National Health Federation BULLETIN

February, 1971

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NHF, America's Largest Consumer Group Devoted Exclusively to Health Issues, Services and Products

NHF Attacks FDA's First Order Implementing New Vitamin Regulations:

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Discriminatory Regulation Possible Under Proposed Medical Device Safety Act

Complete contents on inside of front cover

Dedicated to the Protection of Health Freedoms

THE
NATIONAL HEALTH FEDERATION BULLETIN

Protection of Health Freedoms — *Published Monthly*

Volume XVII — Number 2 — February, 1971

CONTENTS

UNLOCKING THE FUTURE

National Health Federation Bulletin, published monthly January through December, except July-August which are combined, at 211 West Colorado Boulevard, Monrovia, California 91016, by National Health Federation, a nonprofit corporation. Fred J. Hart, Managing Editor; Raymond H. Houser, Editor. Subscription rate of $4.00 per year. $1.50 of the annual membership dues is paid as a yearly subscription to the **National Health Federation Bulletin.** Single copies, 35 cents. Second-class postage paid at Monrovia, California 91016.

THE FAMILY CIRCLE

By FRED J. HART
Chairman of the Board of Governors

As we enter this new year of 1971, it is our desire to express to our members and friends, the appreciation of the officers and staff of the National Health Federation for the wonderful cooperation given us in the crusade for health freedom. We are indeed mindful that the successes and accomplishments of the Federation have been made possible by this cooperation and the devotion of the members to the purposes of the organization and to the projects we have undertaken.

During these coming months, there will be installed at headquarters a bronze memorial tablet on which will be inscribed the names of our members who have departed this life and whose good work goes on because they thoughtfully put into their will a liberal bequest to the Federation. At present writing, there are over twenty-one such individuals whose estates have been probated. It is our hope that many more of our members will invest in the future by putting a bequest in their will, even though it may be a small one. On another page of the *Bulletin* is suggested wording for such bequests.

We appreciate also the many members who have changed their membership classification from regular or sustaining to a LIFE MEMBERSHIP. Such action during the past two years, coupled with the bequests mentioned above, have provided the Federation with working capital which has enabled it to undertake new projects at the time action was needed.

During the past year, the National Health Federation worked very hard in support of legislation to include chiropractic in Medicare. The Federation has enjoyed and appreciated the cooperation of the officers and Washington representatives of the chiropractic associations. It has been gratifying to note the solidarity of the profession in connection with this legislative project. This augurs well for the future health of the American people. It is further gratifying to note the number of members of the profession who are urging their patients to join the National Health Federation.

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WHEN – That's the name of a new health paper that has recently made its appearance. The "W" is for World, the "H" is for Health, the "E" is for Ecology, and the "N" is for News. From the beginning to end, it is packed with facts regarding the health of the public. It is designed to reach and appeal to the young people of our colleges and high schools but it is good reading for adults as well. For example, the third issue just off the press is devoted almost entirely to a presentation of the subject, "Nuclear Power–Is It Good or Bad?" This article was originally written by Don Matchan, Editor of the Alameda Times Star, one of California's leading independent newspapers. Copies of this important issue of WHEN can be obtained from your health food store or you may write directly to the editor of the paper at Post Office Box 1, Palm Springs, California 92262. The price is 35c. This is a new venture in the health field and we of the National Health Federation, because of the purpoes of the paper to reach the young people with facts, should do all we can to make it accomplish that purpose.

NHF Attacks FDA's First Order Implementing New Vitamin Regulations

By MILES H. ROBINSON, M.D.

The first tentative Order by FDA Commissioner Edwards, on the infant foods section of the stayed food supplement regulations, was published October 29, 1970. NHF found certain portions of this Order to be objectionable believing these portions not to be in the public interest. Accordingly, Dr. Robinson, acting on behalf of NHF, filed formal exception to the Order. Here, in the first of a two-part series, is the essential text of NHF's formal exception. It is both noteworthy and gratifying that our exception was given prominent space in the December 7, 1970 issue of "Food Chemical News," the weekly trade journal ($175 per year) "for executives providing in-depth information regarding regulation of food additives, colors, pesticides and allied products."

FDA Commissioner Edwards, in his proposal for infant foods, has introduced into an otherwise useful regulation for infant foods, a highly controversial Finding of Fact, Conclusion of Law, and part of an Order, which are unduly subtle, capricious, arbitrary, and inconsistent with each other and with the evidence of record. They contaminate his proposal as a whole, and set a bad precedent, both generally and in connection with the major part of the food supplement regulations, Orders for which presumably will be announced next.

FDA's proposed Finding of Fact, No. 6, states that *"It makes no difference in terms of infant nutrition whether the vitamin or mineral in an infant food is derived from natural or synthetic sources."**

From this a Conclusion of Law is drawn that *"the label need not state the names of the specific ingredients that are the sources of the vitamin or mineral nutrients supplied by such food."*

Part 125.5(a) of the Tentative Order states, *"If a food (other than a dietary supplement of vitamins and/or minerals alone) purports to be or is represented for special dietary use for infants, the label shall bear, if such food is fabricated from two or more ingredients, the common or usual name of each ingredient, including spices, flavoring, and coloring."*

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*Quotations from the Commissioner's proposal and from the hearing record shown in italics.

TESTIMONY CONTRADICTS FDA'S PROPOSALS

The aforesaid Finding of Fact and Conclusion of Law are not supported by the evidence from the hearing. Part 125.5(a) of the Order, due to its failure to require full disclosure of the common or usual name of each ingredient in supplements of vitamins and/or minerals alone might result in serious or fatal allergic injury to infants.

The United States courts have held that neither the FDA nor any other Agency has the right to dictate the American diet. To restrict the labelling of infant food and not make full disclosure of the source of vitamins or minerals would amount directly or indirectly to dictation of infant food in the American diet.

Concealment of the nature of the vitamin or mineral ingredients in infant foods is favorable to the manufacturers of synthetic foods and supplements, and serves the FDA's purpose to silence as much as possible any information about the natural source of some supplements.

The possible benefit of natural, as opposed to synthetic, ingredients has been a major controversy throughout the hearing. (Tr. 23128). The FDA insisted that there was no nutritional difference.

From the start of the hearing, FDA laid great emphasis on its prosecutions of certain distributors, all of whom were strong advocates of food supplements from natural sources. (Tr. 242).

It is probably no accident that in the current limited proposals realting only to infant foods, as to which there has been only slight controversy, FDA should slip in a conclusion of law on this subject of natural source among its findings of fact, and thus attempt to establish a precedent which could be extended to cover not only infants, but also the adults who presumably will be dealt with when further proposals are issued for the rest of the regulations.

When the full record of these food supplement regulations is examined on appeal of this whole matter to a regular court of law, as seems quite certain, it will be evident that it is and has been a settled policy of the FDA in the area of food supplements to show a callous disregard for fair and legal procedures.

As evidence for FDA's Finding of Fact No. 6, that "*it makes no difference in terms of infant nutrition whether the vitamin or mineral in an infant food is derived from natural or synthetic sources,*" FDA cites only the testimony of one witness, Harold E. Harrison, M.D.

The first citation deals with the "*need for ascertaining the source of foods.*" (Tr. 23138). The reason under discussion for such need to know the source was the possibility of allergic hypersensitivity of the infant to food from a particular source (Tr. 23140), in which case Dr. Harrison testified that it would be desirable for the infant to avoid that food to which he was known to be allergic.

The witness also specified that "the major allergic manifestations in infants is most often to proteins in milk, eggs, and wheat." (Tr. 23140).

He was then asked if the same policy (information available as to source) should not apply to other than milk, eggs, and wheat ingredients. (Tr. 23140). He answered: "*There is a quantitative factor. There are tremendous differences between foods which are ingested in considerable quantities, and trace amounts of materials that might be present in the environment. It is usually the materials that are ingested in considerable amounts that we are most concerned about.*" (Tr. 23141).

Note first that in all this testimony there is absolutely no evidence that the witness was specifically unconcerned, as the FDA assumes in its Finding of Fact, No. 6, with the allergic hazard of vitamins or minerals in or added to the infant food.

The reference to "trace amounts that might be present in the environment" shows that the witness is actually wandering from the subject of what the infant *eats,* (including vitamins and minerals) to the subject of *environment,* which for the allergic infant would include wool blankets, feather pillows, house dust, etc.

That the witness has gone out into the non-food area is further substantiated by the distinction he next draws between the "trace amounts of materials that might be present in the environment" and "the materials that are ingested in considerable amounts," by characterizing the latter as "usually foods, of course." (Tr. 23141).

Since the stayed regulations consider vitamin or mineral supplements to be foods, it is reasonable to believe that the witness was not excluding these substances from his list of that to which the infant might be allergic.

Even if it be assumed that the witness is referring to vitamins and minerals when he refers to "trace amounts," he does not eliminate concern for their allergic properties, because he says merely that he is *usually and most* concerned with materials that are ingested in considerable amounts. (Tr. 23141).

It is common knowledge that of all the fields of medicine wherein one would feel secure if he avoided "considerable amounts" of a hazardous substance, nowhere is such reliance more dangerous than in the field of allergic hypersensitivity. Here a person may abruptly experience a serious or even fatal allergic reaction to extremely minute amounts of a substance, of which he did not have warning that he was about to take it into his body.

In summary, the foregoing testimony of Dr. Harrison is at best

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ambiguous and does not support Finding of Fact No. 6. This testimony does not say that there is no need to specify the source of a vitamin or mineral to protect the allergic infant.

The next citation by the FDA to Dr. Harrison at Tr. 23249-50 is totally irrelevant to the issue. The question of source and of natural or synthetic is not even remotely under discussion.

The next citation was relevant to the issue of source. Dr. Harrison was asked by attorney Ullman whether a buyer, if for reasons of his own wants to know if a vitamin supplement is from natural substances, should he be *prohibited* from having this information (Tr. 23277-8).

The witness said that he did not regard this information as germane or necessary, that it might create confusion, and that it therefore ought not to be on the label. He was then asked to answer the question more directly, but the Hearing Examiner refused to let the witness answer on the following extraordinary ground: *"There is no reason the writer can not write a letter or look it up in the library. There is no prohibition against securing the information."* (Tr. 23278).

It is common knowledge that no library has or could be expected to have literature on the source of a particular vitamin in a particular preparation distributed by a particular vendor of vitamin supplements. If it did, such information (emanating by necessity from that vendor or one of his agents) could constitute illegal labelling under the stayed regulations, the second offense for which is a felony punishable by fine and imprisonment. (Tr. 699, 706).

It is certainly not the FDA's function to force the public to write letters or search in libraries for information it has a right to receive on labels or in promotional literature.

It must be emphasized how far afield the FDA regularly goes to enforce "labelling" in the area of products from natural sources. As was made clear throughout the hearing, the proposed prohibition on information as to source in labelling applies not only to the box and bottle of a supplement, but also to all promotional material, and extended to any spoken or written word which mentions the product.

For example, FDA convicted a medical doctor, Dr. Herman Taller, of a felony charge, on the necessarily combined grounds that (a) his book on weight control constituted labelling in that the book mentioned the name of a distributor of safflower oil with whom Dr. Taller was financially associated, and (b) the FDA did not approve of the author's weight control program (Tr. 121).

Unfortunately for the FDA, its omniscient medical consensus in this matter was destroyed by the revelation at the vitamin hearings

(Continued on page 26)

WASHINGTON REPORT

By Clinton R. Miller, NHF Legislative Advocate

Discriminatory Regulation Possible Under Proposed Medical Device Safety Act

Unless members and friends of the National Health Federation are able to bring sufficient pressure on members of Congress to amend or defeat it, there is grave danger that Congress may rush through a deceptively named "Medical Device Safety Act" which will place all health devices under the same medical control which has been attempting to strangle non-prescription food supplement usage by American consumers for the past 33 years. It is safe to assume that chiropractors, naturopaths, napropaths and members of other health professions which resist medical control and domination, will have absolutely no representation on the "Group of Experts" provided for in the bill or on the "Panels" to be appointed by the group of experts who have the responsibility of classifying all medical devices.

The bill specifically provides that the "experts" may be nominated by the National Academy of Sciences which is the same group that appointed a group of experts which found bioflavonoids to be "ineffective." Chiropractors and other non-medical practitioners who have dared to use non-AMA approved devices to diagnose and treat patients should have their state and national associations carefully read these bills and start an immediate lobby effort to insist on equal and fair representation in the group of experts and panels which will "classify the devices according to their scientific needs for safety, reliability and effectiveness." Unless there is fair representation of competing healing arts on the group of experts to be appointed by the Secretary of HEW, we may expect, and I predict, that a great many devices used by the non-medical health professions, will be found unsafe, unreliable and ineffective while most of those devices used by the AMA member physicians will be found safe, reliable and effective.

For example, the FDA has already announced that it considers thermometers so well designed that they would be exempt from the requirements provided in the bill for "standards" or "premarketing clearance."

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On the other hand, highly sensitive galvanometers used effectively by some chiropractors as an aid in locating spinal subluxations, would probably be banned by requiring them to get "premarketing clearance" which would never be given.

Although it is not generally known by most chiropractors, the FDA lost a court case in Pennsylvania over the Ellis Microdynameter, an extremely sensitive galvonometer once used by hundreds of chiropractors all over America. As a result of this unpublicized FDA court defeat, chiropractors in Pennsylvania are using Ellis Microdynameters with the full knowledge and grudging consent of federal and state food and drug officials. By using an untruthful press release, FDA was able, a few years ago, to persuade hundreds and hundreds of chiropractors to destroy their expensive and valuable Ellis Microdynameter galvanometers in one of the blackest pages in the health history of America. If these chiropractors had refused to destroy their devices until the Pennsylvania court acted, they could be using them today. It is not, nor has it ever been, illegal to use an Ellis Microdynometer. FDA did win a court case against the labeling used by the manufacturer, but that is all they won. FDA destroyed the company, however, by lying in their press release and convincing practically every chiropractor who owned the device that he had no right to own and use it and consequently hundreds of thousands of dollars worth of very valuable galvanometers were destroyed by axe and sledge hammer when all that was won by FDA was a decision by the court that the devices would have to be relabeled before any more could be sold. Those already owned were legal to own and use as proved by the subsequent Pennsylvania court victory!

The story of the Ellis Microdynameter is important here because it is a type and shadow of what will come to pass under the Medical Device Act of 1971 if it ever passes in its present form. With the proved pro-medical bias of FDA against chiropractic, they can use the act to circumvent the Pennsylvania court victory over FDA and proceed methodically to classify most or all devices used by chiropractors and other non-medical practitioners by "requiring pre-marketing clearance." As provided by the bill, "those devices . . . are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety, reliability, and effectiveness of such devices, to be safe, reliable and effective for use."

AUTHORIZES MEDICAL EXPERIMENTS WITHOUT PATIENT CONSENT

The most serious defect in the bill is the blatent provision that investigators using human guinea pigs to test experimental devices need not inform individuals that they are being used in a medical device experiment for investigational purposes, nor do they need to obtain the patient's consent if the investigators doing the experiment "deems it not feasible or, in their professional judgment, contrary to the best interest" of the human guinea pig.

The National Health Federation, in 1962 gave testimony to Congress and lobbied to put language in a Food and Drug Act then being passed, to prevent any person ever being used in any medical experiment without their fully informed consent. We won approval of our now famous "Human Guinea Pig" amendment in the House of Representatives but the AMA got Sen. Dirksen and other Senators to add an amendment to NHF's amendment in a conference session on the bill which was designed to so cripple our amendment that we would withdraw it rather than let it stand with the AMA loophole. We knew that the American people would never knowingly tolerate any law which would let them become human guinea pigs in medical experiments without their consent or knowledge so we lobbied effectively to keep our Human Guinea Pig amendment even though it was amended with the AMA's loophole. We knew the time would come when we could force Congress to debate the issue which was secretly decided in a conference committee in 1962 and was never debated in open public committee hearings. Now that time has come. The nearly identical NHF Human Guinea Pig amendment and its accompanying AMA loophole is now included in the new proposed Medical Device Safety Act of 1971. The 1962 amendment covered drug experiments only. The 1971 amendment will cover only device experiments. But if NHF can convince Congress to take off the AMA loophole from the 1971 Device Act, we will have a strong precedent to demand it be removed from the 1962 Kefauver-Harris Drug amendments leaving only the NHF language which prohibits ANY experiments on anyone without their informed consent.

The following is the exact language proposed in the new legislation on devices:

> ". . . INVESTIGATORS . . . will inform individuals upon whom such device or any controls in connection therewith are used, or the representatives of such individuals, that the device is being used for investigational purposes, and will obtain the consent of such individuals or representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interest of such individuals."

NFH believes the last 20 words are an AMA loophole and we are strongly opposed to having them included.

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Write at once to your congressman and tell him that you are strongly opposed to the Medical Device Safety Act of 1971, and ask him to forward your letter of opposition with one of his own to Rep. Paul Rogers (D. Fla.) who is expected to be chief sponsor. Tell your own representative and both U.S. Senators that you have never given any lawmaker authority to pass any law which will allow any medical (drug or device) experiments to be performed on you without your fully informed consent and knowledge. Tell him that the provision in the Medical Device Safety Act of 1971 which leaves it up to the *judgment of the investigator* whether he will inform you if you are to be used in a medical device experiment OR get your consent is intolerable and urge him to insist it be eliminated from the bill in committee hearings.

At the time this report is being written, I don't know what the number of the bill will be as the bill has not been introduced yet. I expect Rep. Paul Rogers (D. Fla.) to be the chief sponsor because he was the chief sponsor who introduced the bill which was identified as H.R. 19578 in the 91st (last) Congress.

Co-sponsoring the bill with Mr. Rogers were 7 of the 8 members of the House Health Subcommittee which may hold hearings on this bill. This means that there is tremendous momentum behind the bill towards getting hearings early in 1971 so don't delay after reading this report. Wire or write along the lines suggested above and send me copies of any replies you get from your Senators or Representatives.

Rep. Paul Rogers is a very highly respected and fair minded U.S. Representative. He will carefully consider your opinions on his bill if he has your letter forwarded to him by your Congressman. Remember the oft repeated NHF rules for writing Congressmen.

1. Write about one subject at a time.
2. Never scold or berate or use abusive language.
3. Tell why you like (or dislike) proposed legislation.
4. Ask respectfully, that specific action be taken.
   ("Please vote against this bill which would allow me to be used as an involuntary guinea pig in medical device experiments without my fully informed written consent!" Or, "Please forward this letter to Rep. Paul Rogers with supporting letter of your own.")

The address for all U.S. Representatives is:

"Hon. .....,
House Office Building,
Washington, D.C.

ALL SENATORS get their mail at the Senate Office Building.

If, after writing your own Congressman, you have more time, write a letter direct to Rep. Paul Rogers, even though he isn't your Representative. But, under no circumstances be rude or insulting.

Land Of the Free And Home Of the Brave

By CHARLES ORLANDO PRATT
Washington General Counsel

In less than five years from now the citizens of the United States will celebrate the two-hundreth anniversary of our Declaration of Independence.

The citizens living here in 1776 had to fight for and win that independence before self-government could be established and recognized by all the people and nations of the world.

After the Revolutionary War for independence was won, our leaders drew up and adopted the Constitution of the United States, including the first Ten Amendments which we call our *Bill of Rights*. These Amendments symbolize the respect for the individual that is the cornerstone of American political concepts.

The men who wrote the Constitution recognized that true liberty can rise no higher or be made more secure than the spirit of a people to achieve and maintain it. Their prime concern was to devise a form of government for the Nation under which such a spirit might thrive and find the fullest opportunity for expression.

The Amendments comprising the Bill of Rights followed only after the structure of government had been established by the Constitution proper. This resulted not so much from what the framers of the Constitution considered to be new ideological imperatives as from fears among the states that the national government might seek to tamper with individual rights already largely assured under the laws of the various states and their constitutions.

In 1954 Fred J. Hart called together a group of citizens from different parts of America to organize The National Health Federation for the purpose of working for individual rights in matters of health, because the fears were real that the national government in Washington, D.C., was, indeed, tampering with the individual rights of citizens in matters of health care.

Because the Federal Food and Drug Administration, in some actions, was exceeding its statutory and constitutional powers, it became necessary to establish a non-stock, non-profit corporation to serve as a forum for freedom of speech, freedom of press and freedom of assembly in matters of

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health. In 1955 the State of California granted the Corporation a Charter at the request of Mr. Hart and those working under his guidance. The name of this corporation became known as The National Health Federation; and its aims and purposes have been carried on with faith, hope and sacrifices of thousands of Americans all over our country for more than fifteen years.

We have just successfully concluded the Sixteenth Annual West Coast Convention in Los Angeles, which was attended by thousands of concerned citizens including Fred J. Hart, Chairman of the Board of Governors; Charles I. Crecelius, President of The National Health Federation; and all of the officials in California, Washington, D.C., and throughout the States from Canada to the Gulf of Mexico and from California to Maine.

"Liberty lies in the hearts of men and women; when it dies there, no constitution, no law, no court can save it; no constitution, no law, no court even can do much to help it," said the famous Judge Learned Hand.

During the past years since NHF was organized, it officials, members and friends have worked for the right to have safe, clean air; clean, fresh, safe water; safe soil on which to grow food crops and fruits; wholesome natural food grown on soil not depleted nor poisoned with industrial chemical insecticides and fungacides; and to have safe and efficacious drugs. Recently it was reported that more than one million patients entered hospitals for treatment of diseases caused by side-effects of drugs.

NHF is now working, as it has always done in the past, for the right of every American to use and enjoy the care of any and all doctors duly licensed in their states to practice the healing arts professions.

NHF has taken alarm at the experiments by the Federal and State Governments upon our liberties and our religious and conscientious inalienable rights relating to health care and health matters.

Apparently the health of our citizens is not as good as it should be. This is obvious for Americans broke a spending record for health care in 1969 for everything from aspirin to hospitals. This was reported by the Honorable Wilbur D. Mills, Chairman of the Ways and Means Committee of the United States House of Representatives, in the Washington *Star* this past December 1, 1970. The amount or cost given was Seventy Billion Dollars.

It has been reported that the U. S. Department of Health, Education and Welfare has presented to Congress, for appropriation to run that Department, a budget of more than eighty-nine million dollars for the next fiscal year.

The President of the United States has asked Congress for billions of dollars to be used to fight and stop pollution of air, water, land and food.

Congress is considering the establishment of a U. S. Department or Agency for Consumer Affairs as well as other agencies to stop all kinds of fatal pollution to protect all Americans from abuses by government and private enterprise.

In the beginning after the establishment of The National Health Federation, Fred J. Hart, who was then President of the Federation, advocated that the Federal Government should establish a Consumer's Department or Agency to protect the health and welfare of the American consumers. It is evident that Mr. Hart had foresight and faith.

Even though NHF officials and supporters have been attacked in courts, in publications, and in speeches prompted by the Federal Food and Drug Administration, and others, they have never quit working for freedom of choice in health matters.

Your National Health Federation understood human nature as did Thomas Jefferson when he said, "Resort is had to ridicule when reason is against us."

All over America health-minded citizens are joining The National Health Federation and its crusade for freedom of choice in health care so long as that choice harms no other.

Americans are now concerned about ecology. They want wholesome and safe environment in which to live.

Americans believe that the U. S. Department of Health, Education and Welfare should administer all its laws to protect the health and welfare of all Americans, regardless of the economic pressures of the monopolistic powers engaged in the drug or food business or the medical or dental professions.

Americans demand the right to have available to them wholesome food supplements and foods for special dietary uses for physical, physiological and pathological reasons.

Americans are entitled to the right to vote on the question of whether their drinking water will be fluoridated on the ground that no government has the right to mass-medicate its citizens without their informed knowledge and consent.

Americans will work to stop the use of experimental drugs and devices on people without their informed knowledge and written consent after being advised of the serious or fatal dangerous side effects that could result therefrom.

The National Health Federation will support Congressional legislation to include in Medicare the right of all citizens to use the services of all doctors licensed to practice in their respective professions in their States on the ground that all citizens are entitled to the equal protection of the laws. The right to enjoy such health and medical services is provided in the Bill of Rights of the United States Constitution.

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America is the Land of the Brave. Now, America must work to become again the Land of the Free in health matters *provided* none is harmed thereby.

The National Health Federation will always work for the right of freedom of speech on the radio, TV and in assembly halls. We shall work for freedom of press and the right to express ideas on health matters without being subject to ridicule.

In a brief span, as compared to the nine hundred years of the City-State of Athens or to the four hundred years of the Roman Empire, America has become both the richest and the freest nation in the world.

All of this heritage is now threatened by the forces of Communism from without and at home by those who would abandon the ancient landmarks set by our forefathers, and take us down the road to socialism. We may survive a nuclear attack, but we cannot survive, any better than Athens and Rome, moral degeneration and the abandonment of fundamental principles which made America great.

NHF believes that no Federal or State regulatory agency in matters of health is beyond the final reckoning; because it is still true, as Goethe said, "Nothing that shuts truth out is safe from truth."

NHF believes in perseverance, as did William the Silent, Prince of Orange, who fought for and won the unity and independence of The Netherlands. He said, "It is not necessary to hope in order to act, or to succeed in order to persevere."

NHF, with your faith, courage and help, will continue to take positive action in Congress, State Legislatures and the Courts so that we can carry out the precepts expressed by Harvey W. Wiley, M.D., first Administrator of the food and drug laws who said, "We are careful to preserve that life which the Author of Nature has given us, for it was no idle gift."

In 1971 and thereafter, let The National Health Federation strive to make America the Land of the Free and the Home of the Brave, because a nation of sick people cannot be either brave or free.

BEQUEST

Here is a suggested statement for the convenience of those who wish to incorporate into their wills a bequest for unrestricted use in research and the general work of the National Health Federation:

I give, devise, and bequeath to the National Health Federation, a corporation, located in Monrovia, California, the sum of $..... (or property herein described) to be used by its Board of Governors, as they deem advisable, for the benefit of said institution and its program.

Should the donor desire to create a Memorial Fund, insert after "property herein described," *the same to be known and designated as the "..... ..... Memorial Fund."*

News Briefs

By ANNE SIGELE

NADER WANTS ADS BACKED UP—The Federal Trade Commission was petitioned by Ralph Nader to compel advertisers to make available to the public evidence to back up claims they make for the safety, performance and effectiveness of their products and services. He and co-petitioner Aileen Adams told newsmen that they were basing their effort on the failure or refusal of 58 companies to produce substantial data in response to written requests.

Miss Adams began late last year to provide the factual underpinning for the petition to the FTC. Requests were sent to manufacturers for evidence to back up promotional claims. One set of requests involved analgesics, or painkillers, on which three companies together spent $56 million in advertising in 1969.

In July, Nader, Miss Adams, the Consumer Association of the District of Columbia and the Federation of Homemakers, filed a lawsuit charging Bristol-Meyers with "false, misleading and deceptive" advertising of Excedrin. The firm called the suit "irresponsible." The case is pending in federal court here.

The petition asks the FTC to hold prompt public hearings looking toward a rule under which national advertisers, at the time they make claims, would have to have supporting data available to the commission and, through it, to the public. Non-national advertisers would be required to make such evidence available either to the FTC or the public. (Morton Mintz, The Washington Post—12/21/70)

PHILADELPHIA BANS ASBESTOS SPRAY—The Board of Health, citing asbestos fibers as a possible cause of cancer, has prohibited the use of asbestos spray materials on construction projects. The Board said the regulation it adopted is the first such rule in the nation.

Norman Ingraham, City Health Commissioner, said asbestos fibers, released by the spraying method, could cause harm if inhaled. The inhaled asbestos can cause certain kinds of cancer, he said. Asbestos is safely used in many products found in the home and industry, Ingraham said, and presents a hazard only when it is released into the air and inhaled. (Washington Post—12/4/70)

NADER ASBESTOS WARNING—Consumer advocate Ralph Nader urged the Food and Drug Administration to warn art teachers about the danger of "severe asbestos pollution" from a paste used in classroom art projects. In a letter to the FDA's Bureau of Product Safety, Nader said

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teachers should be barred from mixing powdered asbestos with water and wallpaper paste to make a "clay" for students. "Under prolonged use in rooms with air conditioning or closed ventilation systems, this practice could result in severe asbestos pollution," Nader said. He also pointed out that teachers and students who actually mix the clay can inhale large amounts of asbestos dust. The finished product itself can give off large amounts of asbestos dust in the classroom, Nader said.

Under law, the FDA can issue a product warning to consumers. Nader urged the FDA to take the step immediately. He noted that the Canadian government is considering regulatory action. Nader said that Canada's executive assistant to the Consumer Affairs Bureau believes the paste falls under the Canadian Hazardous Products Act. (Washington Post.—11/20/70)

MERCURY PERIL FORCES TUNA REMOVAL—Nearly 85,000 cases of canned tuna fish are to be removed from the nation's supermarkets because of possible mercury contamination.

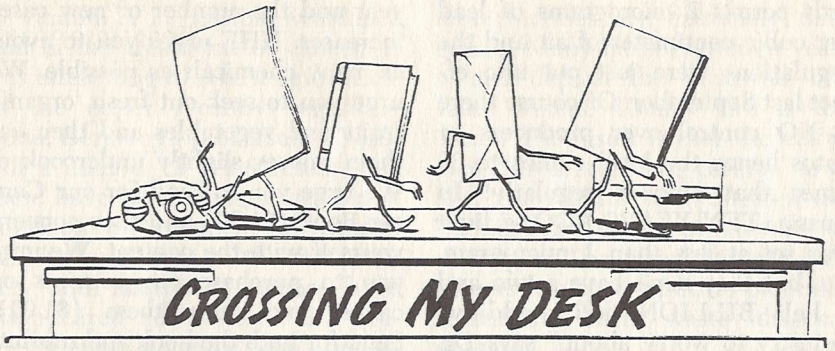
FDA officials made the report as they held an emergency meeting with food and canning industry officials over latest finding of unsafe mercury in at least some cans in five lots of tuna. All were packed by the National Packing Co. of Ponce, Puerto Rico and could include both Atlantic and Pacific ocean fish. The FDA is not yet sure just where the fish came from—or whether the merucry represents man-made pollution beyond natural contamination from mineral sources.

"It cannot be said yet that any major portion of the nation's tuna supply is involved," said John T. Walden, FDA's deputy assistant commissioner for information. "What we are talking about are findings of excess mercury in up to four cans from a lot. This by no means indicates that the whole lot is affected. Our tests and industry tests are continuing." Only a third of FDA's own test data was in so far, however.

Merucry has been found this year in fresh water fish in most parts of the nation. In all the affected tuna, it was found in amounts greater than 5 parts per million, the level FDA calls "acceptable."

New York's State Health Department said it saw no danger to humans unless they ate highly contaminated tuna in large quantities. Doctors have identified no symptoms at all of low-level mercury consumption in human beings—but they worry over hidden brain and nerve damage, or effects on unborn babies.

The latest mercury findings—now in deep ocean as well as fresh water fish—are sure to raise new questions in Congress about the extent of mercury contamination in all foods, and why so little of it has been first discovered by Federal agencies. (Victor Cohn, Washington Post—12/12/70)



NOTES AND COMMENTS BY HOWARD C. LONG

THANKS
RODNEY E. LEONARD

Mr. Leonard, formerly on official of the U.S.D.A. stated recently in Washington that special interest groups so dominate the agency and congressional committees that an effective policy against malnutrition cannot be developed. The Los Angeles *Times* article said that because of pressure groups, civil servants will not move out into the nutrition area. Messrs. Leonard, Cron and Turner each appeared before The Democratic Study Group decrying the problem and also urging that national advertising be used to promote more nutritious foods.

THANK YOU, MARIE

NHF surely has a staunch supporter in Marie Montgomery. She was recently elected President of the San Francisco Chapter. She has been quite active with us for years. Recently one of our staff went to Santa Rosa to speak to a group outside NHF. Who was there? Marie, at a card table, selling NHF memberships. I commented on this to a friend and he said, "Oh, she always comes." Some people, like Marie, just always seem to do more than their share—and without recompense or being asked. Marie, NHF is grateful.

ABSOLUTELY RIDICULOUS

AP reports from Salt Lake City that fish caught to feed animals in the zoo are LOADED with toxins. One test, which was corroborated by an independent laboratory, proved that there was 72 ppm of DDT, 240 ppm of DDE and 28 ppm of DDD. These carcinogenic chlorinated hydrocarbons come from use in agriculture, primarily.

MORE LEAD

Millions of Americans are suffering blood chemistry problems—hard to detect—as a result of inhaling lead! In the San Francisco *Chronicle* reporter Gillette says that anemia and damage to internal organs is caused by lead in the air —95% of which comes from automobile exhausts. California stand-

(Continued next page)

ards permit 2 micrograms of lead per cubic centimeter of air and the regulations were just put into effect last September. Of course there is NO control over producers or autos hence the level climbs to 36 times that amount regularly! In Russia, TEN YEARS AGO, a limit was set at less than 1 microgram, "... but they don't have a two and a half BILLION dollar additive industry to worry about," says Dr. Heslep of the California Department of Health.

WARNING

Dr. T. O. Carver, Idaho Health Director issued a warning recently to the state. AP reported in the *Daily Olympian* that mothers who are nursing, children under 6 and expectant mothers should NOT eat pheasants this year. Pheasants and other game birds are polluted with mercury which can cause illness, death and mental retardation. The mercury comes from mercury treated seeds that birds eat. If anyone is interested, NHF has been suggesting use of a natural product for many years that will supplant mercury. The FDA caused the bankruptcy of the firm making it, but it is now reorganized and the product – a natural one – is available.

THINK ABOUT IT

Yesterday 1,000 people died of cancer–that many will die today. One out of every 3 Americans can expect to get cancer. 305,000 new cases are expected in 1970--and a larger number in 1971. The number of "cures" is decreasing each year and the number of new cases increases. NHF urges you to avoid as many chemicals as possible. We urge you to seek out fresh, organic fruits and vegetables and then eat them raw or slightly undercooked. We urge you to send for our Cancer Book ($1.00) and then concern yourself with the content. We urge you to purchase our reprints on cancer and study them ($1.00). Send for both the book and reprints at one time and we will send them to you for a total of $1.50. We want to help you and your family and friends–please let us do so.

VITAMIN E AGAIN

Drs. Ayers, Jr. and Mihan of the University of California are skin doctors. In recent research reported in the Dayton *Journal Herald* they noted that leg cramps in some of their patients subsided when vitamin E (tocopherol) was given. This vitamin, they say, plays an essential role in body tissues by protecting cells from damage by fats carried in the blood. A deficiency causes acute, extensive degenerative change in skeletal muscles and often in heart muscles, they said. Low blood sugar patients responded dramatically because the E apparently improves storage in the muscles of glycogen – the only form of sugar that brain and muscle cells can use. They concluded that best results were obtained when the E was taken 10 to 15 minutes BEFORE each meal.

VITAMIN A AND CANCER

Many books on cancer in the NHF library indicate the efficacy of vitamin A in possible avoidance and in the treatment of cancer. It was interesting to note a new article in the paper recently regarding Bonn, Germany's Jankersche Klinik. For a number of years researchers there have been using a vitamin A emulsion in treatment of cancer. In 250 cases most of the skin cancers and malignant tumors have disappeared completely. The cancers treated included skin, breast, bronchial, digestive organs and abdominal.

SAD

Swans are laying fewer eggs, thousands in one week suffered from respiratory problems, entire cities are covered with a filthy pall, cedar and pine trees are dying. Sound familiar? This is the situation described recently by the *Christian Science Monitor* in an article on Japan. The outraged *public* has finally caused the government officials to act and stiffer laws are being quickly drawn up and "pollution patrols" are checking automobile exhaust emissions and other sources of filth. Once again it is clear that pollution is a problem that the *people* will have to deal with. What are you doing at home and in your community? What have you written your legislator – or have you written yet? Time is getting short.

POLLUTERS ARE KILLING

AP reported from New York recently that Prof. Grant of the State University of New York just completed a study. It proved that sludge and mud waters from many municipalities are extremely dangerous. Many harbors dredge yearly and deposit the wastes in offshore waters. Usually this is the ocean. The result is that the chlorinated hydrocarbons, carbon, sewage, phosphates and nitrates are "killing" the ocean by robbing it of oxygen. The Army Corps of Engineers has been asked to carefully re-evaluate their waste disposal program.

New Life Members

Dell and Dee Remme
Ella Hacmac
Dr. Robert Statler
Mrs. Helen Kemble
Mary and Lee Breatchel
Miss Effie A. Markle
R. A. Platteborze, D.C.
Dr. James W. Parker
Dr. Grace S. Parker
Abe Kofman
Ray M. Stover, D.C.
Mrs. H. M. Wright
Milton K. Tomkins
Mr. and Mrs. Clarence H. Suedkamp
Mr. and Mrs. Fred Welland
Tom Tate
Mr. and Mrs. Tom Gallo
Jerry Dean Hine
Alfred and Ella Pinter
Jerrold E. Kemp

Received mid - November to mid-December

NOTES FROM THE NEWS

The Washington Post

Mercury-Treated Toothbrushes Cited by FTC as Possible Hazard

The Federal Trade Commission said that Dr. West's "Germ Fighter" toothbrushes do not contain chemicals that fight mouth bacteria and that the mercury chemical on the toothbrush "may constitute a danger to the consumer by adding to the body's burden of mercury." The manufacturers of the toothbrush, the Chemway Corp., denied the FTC charges but said that the company had stopped selling the "Germ Fighter" toothbrushes several months ago. According to the FTC proposed complaint, Chemway advertised that its brushes are treated with a compound "that inhibits the growth of (mouth) germs at least four months."

*

Tulare Advance-Register

Problems with Parathion

After the federal ban on DDT, farmers turned to the pesticide, parathion, but restricted Agriculture Department files show that parathion has produced an alarming toll of dead farm workers, livestock and birds. Unlike DDT, which slowly builds up a lethal residue, parathion can kill quickly or cause serious sickness. By merely touching crops on which the poison has been recently used, a person can get ill. Dying from parathion is particularly agonizing. The patient is first nauseated, then he trembles violently and finally dies in paralysis. Only a speedy shot of the antidote atropine can block the violent effect.

*

San Francisco Chronicle

The Salt in Baby Food

The National Academy of Sciences recommended recently that manufacturers cut substantially the amount of salt added to baby food. Witnesses at Senate hearings have attacked the addition of salt to baby food as a useless procedure adopted only to satisfy the palates of mothers. The undeveloped taste buds of infants are relatively insensitive to salt. Earlier this year, after manufacturers had voluntarily stopped using monosodium glutamate in baby foods, the Academy declared the flavor enhancer should not be added because it was of no apparent benefit to infants. A university researcher had showed monosodium glutamate caused brain damage in infant rats. Dr. Lewis K. Dahl of the Brookhaven National Laboratory has reported that experiments in rats suggest salt in baby food could contribute to high blood pressure in later life.

Rodale's Health Bulletin

People Repellant is Deadly to Mosquitoes

Fact to file for next summer: Mosquitoes would sooner die than put up with garlic! Word comes from the University of California at Riverside, where scientists tested a crude extract of garlic on five species of mosquitoes. In every case, the mortality rate was 100 per cent. The how and why of this lethal reaction is now under study by biologist Eldon L. Reeves and colleagues. Garlic is becoming so popular in the U.S.—in dog food as well as people food—that production has been climbing at a remarkable rate. Within five years production rose from 39 million pounds to 84 million pounds.

*

Chicago Daily News

House Calls Halted by Physicians

The last vestige of an ancient institution—the doctor's house call—disappeared from Chicago on an organized basis January 1. The doctors' emergency service of the Chicago Medical Society voted unanimously to discontinue the calls because of the inability to recruit enough doctors willing to make the house calls. At one time the emergency panel consisted of 290 doctors. Now there are less than 40 among the 6,000 members of the Chicago Medical Society. Suspension of the home service is expected to place an added burden on hospital emergency rooms.

Arizona Republic

Researchers Report Chemical Find That Halts Cancer, Restores Cells

Princeton University announced recently that biochemists have used a chemical to stop cancerous behavior in cells taken from animals and restored these cells to normal. "The chemical, the scientists have found, repairs the surface damage found on cancerous cells, thereby causing them to return to normal growth behavior," the University said. The discovery was made in laboratory experiments using a plant protein call Con A or trypsinized Concanavalin A. "What is most inteersting is that, for the first time, we have found that we can stop the wild multiplication of cells without completely killing them and, although we have not tested the process for an eternity, we have found that a single dose of Con A prevents cancerous behavior for as long as the cell remains alive in vitro for six days. Among advantages of Con A are availability and stability. It comes from the jack bean, a common plant in North America.

*

Houston Chronicle

That Little Piggy is Better Fed Than You Are

Would it shake you up a bit to know that pigs on the farm often get more nutritional groceries than those consumed by you and your family? Think about it the next time that you reach for a loaf of white bread. Bleached flour's short-

comings have been pointed out to us by scientists for years, but a recent report by Dr. Henry Schroeder, Director of Trace Elements Laboratory at Dartmouth Medical School, provided data that should send white-bread manufacturers right up the walls. When white flour is milled, out goes most of the iron, calcium, potassium, magnesium, phosphorous and Vitamnis A, B2, B3, B6 and E. And where do all these goodies go? Aha, you guessed it. Right into the animal feed for the little piggies! White bread is preferred by food-industry executives because it keeps on the shelf longer than the more nutritious whole-wheat bread and insects avoid it because it doesn't have enough food value to keep them alive.

URGENT

WHEN YOU HEAR PRO-FLUORIDATION SPEAKERS OR COMMENTATORS ON RADIO OR TV: Note the station, the program, date and time, and the name of the speaker or commentator. Immediately convey this information to one of your strong, regional anti-fluoridation organizations or to Dr. Dr. Robert H. H. Mick, 915 Stone Road, Laurel Springs, New Jersey. Do this by phone or air mail-special delivery. Equal time may then be requested of the station to refute the proponents statements but this request must be made within seven days.

Book Reviews

THE CHEMICAL FEAST by James S. Turner (Grossman, 125A, E. 19 St., New York, N.Y., 10003, paperback, 237 pages, index, 95c).

When Ralph Nader's student study group began investigations of the Food and Drug Administration in 1968 and 1969, they had faith in the overall quality of the American food supply. True, they had some scepticism, inspired primarily by earlier revelations that meat and poultry quality was low, and inspection of them inadequate. The group also realized that the FDA—as other regulatory agencies—was probably afflicted with bureaucratic density, inefficiency, and self-justification. However, by the end of the FDA investigation, the study group admitted that none of them expected to find "the shocking disarray and appalling failure of responsibility that their investigations revealed almost daily. As the number of altered documents, misrepresented facts, and suppressed studies began to mount, the students' initial scepticism changed to a deep doubt about all the agency's activities and finally ended in the conviction that most agency efforts were a failure. The fact that most of the distortion and failure related directly to the safety or quality of food served to heighten their concern."

THE CHEMICAL FEAST, Nader's study group report on the FDA, is a carefully researched, documented study that becomes a scathing indictment of the agency. The report charges that any regulatory decision made by the FDA is not based on scientific merit, nor for the public interest, nor even a concerted effort to make the agency look good. "The motivation is the desire to insure that whatever is or is not done will not make the FDA look bad."

As a representative case of the ineptness of the agency, and its failure to protect the public, the cyclamate affair is discussed in detail. As far back as 1950, the FDA chose to overlook or ignore warning signals and scientific data, from both inside and outside the agency, regarding the nature of cyclamates. When action was finally taken, the early data were not even mentioned. The American public was misled and confused. The FDA did not bother to explain that the law requires that a food additive must be established as safe before it can be used. The manufacturers of cyclamates had failed to meet this responsibility, and the FDA failed to take action.

When curbs were instituted, the then Secretary of HEW Finch chose to dismiss all but one narrow study that suggested a connection between rat cancer and cyclamates. Instead of clearly asserting authority, Finch backed into an apologetic enforcement of the Delaney Clause. By doing so, he chose to minimize the basic concept of the food additive law that only items proven safe can be allowed in the food supply. There was no need to rely on the Delaney Clause in moving against the cyclamates. By doing so, it put the action on the slenderest available legal basis. As a result, the decision has been easily eroded by special interests. It fails to serve as a strong precedent against future industry challenges and interpretations.

The study group points out that the dangers of the cyclamates and how they were obscured both by the FDA and Finch, should serve as a waring to the public: It is possible for the FDA to call a potentially hazardous substance safe. The FDA has been less than diligent in applying the food protection laws. It has given uncritical reliance to the pronouncements of those who agree with the agency, and has ignored scientific evidence that runs counter to its policy. The FDA's bungling of the cyclamates serves as a reminder of how the agency fails to provide protection of the food supply (as well as drugs and cosmetics) which the American consumer expects (and often thinks he is getting).

THE CHEMICAL FEAST, coupled with THE DICTOCRATS (see review, *NHF Bulletin*, Sept. 1970) reveal the shocking truth

(Continued next page)

about the FDA. Both books deserve widespread distribution, and should be read by all thinking Americans. Armed with the facts, concerned consumers can take appropriate actions to make certain that the food supply is safe, and that the agency responsible for this task enforces the laws vigorously.

—Beatrice Trum Hunter

NOTE: NHF does not ordinarily sell the books reviewed in its columns but due to the importance of the contents of THE CHEMICAL FEAST, it has arranged to make the book available through the Monrovia headquarters office for those who do not find the book at their local health food store or book dealer. California residents, please include 5% for state sales tax.

MARCH OF TRUTH ON CANCER (Seventh Edition) by Arlin J. Brown, published by Arlin J. Brown Information Center, P. O. Box 251, Fort Belvoir, Virginia 22060; 144 pages, paper bound, $2.50).

This book is primarily a directory describing some 80 different remedies or therapeutic approaches for the treatment (and in some cases, the prevention) of cancer. Mostly, these are the unorthodox approaches meaning, of course, that the methods do not "enjoy" acceptance by the American Medical Association or, in those in which products are involved, the approval of the FDA. Not only are these cancer treatment methods excellently summarized but also the names of some of the doctors who are treating cancer by these methods are given.

With the obvious failure of the orthodox methods to reverse the tide of the ever-increasing incidence of cancer, it is no surprise that there has been a growing demand for this book and that it is now in its seventh edition. It is a treasurehouse of information for those seeking facts concerning nontoxic cancer treatment methods.

In addition to the directory of cancer treatment methods, some special diagnostic methods are described and then there is a comprehensive listing of books on cancer, cancer organizations, good sources of informative literature on cancer, and important reprints concerning the suppression of cancer treatments. Several pages are devoted to general advice for cancer patients. A few diseases other than cancer come in for mention in a short section which the reader will find both interesting and revealing.

The author is to be congratulated for this remarkable collection of valuable information. We know of no other similar, single source of such information. His efforts apparently have been inspired by his sincere devotion to helping those stricken with cancer.

All things come to him who waits—
And her who carries charge-a-plates.

as we go to press...

● Since the phosphates contained in most detergents have been recognized as a major pollutant of our lakes and streams, some detergent manufacturers have been replacing some of the phosphates with NTA (nitrilotriacetic acid). Now, studies made at the National Institute of Environmental Health Sciences have shown that NTA is capable of producing grave birth defects in animals.

● Robert E. Lehmann, owner of the 1970 Kentucky Derby winner, Dust Commander, has filed suit in the U. S. District Court in Columbus, Ohio against the Ohio Medical Board's ban of a cancer treatment device. It is said that the device works on a series of electrical charges that are intended to stop the diseased cells from reproducing. Lehmann says he has suffered from leukemia for the past three years and after receiving treatment with the device for two months, his blood counts are near normal levels.

● During 1969, hospital costs, on the average, increased 12%. At the beginning of 1970, the American Hospital Association predicted another 10.8% increase during the year. However, hospital charges went up 10.2% in the first nine months, and the third quarter saw a further 3.8% rise. Still higher costs are certain to come in 1971.

● Some doctors routinely pay laboratories for the lab work done on his patients and then charge the patient a higher price than charged by the laboratory. Some states have passed laws to end this practice. New York now bars doctors from billing patients for work done by outside laboratories. California and Arizona also have passed laws to control the practice. In these states, the doctor may still bill the patient but his statement must show exactly what the laboratory has charged.

NHF ATTACKS FDA'S FIRST ORDER . . .

(Continued from page 6)

that Dr. Taller's program had the sanction of one of FDA's own nutrition experts. (Tr. 24713-7); see also *NHF Bulletin*, Behind The FDA Facade, December, 1969).

Dr. Harrison was the only witness which the FDA is now citing to support its proposed prohibition on allowing the buyer to know that a vitamin or mineral is from natural sources, an issue which was raised continually throughout the two years of the hearing, and yet the Examiner blocked legitimate cross examination on the grounds that the buyer has recourse to a library! Examiner Harris at this juncture clearly revealed his fundamental prejudice and bias in favor of the FDA position.

Similarly, on another occasion, the Examiner, on his own initiative, refused to let an FDA medical witness under cross examination answer whether he had any objection to a person obtaining his vitamins from natural sources (Tr. 7036, Hodges).

The Examiner also demonstrated a wavering between his prejudice and his conscientious knowledge of fair cross examination, when in answer to a consumer representative's, Mrs. Meeter's, protest that the public should not have to go to a public library, he told her: *"You may cross examine on the subject when we get to you."* (Tr. 23280).

Examiner Harris thus blocked a highly capable and experienced lawyer, Mr. Ullman, on his cross examination of Dr. Harrison, but agreed to let an inexperienced layman cross examine the witness later on precisely the same subject. An examination of the record will show that Examiner Harris has pursued this same prejudicial tactic many times throughout the hearing.

Later cross examination of Dr. Harrison by Mr. Ullman brought out that prior to the time the FDA counsel broached the subject in preparation of his written direct testimony, Dr. Harrison had never expressed an opinion to anyone that it was reasonable to ban information about source on labelling (Tr. 23282-3).

This raises the question of whether Dr. Harrison, on his own initiative, could have ever considered it reasonable and necessary to ban information about source, if apparently the FDA had not pressed him to adopt its view. As we shall describe shortly, under our cross examination, Dr. Harrison eventually contradicted his testimony (Tr. 23277-8) upon which the FDA most depends.

The last citation by which the FDA attempts to support Finding of Fact No. 6 is the last question and answer, No. 37, of Dr. Harrison's written direct testimony, as follows:

Q. Is it reasonable to prohibit manufacturers of dietary supplements of vitamins and/or minerals from designating on the label the specific sources of the vitamins and/or minerals contained therein?

A. Since this information is of no relevance to the value of a dietary supplement and since the designation of source tends to confuse rather than inform, I think this would be a reasonable approach to take.

This is the strong and categorical opinion of Dr. Harrison repeated early in his cross examination as we have described. The witness, however, was not qualified by the Examiner to express an opinion on what might confuse consumers, nor would Examiner Harris permit the witness to be asked the question, *"What kind of study or test would you require, as a scientist, to arrive at the conclusion that the consumer would be confused, by a designation of the sources of a dietary supplement of vitamins and minerals?"* (Tr. 23279).

Thus, the answer as to confusion is not material, and opponents were barred from probing what was the scientific basis of it.

When faced with specific examples of cod liver oil and yeast under cross examination by NHF, Dr. Harrison contradicted his original sweeping statement that information as to source on the label was not germane or necessary, and would confuse the consumer. He testified that the vitamin content of cod liver oil should be on the label, and the consumer should know the source of this food supplement. (Tr. 23361, 23396).

It is necessary to explain that the stayed regulations, with their emphasis on barring information as to source, especially natural source, are set up so that they would allow either (1) the revelation of the source of the oil implicit in the use of the name, *cod liver* oil, or (2) the revelation of the amount of vitamins in it. To give both of these items of informatoin would be forbidden. Under the stayed regulations, they would be mutually exclusive. This peculiar effect of the stayed regulations is achieved by the following provisions and FDA's interpretation of them.

Sec. 125.1(a)(3) defines a food for special dietary use as one supplying a vitamin, mineral, or other dietary property to supplement a diet. But what distinguishes a natural food supplement from an ordinary food under the stayed regulations?

FDA official John Boehne answered that question when he testified that if the *quantitative* content of a vitamin or mineral is stated on the label of *any* food, it automatically becomes a food supplement which comes under the provisions of the stayed regulations, even if that food is a common article such as an orange. (Tr. 4020).

This FDA opinion is related to Sec. 80.1(b) of the stayed regulations which states that a given vita-

(Continued next page)

min or mineral in a food supplement shall be present in a certain range of concentration in that food, which is the Recommended Daily Allowance (RDA).

Once the food is categorized as a food supplement, FDA officials have stated that it becomes subject to the stringent provisions which forbid naming the source of any food supplement. (Tr. 2957, 3830).

Thus, if the vitamin or mineral content of an orange is stated in labelling or promotion, it would be forbidden to state that this "food supplement" is an orange, because that would reveal the source of the vitamins and minerals. (Tr. 4020, Boehne).

The provisions of the stayed regulations which specifically act to prohibit naming of the source are as follows: The "special information" or so-called "crepe label" provision of Sec. 80.1(f) which states that *"Vitamins and minerals are supplied in abundant amounts by commonly available foods,"* and that *"Any statement in the label or labelling inconsistent with this statement shall be misleading and cause the product to be deemed misbranded . . ."*

FDA officials have made it abundantly clear that labelling a food supplement as natural would be considered a misleading attempt to claim superiority over "commonly available foods" which in the FDA's view already contain "abundant amounts" of vitamins and minerals.

In addition, Sec. 80(1)(g) specifies that *"No other ingredients shall be identified by name except as specifically prescribed by paragraphs (i) and (j) of this section."* The latter refer to preservatives, coloring, flavoring, etc.

Thus, it would be forbidden to identify the product as natural. (Tr. 2477-8, FDA lawyer Anderson).

Finally, Sec. 125.2 contains the phrase that *"The label of the food shall not bear any statement concerning the dietary properties of the food if such properties are of no significant value or need in human nutrition . . ."*

This provision would rule out any mention of natural source of the product, if the FDA were able, as it unsuccessfully attempted with Dr. Harrison, to obtain testimony that natural source was of no value or need to the consumer.

Lest it be thought that there was something untypical about the cod liver oil example, the FDA Hearing Examiner made it perfectly clear that the cod liver oil example was typical:

> *"Dr. Robinson: I want to be sure I understand just what the bar is you feel it advisable to lay down here. Are you barring me on answer 37 and answer 36 from going into the question of particular named dietary supplements as examples of what the witness was talking about in those two questions?*

> *Examiner Harris: I do not understand your question. But I will tell you why I have ruled against you. First, it makes no difference whether the product is cod liver oil or something else. The Doctor's statement as to whether he considers it reasonable that the source of the vitamin in a supplement not be given on the label, that applies to all, including cod liver oil. In addition to which, the matter was rather exhaustively covered by Mr. Ullman yesterday.*
>
> *Dr. Robinson: I wanted to probe the basis for his opinion in terms of specific examples and the fact that cod liver oil was not discussed yesterday, and that fact does not alter your ruling?*
>
> *Examiner Harris: No, Dr. Robinson.*
>
> *Dr. Robinson: May I make an offer of proof?*
>
> *Examiner Harris: No, Dr. Robinson.* (Tr. 23364).

Dr. Harrison also testified that the consumer should be allowed to know both the vitamin content and their source, in the case of yeast. (Tr. 23354).

It is quite evident that Dr. Harrison never understood the real meaning and impact of the stayed regulation regarding banning of source, at the time when he and the FDA prepared his written direct examination.

We wish to call attention to the fact that Dr. Harrison stated that there were about half a dozen forms of viamin D, but that *only two* of these D-2 and D-3, have been tested in humans and are of nutritional importance. (Tr. 23317). D-3 is produced by man in his own skin from sunlight, while D-2 is made synthetically by irradiation of vegetable ergosterol, and is the major source of vitamin D used in food supplementation. (Tr. 23320).

However, when the questioning narrowed down to a *natural* product, cod liver oil, containing vitamin D, Dr. Harrison admitted that it may contain *three* active vitamin D substances. (Tr. 23321).

In view of the extraordinary public health measure of almost routinely adding vitamin D to milk, showing the crucial need of vitamin D by the population, it would seem not in the public interest to conceal from the public that a famous and natural source of vitamin D, cod liver oil, has the actual, or at least, potential advantage of containing three varieties of vitamin D. Whereas, only one of these, synthetic vitamin D-2, would be used in food supplements under the stayed regulations.

Dr. Lowe, FDA's other pediatric witness, stated unequivocally that the source of *all* ingredients in infant food should be listed on the label, because of the extra sensitivity of infant digestive systems. (Tr. 12578). He made no exception for vitamins or minerals fed to infants, whether in food or separate-

(Continued next page)

ly. He extended his view into a general principle applicable to persons of any age, when he stated a growing concern over undesirable allergic reactions affecting adults as well as infants, which could be avoided if the source of the ingredients is known. (Tr. 12579).

FDA PROPOSAL IS INTERNALLY CONTRADICTORY

Certain major proposed Findings of Fact and portions of the tentative Order are contradictory of each other, with respect to the importance and requirements for naming the source of "any ingredient" [(b) of tentative Order] in the labelling of foods for special dietary use for infants.

Finding of Fact, No. 5, emphasizes that the risk of allergic hypersensitivity in infants is so important that a label should show *"what is in a prepared food for infants,"* and should *"identify all ingredients."*

Finding of Fact, No. 7, reiterates the importance of *"identifying on the label by their common or usual names all ingredients, including spices, flavorings, and colorings . . . because of their potential as offending substances in the diet of infants."*

Note that even spices, flavorings, and colorings are included, although their actual physical concentration may be very slight, presumably and hopefully less than the concentration of some of the vitamins which also (Finding of Fact, No. 17) are added to the food.

Finding of Fact, No. 8, again reiterates that *"the specific plant or animal source of each ingredient"* be identified on the label.

In view of the foregoing strong findings that it is very important to know exactly the nature and source of every ingredient in infant food, any exception to these sweeping statements, as a matter of simple logic, seems strange and should require strong supporting evidence.

Finding of Fact, No. 6, (in that part which is actually a Conclusion of Law) unsuccessfully attempts to exempt, *"the specific ingredients that are the sources of the vitamin or mineral nutrients supplied by such food,"* which exemption would then constitute a specific disclaimer to the unequivocal statements in Findings of Fact, Nos. 5, 7, and 8.

There is no evidence, and the FDA has cited none, showing that only vitamin and mineral nutrients deserve such an extraordinary exception. There is no evidence that these particular substances cannot or do not precipitate allergic symptoms in either infants or adults.

On the contrary, it is well known that even synthetic vitamin B-1 can do this, as well as vitamin E derived from wheat. (Tr. 3888, 23140). Dr. Kailin, whose qualifications as an expert allergist were not challenged by the FDA, testified in detail that allergy in some persons is caused by vitamins A, D, C, and E from certain sources. (WD-23-Kailin, pp. 5, 9).

Secondly, we have shown that in attempting to justify this exemption, the FDA relied exclusively on the broken reed of Dr. Harrison's testimony. Under cross examination, Dr. Harrison's strong, unequivocal, and forthright statement on this issue, made in his written direct, which he had never expressed to anyone prior to this time, collapsed. When faced with specific examples, he changed his testimony, and considered it reasonable for the label to reveal the source of the vitamins in a food supplement.

Turning now to the tentative Order, we find that part (a) requires that the common or usual name of each ingredient shall appear on the label, except in the case of *"a dietary supplement of vitamins and/or minerals alone."*

Since FDA's Finding of Fact, No. 17, and part (c)(3) of the tentative Order anticipate that vitamins or minerals shall be added to the food,* and thus these would not constitute a dietary supplement of vitamins and/or minerals *alone*, part (a) of the tentative Order sets up a double standard for identifying the common or usual name of ingredients which are vitamins or minerals. (Merely requiring the common name is obviously the first and sometimes the complete step in revealing source; for example, cod liver oil).

That is, the common name of a vitamin or mineral added to an infant food must be given, but not so if the vitamin or mineral is part of an exclusively vitamin or mineral supplement, such as a bottle which contains nothing but a vitamin and/or mineral supplement.

We have cited the record to show that it is not reasonable to make a special exception for vitamins and minerals from the general precaution of identifying all ingredients in an infant food.

Furthermore, part (b) of the tentative Order unconditionally states that the source of *any* ingredient, which consists in part of plant or animal matter, must be stated on the label. No exclusion of vitamins or minerals is made. Therefore, part (b) contradicts part (a) of the tentative Order.

An additional reason why part (b) requiring that the source of *all* ingredients be revealed should apply to vitamins and minerals is that at least two vitamins are regularly obtained from plant or animal sources. Vitamin B-12 cannot be made synthetically, and vitamin E is regularly obtained from wheat (Tr. 3888, Boehne), which is one of the prominent causes of allergy in infants (Tr. 23354, Harrison).

It must be kept in mind that just as in the case of ambiguities in statutory law which are settled by

(Continued next page)

*Finding of Fact, No 17: "If a vitamin or other than the aforementioned is *added to the food* . . ."

Tentative Order, part (c)(3): ". . . other *added* vitamin(s) and mineral(s) . . ." (Emphasis supplied).

reference to legislative reports, FDA prosecutions will interpret any ambiguities on the subject of source in the tentative Orders by reference to its Finding of Fact, No. 6.

Note particularly that in FDA's Finding of Fact, No. 6, the criterion of allergic hazard so heavily emphasized in its Findings of Fact, Nos. 2, 5, 7, and 8 is totally ignored. Instead, the term "infant nutrition," very vague in this context, is used. In effect, this term is a red herring drawn across the trail, introducing the highly controversial issue of the relative nutritive *efficacy* of natural vs. synthetic vitamins.

FDA has sandwiched this different issue of efficacy in the midst of the allergic hazard issue, in order to make illogical exception to its own rule of identifying all substances for allergic reasons.

On its face, this FDA maneuver is illogical. By analysis of the evidence cited for it by the FDA, it has no merit.

In summary, the tentative Order would be reasonable if dietary supplements of vitamins and/or minerals were included in the foods of part (a). Then, there would be full disclosure of the common name and source of *all* ingredients in infant food, in conformity with an across-the-board policy of informing the infant's parents and doctor of the presence of substances to which the infant might be allergic. (Tr. 12578, 12560, 12622, Dr. Lowe).

The concluding portion of this formal exception to the FDA Order will appear in the March issue of the NHF BULLETIN. In the forthcoming portion, Dr. Robinson affirmatively cites many references drawn from testimony given during the food supplement hearing, to establish the claim that it does make a difference in infant nutrition whether vitamins or minerals are derived from natural or synthetic sources — a claim contrary to the FDA stand.

MEMORIAL CONTRIBUTIONS

The idea of memorial contributions, of course, is not new. It would seem that there could be no finer way to express remembrance and give honor to a deceased friend or loved one than to make a memorial contribution, in the name of the deceased, to a church, charity, foundation, or other nonprofit organization. The National Health Federation has received a number of memorial contributions and we trust that we shall always remain a worthy recipient of such contributions.

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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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