices could result in "safety over-kill" and delay production of devices that might help saves lives, witnesses representing medical societies and medical device manufacturers told a Senate Health subcommittee recently.

The subcommittee is considering bills introduced by its chairman, Sen. Edward M. Kennedy (D-Mass.), and by others that would require that medical devices receive pre-marketing clearance from the Food and Drug Administration.

Dr. W. Gerald Rainer, past president of the Association for the Advancement of Medical Instrumentation, said that "in some instances four to five years of FDA review have been required before a new drug is released. Consider the number of patients who would die or become cardiac cripples if four to five years are required before improved new heart valves or pacemakers are available for patient use."

While 500 patients may have died because artificial heart valves "are not perfect due to limitations in the state of the art of biomedical engineering, more than 200,000 patients are alive today who would already have been dead had not these artificial valves been available and used," said Dr. Arthur C. Beall, Jr., chairman of the board of regents of the American College of Chest Physicians.

Witnesses said manufacturers lack financial incentive to improve medical devices, and if the regulatory process is too cumbersome and expensive, patients might not benefit from the new technologies.

While criticizing the stringency of the proposed controls most of the witnesses, including a representative of the American Medical Association and representatives of the manufacturers, generally supported the concept.

Foster B. Whitlock, vice chairman of the board of Johnson and Johnson and chairman-elect of the Pharmaceutical Manufacturers Association, called the legislation "responsive to the needs of the public." But he objected to giving the Secretary of Health, Education and Welfare "unfettered discretion to subject any and all medical devices to pre-market clearance."

And Carl Parker, chairman of the Dental Manufacturers of America, asked that dental devices be eliminated from the bill because clearance requirements "will certainly put many small manufacturers out of business."

—From Washington Post

HEADQUARTERS OF THE NATIONAL HEALTH FEDERATION
212 West Foothill Boulevard, Monrovia, California

You have been reading about our new headquarters building in the recent issues of the NHF Bulletin. Now, you will have a special opportunity to tour the new facilities during one of the open houses being planned . . . and we wish every member could come in person to see our new home. We know this isn't practical, however, so for those who can't come, we are printing a picture of the building so that you can better visualize the headquarters of your organization.

The picture doesn't do justice to the building, however, because the most striking features of the building are on the inside. On the inside, you will find 20,000 square feet of floor space, tastefully decorated and arranged for efficient operation. We shall always be grateful that just at a time when a move to larger quarters became a necessity, this attractive five-year-old concrete building located on one of Monrovia's main streets became available to the Federation at a cost far below replacement value.

Our first, formal Open House has been planned for Saturday, January 5th, 2:30 to 9:00 p.m. The public as well as members are being invited. Light refreshments will be served and some films will be shown for those who are interested in these after touring the building and meeting the staff members.

In addition to the Open House on January 5th, visitors are especially invited to visit the headquarters on January 16th or 21st the day before and the day after the annual convention in Anaheim. This may give some of our members coming from out of the Southern California area for the convention an opportunity to visit the headquarters office. Monrovia is approximately 30 miles from Anaheim. If you need transportation from Anaheim to Monrovia on Monday, the 21st, let us know when you register at the convention. If there is a sufficient number, a bus will be arranged.

The Fluoride Controversy

By LEE HARDY

No. 5 In A Series

It is entirely normal that such a matter as introducing into public water supplies a substance of such known toxicity as fluoride should result in controversy. Citizens as a whole are concerned with finding a remedy for the curse of dental decay, and many have grasped at the idea of fluoridation as a hope of removing that curse, without questioning the safety, the practicality or the possible effects. Relatively few people are qualified to judge on such points, and hence many have accepted the dictum of the U.S. Public Health Service, which is look to for the promotion and the protection of our health. It probably has never occurred to them that a beneficial measure should not need to be accomplished by stealth, as has often been done with fluoridation, or that the guardian of their health might impart to them information which could possibly be false. As noted by Dr. Frank Bull, PTA groups are among the most concerned in regard to the welfare of children, and have in many communities led in the promotion of fluoridation. Truly, they believe they are taking the right course. They cannot be blamed for their opinion because they have had little opportunity to learn the facts about fluoridation, which are as carefully as possible concealed from the public.

On the other hand there has been alarm but not dismay on the part of scientists and others who have the background to understand the dangers of fluoridation. Many informed individuals have taken to the platform and to the published word to speak out against the threat. Among these are George L. Waldbott, M.D., allergist, of Detroit, Michigan; Frederick B. Exner, M.D., roentgenologist, of Seattle, Washington; Jonathan Forman, M.D., professor emeritus of medical history, Ohio State University; Joe D. Nichols, M.D., President of Natural Food Associates, Atlanta, Texas; Alfred Taylor, Ph.D., biochemist, of the Biochemical Institute, University of Texas; Albert W. Burgstahler, Ph.D., Professor of Chemistry, University of Kansas. These and others will be quoted in following articles.

The contention of fluoridationists is that there is no danger of harm in the ingestion of fluorides in water at the rate of one part per million; that fluoridation has resulted in proven dental benefits to children; that fluoridation is no longer a debatable question. Opponents state that the safety of fluoridation has never been proved; that it has resulted in harm; that it is an entirely immoral and irresponsible violation of the rights of individuals; that fluoridation opens up further possible compulsions and misuse of power; that there are entirely safe and effective ways of improving the dental health of children.

Some members of the dental and medical professions have been reluctant to speak out against fluoridation through fear of expulsion from their national or regional organizations. H. L. Richardson, M.D., formerly of the University of Oregon at Portland, who had "accumulated important original data proving that fluoride causes abortions, stillbirths, infertility and unexplained deaths in chinchillas," gave up further research because of "political" pressure.[1] Max Ginns, M.D., was expelled from the Worcester District and the Massachusetts Dental Societies because of his stand against fluoridation.

The American Dental Association endorsed fluoridation in 1950, greatly through the work of Dr. Trendley Dean, Director of the National Institute of Dental Health. In fact, chiefly through Dr. Dean's influence endorsements were made from a number of prominent organizations, of which he had become an active and influential member. American Water Works Association personnel, however, were reluctant to support fluoridation, clinging doggedly to the tenet that their obligation was to deliver pure, safe water to their communities.

Proponents claim that the American Medical Association has endorsed fluoridation. On November 2, 1951, two councils of the AMA, that on Pharmacy and Chemistry and that on Foods and Nutrition, with the help of F. J. McClure, of the U.S. Public Health Service, reported they believed "the use of drinking water containing up to one part per million of fluoride is safe." However the Secretary of the AMA twice told Congress that "the House of Delegates (the policy body of the AMA) did not urge or recommend that any communities undertake to fluoridate their water supplies," and a letter from the Law Department of the AMA in September, 1961, stated that "the AMA does not engage in the approval, endorsement, guarantee or acceptance of unfluoridated water or of fluoridated water."[2]

Various medical and scientific organizations and individuals have officially and personally taken a stand against fluoridation. The gist of the arguments of many of these will appear later in this series.

1. National Fluoridation News, June-Aug. 1961, p. 8.
2. Exner, F. B., "Fluoride vs Freedom," Natl. Health Fed. Bull., Mar. 1965, p. 25.

WE NEED INFORMATION

We are deluged with inquiries asking, "Where can I find a doctor who is nutritionally oriented and uses nutrition as a part of his treatments?" You can help us by sending in the names of such doctors you may know. If you have sent in names in the past, please do so again so that we may up-date our list. Be sure to include their full name, address, specialty and/or degree held.

Book Reviews

THE ARTHRITIC'S COOKBOOK, by Collin H. Dong, M.D. and Jane Banks (Thomas Y. Crowell Co., 666 Fifth Avenue, N.Y. 10019, hard cover, 184 pages, index, $6.95)

When Dr. Dong was stricken with arthritis in his 35th year of life, he recalled a wise Chinese folk saying, repeated by his father when Dr. Dong was still a child: "Sickness enters through the mouth, and catastrophe comes out of the mouth." Could diet possibly have any relationship to arthritis? Dr. Dong knew that the Arthritis Foundation repudiated this notion, in its publication, *The Truth About Diet and Arthritis* in which the Foundation had stated, "The fact is, the possibility that some dietary factor either causes or can help control arthritis has been thoroughly and scientifically investigated and disproved. The only exceptions are in gout."

Despite this pronouncement, Dr. Dong experimented, using the Chinese diet of his youth: a simple regimen consisting of seafood, vegetables and rice. Within weeks, he experienced a transformation. He regained his former agility. The stiffness and joint pains disappeared. Today, at age 71, Dr. Dong leads a full, active life, free of arthritis. He continues with an active medical practice, and successfully treats many arthritic patients by dietary means.

The Arthritic's Cookbook consists of the basic diet: high-protein, low-calorie foods, combined with natural ingredients, with a full range of gourmet recipes for all types of meals. Jane Banks, a former arthritic sufferer and patient of Dr. Dong, has collaborated with him on the recipes.

Dr. Dong believes that one cause of rheumatic diseases is allergy to food additives and preservatives. He stresses that arthritics should avoid any foods that are artificially colored or flavored, and to avoid all food preservatives. Interestingly, he also recommends that such individuals avoid the use of monosodium glutamate – a substance long used by Dr. Dong's ancestors in the Orient.

Dr. Dong feels strongly that the Arthritis Foundation's attitude toward dietary approaches is not only unwarranted but discourages further research. He poses the question "Who were the people who did this research? What is their background? Are they just doctors, nutritionists and dieticians, sitting in a weekly conference, smoking their cigarettes and stuffing themselves with breakfacts, luncheons and dinners served to them contaminated with preservatives, artificial flavoring and coloring, and monosodium glutamate? If any of these research groups wish to investigate the nutritional aspect of the etiology of arthritis, let me make a suggestion! Ask for volunteers among the group of dedicated rheumatologists who are willing to spend a few months of their lives to go into food-processing factories and the kitchens of restaurants, hotels, convalescent homes, and sandwich makers to see how the food is prepared and what chemicals are added to preserve it, color it, or make it taste better for the consumer. Then if they wish to investigate further, they should go into the slaughterhouses and watch how the meats are prepared and what is done with the leftovers and the various organs of the animals, which eventually become hot dogs, luncheon meats, and sausages. Then, and only then, can they say "Dietary factories have been thoroughly investigated." And if among the investigating team there should be one who is afflicted with arthritis, his opinion will bear more weight.

The Arthritic's Cookbook includes recipes for appetizers, soups, salads, seafoods, chicken, vegetables, breads and desserts. There is a special section on Chinese cooking, and another on Hawiian cooking. There are chapters listing the "do's" and "don'ts" for arthritics, as well as special hints on entertaining and eating in restaurants.

—Beatrice Trum Hunter

Hearing On Hosmer Bill . . .

Continued from page 6

attacked the critics of the regulations. He accused the "health food industry" of waging a "vicious campaign of deceit and deception" in its efforts to win support for the Hosmer bill. At one point in his testimony, Brickfield commened on Dr. Linus Pauling's statement published in the *NHF Bulletin*, ". . . if the proposed limitation of the sale of vitamins were extended to food, prescriptions would be required for serving one-half ounce of boiled lamb liver or two ounces of sweet potatoes" saying "the opinion [Dr. Pauling's], of course, is irrelevant for the regulations do not extend to food." It would seem that Mr. Brickfield missed a very obvious point here—a point which emphasizes the ridiculousness of the FDA regulations. Apparently FDA believes an intake of more than 10,000 units of vitamin A is potentially dangerous only if consumed in the form of a dietary supplement and is not hazardous if consumed in the form of food.

NRTA-AARP Accuses Health Food Industry Of Deceit and Deception

At another point in his testimony, Brickfield charged that the public is bombarded with unsubstantiated claims for the value of vitamin and mineral supplements and implying that it was the manufacturers and distributors of dietary supplements who were responsible for this flood of "misleading information." His testimony presumably was intended to further imply that passage of the Hosmer bill would remove from FDA all authority to prevent false

(Continued on next page)

claims and advertising in connection with any dietary supplement. The Hosmer bill would do no such thing, of course. Furthermore, with some possible exceptions, the so-called unsubstantiated . claims, which seem to cause so much alarm among the critics of food supplements, do not originate from the manufacturers and distributors of the products because they know full well that making so-called false or misleading claims for their products would invite an FDA seizure and later court action followed by fine or imprisonment as provided for in the Food, Drug and Cosmetic Act in sections not to be amended by passage of the Hosmer bill. Rather, the so-called unsubstiantiated claims are to be found in books, journals and magazines authored generally by reputable doctors, biochemists, scientists and nutritionists who have devoted years in the study and use of the nutrients about which they write.

BEQUESTS and GIFTS

BEQUEST IN WILL: Here is a suggested statement for the convenience of those who wish to incorporate into their wills a bequest to The National Health Federation:

"I give, devise and bequeath to The National Health Federation, a non-profit corporation, incorporated under the laws of California, with headquarters at Monrovia, California, the sum of.....($.....) (and/or property herein described) for its discretionary use in carrying out its general aims and purposes."

INSURANCE POLICY GIFT: For those who wish to name The National Federation as sole beneficiary, or one of the beneficiaries, in an insurance policy, it is suggested that you obtain from your insurance agent the necessary legal form or application for your signature, before witnesses if required. The following designation is suggested:

"The National Health Federation, a non-profit corporation, incorporated under the laws of California, with headquarters at Monrovia, California, the sum of.....($.....) for its discretionary use in carrying out its general aims and purposes."

MEMORIAL FUND: Should the donor desire to create a Memorial Fund in a will or insurance policy, state, after the sum of property described in the beneficial gift, that the fund is to be known and designated as the "....(name).... Memorial Fund."

Dr. Roger Williams Stresses Nutrients Are Not Drugs

The University of Texas Professor Emeritus Dr. Roger Williams, noted nutrition scientist and author of several books, gave succinct testimony providing scientific background which supports the Hosmer bill.

Dr. Williams stressed that nutrients are not drugs stating, "It is a scientific fact that nutrients do not act like medicines or drugs. They therefore should be considered in a separate category of substances that are normal constituents of the body and commonly act constructively and in cooperation with other nutrients."

Dr. Williams provided the subcommittee members with a copy of a relevant statement which he had previously presented to the Food and Drug Law Institute, which states:

"A basic distinction between nutrients—minerals, amino acids and vitamins—and typical drugs lies in their mode of action.

"Nutrients enter into metabolism by furnishing building blocks for the construction of the enzyme systems which make metabolism possible. Drugs do not do this, and if a substance acts constructively, it must be a nutrient (or possibly a hormone), not a drug.

"Unlike nutrients which act as a team, drugs act individually by entering into and interfering with metabolisc processes. This interference, hopefully, brings about changes that are favorable to man and unfavorable to his enemies.

"Another basic distinction between nutrients and typical drugs is the fact that nutrients are native to our bodies while drugs in general are foreign or alien substances."

In connection with the recommended daily allowances upon which the restrictions in the FDA regulations are based, Dr. Williams said, "Because of the serious deficiencies of nutritional science, nutrient requirements are very imperfectly known, and the 'recommended allowances' cannot be accepted as being definitive for any nutrient or for any individual.

"Dr. Man-Li Yew, in our laboratories, has found strong evidence that the recommended allowance for vitamin C may be too low by a factor of 20 or more, especially in light of the tremendous individual variation which exists.

"This finding alone is enough to make one question the validity of using the 'recommended allowances' as figures on which to base restrictive measures. Because body chemistries are far from identical as set forth in my book, *Biochemical Individuality*, it necessarily follows that individuals have quantitatively highly distinctive nutritional requirements.

"The facts, not theories, of biochemical individuality complicate greatly the problem of restricting wisely the sale of vitamins and other nutrients. A consideration of these facts lead to a demand that a change be made in the current FDA regulations."

In summarizing his attitude regarding the pending FDA dietary supplement regulations, Dr. Williams said, "The current FDA regulations are unrealistic, and those who have made them have been operating in a confusing fog."

In closing his testimony, Dr. Williams suggested that instead of restricting the sales of vitamins and other nutrients, the public could be protected from their indiscriminate use by requiring labels which carry warnings in any case where certain high levels of intake are definitely known to be dangerous.

Clinton R. Miller and Kirkpatrick W. Dilling Represent NHF

The National Health Federation was represented at the hearings by Clinton R. Miller, NHF's Washington, D.C. legislative advocate, and by Kirkpatrick W. Dilling, NHF's special legal counsel in the matter of the pending dietary supplement regulations.

Mr. Miller expressed to the subcommittee members, the gratitude of the members of the National Health Federation and the millions of aware and deeply concerned nu-

(Continued on next page)

tritionally minded consumers for scheduling the hearings. He closed his statement by saying that twelve words summarize NHF's position in this matter:

CONSUMER PROTECTION? YES!
NUTRITIONAL TYRANNY? NO!

And we can discern the difference!

Mr. Dilling briefly reviewed the history of FDA's repeated attempts to severely limit the variety of formulations permitted as dietary supplements and to limit the freedom of choice by the consumers. Dilling pointed out the nutritional absurdity of the pending regulations observing that the thirteen vitamins and seven minerals permitted in dietary supplements comprise only a minor proportion of the total number of nutrients known to be vital for human health. He further pointed out that the regulations forbid combinations of food factors which are commonly found in natural foods. Also, he emphasized that the restricted potencies of some of the vitamins permitted under the regulations are far below that which may be found in a single serving of some foods.

Dilling said FDA's thesis that the American public must be "protected" through bureaucratic interference, from "too much" nutrition, is false. This becomes even more obvious, he said, in the face of a national survey published by the U.S. Department of Agriculture in 1968 which revealed that approximately one-half of the families in the U.S. fail to receive nutrition recommended for their best health.

Milton A. Bass For NNFA Clarifies Issues

Mr. Milton A. Bass, a member of the New York law firm of Bass and Ullman representing the National Nutritional Foods Association, sought to remove some of the confusion and misunderstanding concerning the Hosmer bill. He said, ". . . a great deal of confusion has surrounded this bill and a great deal of misinformation has been disseminated by opponents of said bill. First, this bill has nothing whatsoever to do with any question of fraud or false and misleading claims involved in thes sale of products. Our existing statutes extensively cover these questions. Any product which is sold with false or misleading claims is subject to seizure, injunction and criminal action. This bill does not change the existing law which provides for the control and prevention of fraud and misleading claims in connection with the sale of products.

Second, this bill has nothing to do with any question of danger or safety of any product. The existing statute contains provisions to bar and prevent the sale of any product which is injurious to health."

Bass said, "The present regulatory pattern is consistent with Congressional intent as set forth in Sec. 403(j) of the Act. Beginning in 1962, however, the Food and Drug Administration began an attempt to change the very direction laid down by Congress. The FDA began an attempt, which is continuing up until today, to limit the sale of food supplements as distinguished from giving information to the consumer. Rather than require information on the label stating whether the ingredient is recognized as essential in human nutrition and what percentage of the minimum daily requirement is contained in the product, the FDA now seeks to impose prohibitions as to what can be sold and what the consumer can eat.

"We are, therefore, really dealing with a question of philosophy," said Bass. "The issue presented by this bill is whether we shall require giving information to the consumer or whether the FDA shall have the power to dictate the dietary habits of the American people. This is the only issue raised by this bill. This issue would not have come into being if it were not for the fact that the FDA is now seeking to disregard the intent of Congress and to change the entire philosophy in the regulation of food supplements. The FDA is in reality attempting to legislate rather than have that function performed by Congress."

Eight members of the House of Representatives were on the witness list to support the Hosmer and related bills. Antonio B. Von Pat, a delegate to Congress from Guam, said that the FDA "recently saddled with an apparatus in drug investigations leading to a virtual standstill in new drug entities . . . is apparently determined to produce a similar immobility in food supplement formulations."

(Continued on next page)

Dr. Linus Pauling Submits Statement

Dr. Linus Pauling was not present to give an oral statement but did submit a written statement for the record giving support to the need for a Hosmer-type bill. He has expressed the opinion that the FDA regulations will hamstring nutritional research and deprive the public of health-giving vitamins.

Dr. Carlton Fredericks Testifies

Dr. Carlton Fredericks, famed nutritionist, author and lecturer, gave valuable testimony in behalf of the Hosmer bill but was rudely interrupted by Rep. Carter (R-Ky.), a physician member of the subcommittee, who called Fredericks' testimony "absolutely incredible" and questioned his Ph.D. degree. The details of the Carter-Fredericks confrontation is told by Clinton Miller on another page in this issue of the *Bulletin.*

David S. King, a former congressman and now Legislative Advocate of the National Nutritional Foods Association charged the curren law "has not given to the FDA the right to impose its philosophy of nutrition on those who claim to follow a different one, so long as the latter does not injure or deceive the public."

Excellent testimony was given by others. It is unfortunate that space does not permit a summary of their testimony also.

NHF Legal Defense Fund Needs Support

A brand new phase in the activities of NHF was marked by the establishment of the **NHF Legal Defense Fund** out of which financial help can be given to defendants in health related cases where constitutional issues are involved, where important precedent may be involved, or where the case is clearly one of harassment and entrapment.

The Legal Defense Fund became an actuality when all the revenue received from our recent Liberty Stamp Drive was deposited in the account. Then, at the suggestion of a member, a DOLLAR-A-MONTH CLUB was established to provide a continuing source for the Fund. Anyone may become a member of the Club merely by sending in a dollar and then each month, without being billed or reminded, sending in another dollar. Many who have already joined, have sent in a check for $12.00 for the entire year and thus saving the inconvenience of mailing a dollar each month to the **Legal Defense Fund** is to adequately fulfill its intended purpose however, we must have at least 1000 members in the Dollar-A-Month Club. If you have already joined or have contributed in other ways to the Fund, we extend to you our heartiest thanks. If you have not, please give this need your thoughtful consideration.

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 industries, 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 harrassment 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

Kurt W. Donsbach, N.D., D.C., B.T.S., Vice President

Betty Lee Morales — Secretary

Dorothy B. Hart — Treasurer

Fred J. Hart—Chairman of the Board of Governors and Managing Editor of the **Bulletin.**
Address: P.O. Box 688, Monrovia, California 91016

PAID FEDERATION STAFF AND THEIR FIELDS OF ACTIVITY

Clinton R. Miller — Vice President in charge of the Washington Office, which includes Legislation and Regulations.
Address: 121 2nd Street N. E., Washington, D.C. 20002
Phone: (202) 547-2547

Arthur Koch—NHF Legal Counsel
Address: 121 2nd Street N. E. Washington, D.C. 20002

R. A. Laurye—Business Administrator
Address: P.O. Box 688, Monrovia, California 91016. Phone: (213) 358-1155

Convention Bureau — Plans and coordinates all convention activities.
Address: P.O. Box 688, Monrovia, California 91016
Phone: (213) 358-1155

Willadean Vance — Director of Public Relations
Address: 17241 Santa Barbara St., Fountain Valley, California 92708
Phone: (714) 842-9422

Raymond H. Houser — Editor of the **NHF Bulletin.**
Address: 5366 Auburn Drive, San Diego, California 92105

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

NATIONAL HEALTH FEDERATION
P.O. Box 688
212 West Foothill Boulevard
MONROVIA, CALIFORNIA 91016

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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.

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