National Health Federation
BULLETIN

OCTOBER, 1973

35c

Dr. Linus Pauling Condemns FDA's Dietary Supplement Regulations — May Sue FDA

NHF FILES COURT ACTION

in response to

Final Dietary Supplement Orders Issued By FDA

Within days after the issuance of the final Dietary Supplement Orders by FDA, NHF petitioned a United States Court of Appeals to make a judicial review of the finalized Orders. NHF is prepared to show that FDA has exceeded its legal authority in promulgating the far-reaching regulations; that FDA's actions are unwarranted, capricious, and contrary to the best interests and welfare of the people; that the regulations are not based on the best evidence in fact inasmuch as FDA has largely ignored the competent testimony of experts who gave facts and opinions contrary to FDA's stand; and that the regulations infringe upon the basic freedoms of the people.

Dedicated to the Protection of Health Freedoms

THE
NATIONAL HEALTH FEDERATION BULLETIN

Protection of Health Freedoms — *Published Monthly*

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Betrayal From the Top

An inestimable number of members of the American Association of Retired Persons were shocked and disappointed early in August when they read in the *AARP News Bulletin* that their association "strongly endorsed" FDA's proposals for the regulation of vitamin and mineral supplements. We know this by the flood of letters sent to NHF headquarters by a significant percentage of the many thousands of NHF members who are members also of the AARP. The general tone of these letters from AARP members has been, "we've been betrayed."

It is unfortunate that the top echelon leaders of a very worthy organization chose to speak for the millions of its members on a highly controversial and personal matter without making the slightest effort to determine the feelings of its members on the matter. The truth of the matter is, it is only the top leaders of NRTA-AARP that "strongly endorse" the FDA regulations—in no way have the members endorsed FDA's actions. In other words, with the attitude of "Big Brother knows best," typical of the FDA itself, the officials of NRTA-AARP have attempted to tell its members what they should think and what they should have.

We have the highest respect for the NRTA-AARP, its purposes, programs and excellent services it makes available to its senior citizen members. In this instance, however, we suggest that instead of endeavoring to speak for the entire membership, without consultation with these members, the officials of NRTA-AARP might better have withheld an endorsement and instead, presented both sides of the controversy in their *News Bulletin* thus giving the membership credit for having intelligence sufficient to make their own discernments in the matter and to act accordingly.

The *AARP News Bulletin* article states that the endorsement was given "after a thorough investigation by representatives of the NRTA-AARP Pharmacy Service." There could be some question as to the objectivity of the "investigation." The pharmacists' as well as the pharmaceutical manufacturers' organizations have also endorsed the proposed regulations—but this is to be expected since the implementation of the new regulations will shift a major portion of the food supplement sales from the health food stores to the pharmacies.

The NRTA-AARP Pharmacy Service should have a pretty good idea how many of their members take vitamins. The service carries a very complete line of vitamin and mineral products including well-known brand

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names as well as products under their own label and at least 26 of the products under their own label provide potencies in excess permitted under the new regulations as dietary supplements. We might safely assume that these products were placed in the line because of a demand for them. It is unlikely that the members would continue to purchase these higher potency products if they did not provide benefits to their health and well-being. Certainly these members would have no desire to endorse the proposed FDA regulations. *If* it is true that these higher potency vitamin products are both dangerous and a waste of money, certainly the Pharmacy Service should have been aware of this several years ago and, in the interest of their members, should have removed these products from their line inasmuch as the national manager of the Pharmacy Service alleges "... we are not in business to make a profit; rather we seek to provide a *useful* and *necessary health service* for our member-consumer." (italics ours)

AARP Article Parrots FDA Propaganda

Over half of the *AARP News Bulletin* article is an almost word-for-word quote from a release put out by the Food and Drug Administration seeking to explain the necessity for the proposed regulations. This makes one a bit suspicious of the nature of the "thorough investigation" which was supposedly conducted by representatives of the NRTA-AARP Pharmacy Service.

A casual reading of the FDA explanatory statement gives the impression of containing a certain logic but we take exception to the FDA explanations because of what we (and many scientists) believe to be a faulty basic premise and because they are misleading in that the whole story is not revealed.

The FDA has been emphatic in saying that the regulations will not take away the vitamins now available with the exception that vitamins A and/or D in potencies higher than 10,000 and 400 International Units respectively, which will be available only on prescription. Vitamin and mineral products providing between 50% and 150% of the Recommended Daily Allowance (RDA) will be considered as dietary supplements. Products providing potencies greater than 150% of the RDA will be considered drugs and available over the counter the same as laxatives and aspirin. This sounds simple enough until one learns the full implications of the classification of these nutrients as "drugs."

As "drugs" the higher potency vitamin and mineral products will be subject to a different and more complex set of regulations bearing on safety and efficacy. Among other rules, the label must state the indications for use, i.e., the label must state the symptoms or diseases for which the product is effective. Effectiveness (and safey) must be established through very elaborate, time-consuming and costly studies. They may not present a problem in the case of those vitamins for which specific deficiency diseases have been identified such as beri beri (vitamin B1), pellagra (B3), or scurvy (vitamin C). However, specific deficiency diseases apparently do not exist in connection with some of the other vitamins even though essential. In most cases, these vitamins seem to work in conjunction with other vitamins or nutrients to perform their functions, for example, in making up the co-enzymes so necessary in our metabolic functions. Therefore, how is a higher potency vitamin E product, or a vitamin B6 product, for example, to be labeled to satisfy the regulations pertaining to drugs? Chances are, there will be no higher potency products of this nature available even as drugs.

FDA Seems Incapable Of Understanding Nature Of Nutrients

Herein lies the basic problem. The FDA seems so disease-oriented and so drug-oriented they seem incapable of understanding the nature of nutritional substances. They expect vitamins and minerals to behave like drugs and they insist that efficacy studies to determine their value to be conducted in the same manner as required for medicinals. Roger J. Williams, noted nutritional biochemist, states the case well in his latest book, *Nutrition Against Disease*, where he writes, "Testing a drug is fundamentally quite different from testing a nutrient. If one wishes to know whether quinine is effective as a treatment for malaria, it is tested *by itself*, and one find the answer. If one wishes to test the effectiveness of digitalis for certain heart conditions, one tests it *by itself* and gets a positive answer. Drugs, in general are *by themselves* effective agents.

"Testing a nutrient for its effects is quite different from testing a drug. When a nutrient is tested by itself, it is like a professional football coach trying out a quarterback without providing him a football team to work with. Nutrients are effective because they are constructive; they enter into the makeup of enzyme systems and can function in this constructive way only when all other building blocks are available. If only one link is conspicuously missing, then supplying this one link by itself will be effective. This is exceptional, however. When a single nutrient is tested, it cannot be effective unless it happens to strengthen the weakest link. For it to work, all other members of the team must be playing ball."

The Fundamental Difference Between Nutrients and Drugs

Nutrients are not, and never will be, drugs per se regardless of their level of intake or the intent of their use because they are essential and normal in the body's internal environment, possibly playing a multitude of subtle, obscure, and perhaps small but essential roles in the biochemical processes of the body. On the other hand, with the exception of those drugs consisting of hormones, enzymes, etc. normally found in the body and ocassionally used for substitutive therapy, drugs are substances not normal to the body and, under usual conditions, are not required in the

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body's physiological and biochemical processes. Therefore, we contend that nutritional substances must be considered apart from drugs and subject to a separate and different set of regulations.

FDA Regulations Ignore Individualized Needs

Furthermore, the restrictive FDA regulations ignore the wide differences in the need for these nutrients which exist among people. The Recommended Daily Allowance levels are based on levels needed by a mythical "average" person. Many authorities recognized in the field of nutrition have long emphasized the biochemical individuality as it relates to the needs for vitamins and minerals—not because these individuals suffer from any discernable diseases but rather only because of the functioning of their individualized metabolic machinery.

Some authorities have stated that the needs for specific nutrients in one individual may be a hundred-fold greater than in another person. Dr. Roger J. Williams is the author of two books, *Biochemical Individuality* and *You Are Extraordinary* which deal with these individual variations.

Are there really any compelling reasons for imposing the severe restrictions on potencies and availability of vitamin-mineral products? How many persons have been harmed thus far? If no sound reasons exist, is not this FDA action a clear case of an unwarranted exercise of dictatorial power and an invasion of fundamental freedoms which have no place in the American way of life?

FDA Finalizes Two Supplement Orders

NHF FILES COURT ACTION

The Food and Drug Administration, on August 2, 1973, issued two *final* Orders affecting the labeling and sale of vitamins, minerals and other concentrated food substances. The August 2 action makes final a *proposed* Order issued on December 14, 1972 affecting only vitamins A and D, and a *tentative* final Order issued on January 19, 1973 affecting all vitamin and mineral products.

The December 14, 1972 proposed Order, now made final, will classify as *prescription drugs* all products providing more than 10,000 International Units of vitamin A and/or more than 400 I.U. of vitamin D in the daily intake as recommended on the label. This Order becomes effective 60 days after issuance.

The other Order, now finalized, consists of many restrictive and far-reaching regulations. It replaces the present *Minimum Daily Requirement* with a new definition—*Recommended Daily Allowances* (RDAs)—which FDA claims is the level of intake of the various vitamins and minerals necessary to maintain good health. Products to be labeled as dietary supplements must provide at least 50% but not more than 150% of the RDAs of the vitamins and minerals contained in the products, thus potencies in dietary supplements are to be severely limited. Products furnishing more than 150% of the RDA must be labeled as *drugs*. In addition, the Order restricts the combination of ingredients permitted in dietary supplements as well as forbidding the use of several statements (though true) in the promotion of the sale of the dietary supplements.

The Order affecting all vitamins and minerals will be implemented over a period of a year. All products for which labeling is ordered after December 31, 1973 must comply with the new regulations. This permits the continued sale of the products "on the shelf" which were manufactured and labeled prior to December 31, 1973. After December 31, 1974, all products must be in compliance with the new Order. This means that during 1974, there will be a gradual disappearance of about 80% of the supplements now marketed unless the manufacturer desires to comply with all the complex regulations relating to drugs and re-label and distribute his products as drugs.

Court Actions Filed

Within days after the issuance of the final Orders, Kirkpatrick W. Dilling, NHF's special legal counsel, filed a petition, on behalf of the National Health Federation, in the United States Second Circuit Court of Appeals asking the court to make a judicial review of the Orders. NHF believes it has sufficient sound evidence to convince the court that the FDA lacks the constitutional authority to promulgate such far-reaching regulations, that the regulations infringe upon the basic freedoms of the people, that the hearing held by FDA prior to the issuance of the Orders were conducted in an illegal manner in many instances, that the FDA failed to hold hearings at all on their proposed Order issued December 14, 1972 affecting vitamins A and D, that the regulations contained in the tentative final Order issued January 19, 1973 are *not* based on the best evidence in fact, that the FDA has largely ignored the competent testimony of the experts who gave facts and opinions contrary to FDA's stand, and that the implementation of the Orders will be contrary to the best interests and welfare of the people.

Court actions by other groups and individuals are planned or have been filed. The National Nutritional Foods Association, a trade organization composed of manufacturers, distributors and retailers of health food items, through their attorneys, Milton Bass and Robert Ullman, has initiated multiple actions in the U.S. Court of Appeals and the U.S. District Courts to set aside the FDA regulations. Dr. Linus Pauling, the famed recipient of the Nobel Prize, has indicated his inten-

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tion to start an action in federal court and, as this is being written, is conferring with his Washington attorneys with this objective in mind. In addition, we have unconfirmed reports of other planned court actions. Included in the actions filed are petitions to the court asking for a temporary stay of the compliance until the court has had an opportunity to hear the case.

Legislative Campaign Continues

In the meantime, on the legislative front, Congressional support for the Hosmer bill (HR 643) continues to gain. Passage of the Hosmer bill would amend the Food, Drug and Cosmetic Act in a manner that would nullify the FDA Orders and make it impossible for the FDA to issue similar new regulations in the future. The Hosmer bill defines a food supplement for the first time in the food and drug act. By defining a food supplement as a *food*, it indicates that it is the will of Congress that FDA shall regulate vitamins and minerals and other concentrated foods and food supplements as *foods*, not as *drugs*. The bill is short, simple and easily understood. It will prevent FDA from banning the sale of vitamins and minerals or restricting their potency for reasons other than lack of safety or existence of fraud. And, contrary to what FDA would like you to believe, the bill keeps all the consumer protection provisions of the food and drug act as they now exist.

There is a greater need now than ever before to work diligently to procure more cosponsors for H.R. 643 in the House. If your representative has not yet cosponsored the Hosmer bill, write him a letter —it need not be a long letter, just a simple request—asking him to cosponsor H.R. 643 with Representative Hosmer. If you don't know whether or not he has already cosponsored, write him and say something like this: "I urgently favor the passage of the Hosmer bill, H.R. 643. If you are not yet a cosponsor on this bill, I respectfully urge you to do so immediately. If you have already cosponsored, you have my appreciation and I now ask you to work for early hearings on the bill and to urge your colleagues to cosponsor also."

By the time this issue of the *NHF Bulletin* reaches you, a bill similar or identical to the Hosmer bill is almost certain to have been introduced in the Senate. Now is the time to write your two senators telling them that you strongly support any bill which will block FDA's attempts to restrict the sale of vitamin and mineral supplements in any combination or potency unless proved hazardous to health and that you urge him to cosponsor such a bill and to give it his fullest support.

In spite of the apparent "finality" of the latest FDA Orders, remember that the law provides that citizens adversely affected may seek relief through remedial legislation or through the exercise of various appeals to the courts. NHF, for one, will utilize every avenue open to us.

NNFA Registers Strong Points Against FDA's Regulations

In the allowed period following the issuance of the tentative final dietary supplement Order by the FDA on January 19, 1973, a number of trade organizations, consumer groups and a few individuals filed formal "Exceptions" to the proposed Order setting forth strong technical, scientific and legal points opposing the regulations contained in the Order. The National Health Federation filed a lengthy document prepared by Attorney Kirkpatrick W. Dilling. The National Nutritional Foods Association filed Exceptions consisting of 183 pages prepared by Bass and Ulman, NNFA's legal counsel.

Mr. Dave Ajay, a council member of NNFA and a member of NHF Board of Governors, prepared the following very brief synopsis of some of the key points covered in detail in the Exceptions filed by NNFA:

1. The FDA is trying to create a new definition for the word "drug" under the Food, Drug, and Cosmetic Act; in defiance of the fact that only Congress has that power, and not the FDA

2. The FDA apparently is trying to perform legislative acts, instead of staying within their own bounds.

3. The FDA proposals violate the constitutional issues involving freedom of speech and the basic freedom of the individual against the exercise of the police power of the government.

4. The FDA is literally attempting to regulate what the individual may eat, and actually how much he may eat!

4. The FDA is employing more subtle means now than in 1966.

6. The FDA proposals are proved invalid when their spokesmen say you may not have a combination of Vitamin C and Bioflavinoids; yet they say the consumer will still be able to buy one tablet of Vitamin C and a second tablet of Bioflavinoid! Doesn't make sense!

7. The FDA have made erroneous references to scientific evidence in hearings, apparently choosing to disregard scientific evidence that is not sympathetic to their stand.

8. There is no basis for the FDA creating a new term called a "U.S. Recommended Daily Allowance" (U.S. RDA). It was never mentioned even once in their previous proposals of 1962 and 1966; therefore a new and further hearing is called for if the FDA intends to consider the creation of a U.S. RDA.

9. FDA is trying to change vitamins and minerals, which are classed as nutrients, into drugs! (Congress has already defined the word "drug.")

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10. However, the FDA has not been given the power, as yet, by Congress to create a new and additional definition of the word "drug!"

11. The FDA spokesmen refer to the Food and Nutrition Board as their basis of imposing maximum and minimum potency limitations for vitamins and minerals; yet, the Food and Nutrition Board has made itself clear that the RDA's were never intended to establish fixed limitations upon the amount of nutrients a given individual should consume!

12. Witness after witness have testified at the previous hearings against the use of the RDA's, citing the fact that all individuals are different in their needs.

13. Dr. Frederick Stare's testimony was thrown back into the teeth of the FDA that the RDA's will not provide a reliable index, since they are based in groups!

14. Someone who suffered from malnutrition would be severely handicapped in being limited to potentcies not sufficiently adequate to overcome his condition.

15. Most government witnesses had to agree, under cross-examination, that there was very little possible toxicity at all with the intake of vitamin and mineral supplements!

16. The FDA has no power over advertising or promotional material; that being the province of the Federal Trade Commission (FTC).

17. The FDA's proposed six prohibitions would prevent the dissemination of even truthful scientific facts!

18. FDA's own witnesses have testified that it *is* important to know the sources of vitamins and minerals; since some individuals are allergic to different substances!

19. If the consumer is to be prohibited from using Bioflavonoids and such; then are we going to require him to spit out the Bioflavoinoid part of the orange he eats and allow him to consume the Vitamin C content, but not to exceed more than 90 mgs.?

20. Consumers should be free to choose their food or their dietary supplements.

21. Research scientists in the employ of other government departments were quoted to refute the FDA prohibitions on saying, or implying, that overcooking and storage of foods, etc., can lower the nutrient content of foods!

22. FDA scientist witnesses previously admitted under cross-examination that a difference in soil nutrients results in a difference in foods produced!

23. Scientific government reports (USDA) show that one-half of U. S. households do not eat a sufficient diet to satisfy all daily nutrient needs!

24. FDA's own witnesses have admitted that vitamin and mineral deficiencies are associated with a wide variety of disease conditions!

25. Points out the fact that Congress established the regulatory pattern which allows for the changing nature of nutritional information; for example, Vitamin E, where once the need for it was not recognized, it is now admitted.

26. NNFA and NHF were denied the right to examine favorable witnesses on the ruling of the Hearing Examiner.

27. David E. Harris, the Hearing Examiner was "hand-picked" by the FDA to do the job for this one special hearing; this being contrary to the rule that hearing examiners are to be taken in rotation.

28. Also, in view of the fact that hearing examiners are supposed to be impartial, let it be noted, for the record, that said Hearing Examiner plainly showed his bias in favor of the FDA!

Linus Pauling May Sue FDA

By JAY PATRICK

"Vitamin C is not a drug," says Dr. Linus Pauling, "but a concentrated food, just as is sugar. Yet no one could get sick and die from it as is possible with a high intake of sugar."

The Nobel Prize winner's remarks were made at a two day symposium sponsored by Stanford University's Departments of Chemistry and Chemical Engineering.

"The upcoming restrictions would be a catastrophe for the American people, as many do not have the money to go to a doctor for a prescription. In addition, on a prescription basis, vitamins will cost substantially more than they do now," the eminent scientist observed.

Pauling said he has talked to attorneys in Washington and is planning a suit against the FDA, which may be instituted within a few weeks.

"I now think Vitamin C is much more valuable than when I wrote the book (in 1970)," said Pauling. "All diseases to some extent are affected by it."

"Vitamins A and D are considered the most toxic, but they are not as dangerous as aspirin. Practically no one ever died from an overdose of vitamins." (The United States Department of Agriculture reports that some 200 persons die annually from aspirin, not counting those whose health is impaired by ingestion of the product.)

Many researchers reported at the symposium on studies that had been done in the three years since Pauling's book was first published.

Dr. John L. Coulehan, director of the Lower Greasewood Indian Health Center in Ganado, Arizona, outlined an experiment conducted at the Toyei Indian Boarding School there.

Children from six to 15-years-old were given Vitamin C while another group was given a placebo in a double-blind experiment.

Youngsters in grades one through four had 28 per cent fewer days of illness than the boys and girls taking placebos, and among fifth through eighth graders the rate was 34 per cent.

Washington Report

By CLINTON R. MILLER, NHF Legisilative Advocate

In January, 1972, the Food and Drug Administration proposed plans for a sweeping review of the safety and effectiveness of all over-the-counter (OCT) drugs (those not requiring a prescription). The FDA proposed to group all the OCT drugs now marketed into one of 26 different therapeutic categories such as antacids, laxatives, cough and cold remedies, pain killers, sleep aids, etc. and then to appoint a separate review panel composed of experts outside the FDA for each of the categories. The panels would consider evidence of safety and effectiveness submitted by the manufacturers as well as data from other sources and then decide what formulations are effective within each category and what kinds of claims should be permitted. In the proposal, FDA announced its intention to publish these conclusions, which would specify formulation, labeling and other manufacturing details for each category of drugs, as legally binding "monographs."

Although manufacturers would be given an opportunity to contest the content of a monograph and even go to court over it, the FDA announced that once the document was issued in its final form, all companies would have to comply with it. Companies whose products failed to comply with the monograph requirements generally would have to reformulate and relabel their drugs or withdraw them from the market.

The Food and Drug Administration went ahead with the implementation of their proposal and in March, 1972 assembled the first review panel for the consideration of antacid products. Since then several additional panels have been assembled for the consideration of other drug categories. As a result of the conclusions of these panels, many well-known products have had to be reformulated to correct what the review panels have called, irrational combinations of ingredients, ineffective ingredients, or unsafe levels or combinations of certain ingredients. Label claims have had to be revised on a large number of products. For example, some mouth washes claiming to kill germs were found to be quite ineffective as germ killers and thus the label had to be changed to "a refreshing mouth wash" or something similar.

A few months ago, the Food and Drug Administration announced its intention to appoint a review panel for the consideration of hematinics and vitamin and mineral products in the over-the-counter classification. Accordingly, the National Health Federation was invited to submit names of experts we believed to be qualified as panel members. These names, along with the names submitted by other organizations would then be considered by FDA where the final selection would be made. FDA's letter to NHF on this matter follows:

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
Rockville, Maryland 20852

Mr. Clinton Miller
National Health Federation
121 2nd Street, N.E.
Washington, D.C. 20002

Dear Mr. Miller:

As you are aware, the Food and Drug Administration is currently engaged in an extensive review of the safety and efficacy of over-the-counter (OTC) drug products. This review is being conducted by means of several panels, each assigned to a different therapeutic category. These review panels will be formed at regular intervals over the next three years and will be composed of consultants qualified by training and experience to review scientific data.

We are taking this opportunity to announce that within the next few months we shall be forming a review panel on the following therapeutic categories:

Vitamins – Minerals and Hematinics

To assure that the members for this panel are selected from lists of well qualified individuals, we are requesting a number of organizations to provide us with their recommendations for nominees. We wish to offer you this opportunity to submit the names of individuals you feel to be qualified to participate on this panel, together with a brief curriculum vitae.

Among the factors that we must consider in forming each panel are, of course, the proper representation of women, minority groups, geographic distribution, and panel members without conflicts of interest.

In general any nominee who is currently a paid investigator or who currently holds an investigational grant in the therapeutic category involved or any person who otherwise has a relationship with a company that creates a substantial appearance of a conflict of interest will have to be excluded from panel membership. Also, prospective panel members should not have membership in any other DHEW Advisory Committee because only in rare instances will dual membership be allowed. Persons who are not United States citizens may be employable only in certain circumstances. It is felt that the panel members should be members of the medical or allied professions.

Your early consideration of this request would be greatly appreciated.

Sincerely yours,
Gary L. Yingling, Esq., Director,
OTC Drug Products Evaluation Staff
Bureau of Drugs

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Following the receipt of the FDA letter, the NHF Executive Committee, in company with its advisors, gave careful study to the significance of the contents of the letter and possible implications of our acceptance or non-acceptance of FDA's invitation. Finally, after due deliberation, the National Health Federation declined FDA's invitation to submit names of qualified experts for consideration of appointment to the review panel. Basically, the invitation was declined because the very task assigned to the panel is inconsistent with the stand NHF has taken in connection with the recently finalized dietary supplement regulations. Because we believe our members should be informed of the stand NHF has taken, the reply sent to the Food and Drug Administration follows:

Gary L. Yingling, Esquire, Director
OTC Drug Products Evaluation Staff
Food and Drug Administration
Rockville, Maryland 20852

Dear Mr. Yingling:

Please excuse the delay in my response to your invitation to the National Health Federation to submit the names of individuals to participate on a panel to review the allowable claims for the safety and efficacy of vitamin and mineral products as over-the-counter drugs.

NHF believes that vitamins and minerals should be classified and then regulated as *foods* not *drugs*, if no drug claim is made for them. Therefore we respectfully decline your invitation. This in no way should be interpreted as a lack of willingness to cooperate with FDA in submitting names for any panel concerned with the manufacture, sale, and distribution of foods, food supplements, concentrated foods, vitamin and mineral products, and foods for nutritional or special dietary purposes. Likewise, it should not be interpreted as an unwillingness by NHF to make recommendations for panel members to review drugs for which drug claims are made.

To clarify the position NHF takes, let me state that for NHF to participate in a review of mandatory drug claims for food supplements, before they may be legally sold as drugs, is akin to asking free men to approve a review of conditions under which they may serve as slaves.

NHF has conducted a sincere and justified war for many years to prevent the American Medical Association, the refined-synthetic-artificial-fabricated food industry, the drug industry, and other related vested interests from maneuvering FDA like a puppet into classifying, then regulating safe foods, concentrated foods, and vitamin and mineral products as drugs when no drug claims are made.

Consumers and the Congresses they have elected have wisely recognized a need to keep vitamin and mineral products sold and used for nutritional purposes separated from "drugs."

The single exception where Congress has ever given FDA authority to classify foods and food supplements as drugs, and then regulate them as such, is when the manufacturer makes a *drug* claim for them. It follows, naturally, that we will not dignify, or lend in any way legitimacy to, any panel engaged in reviewing safe concentrated foods, vitamin and mineral products as drugs when drug claims have not been made or implied. NHF maintains that FDA may be trying to blur, and then erase the Congressional line of distinction between foods and drugs by its new proposed restrictive vitamin regulations and by establishing this panel. We do not recognize FDA's statutory authority for such regulations or the panel proposed for such a purpose.

It is improper and futile for scientists, no matter how honest and well qualified they may be, to recommend what labeled *drug* claims must be made for vitamin and mineral products when the Consumer doesn't want to buy his vitamin and mineral products as drugs, with such drug claims for therapeutic uses, nor does the vitamin manufacturer want or intend to make any drug claims for his product.

This cleverly engineered ploy is a reprehensible insult to the Consumer's long established position which we shall emphatically state once again:

1. Foods and food supplements are not drugs! The only, and rare, exception is when drug, as distinguished from nutritional, claims are made for them.
2. To force Consumers to buy safe food supplements, vitamin and mineral products as drugs with drug claims and compel vitamin and mineral manufacturers, under threat of fine and imprisonment in a federal penitentiary, to label vitamin and mineral products with drug claims is the rawest form of tyranny. Consumers do not want to buy vitamin and mineral products with drug claims. Manufacturers of vitamin and mineral products do not want to sell their products with these drug claims.
3. Nutritional claims are not drug claims.
4. Foods, food supplements, concentrated foods, and vitamin and mineral products do not become drugs because of their shape, form, combination, potency, or nutritional claims. Even if they are considered hazardous in excessive quantities, these products do not become drugs, although they may be held by a Court to be adulterated foods. All "safe" food is hazardous in excessive quantities. This universal fact does not make foods – drugs.
5. NHF does not endorse the manufacture or sale or distribution of any adulterated, unsafe, or misbranded food. We will support all provisions in the act to give FDA authority to protect consumers from such adulterated, deleterious, unsafe, or misbranded food products.

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6. There is no additional protection afforded consumers by classifying, and then regulating, foods as "drugs." In fact, the exact opposite is true. "Safe" drugs may be legally sold under FDA's current policies which are many times more toxic and dangerous than FDA's "safe" foods. It is well known that FDA has a double safety standard for foods and drugs with the strictest standards being set for foods.
7. The criminal and civil seizure provisions set forth in the Federal Food Drug and Cosmetic Act, as amended, have adequately protected the consumer against adulterated and misbranded foods since 1906; and against adulterated and misbranded food supplements under the 1938 Act and the FDA Food Supplement Regulations adopted November 22, 1941. The Federal and Supreme Courts have consistently upheld this authority for FDA to protect consumers against adulterated, unsafe, misbranded foods and food supplements.
8. FDA has adequate authority to protect the consumer against unsafe, adulterated vitamin and mineral products with false and misleading advertising without resorting to OTC drug review panels, as proposed by your letter of invitation to us.

NHF, therefore, respectfully but firmly, declines your invitation to recommend individuals for this review panel. We hold the entire approach to be illegal, unconstitutional, unauthorized by Congress, and against the will of the consumer – the citizen for whom these panels are supposed to be organized to protect.

NHF will gladly recommend participants to any of the other review panels which you stated "will be formed at regular intervals over the next three years," assuming these panels will be formed to review drug claims for drug products. Please notify us when you are considering the future review panels.

Sincerely,
Clinton R. Miller

With the mailing of the above letter, we assumed the whole matter was a closed issued as far as NHF was concerned. We scarcely expected a reply, or at least nothing more than a simple acknowledgement. It surprised us then when we learned that our refusal to nominate members to the OTC review panel for vitamins and minerals and our reasons for the refusal were fully reported in the top trade publication and that the whole matter was being watched with great interest by industry and consumer groups. Apparently, it is the first time that someone has had the foresight and courage to refuse participation in making up FDA's lynching party.

It appears as if we may have disappointed FDA by not submitting the names of qualified experts who might be considered for appointment

as panel members. In any event, the following letter has just been received from FDA containing what we interpret as an "ominous warning" at the close of the second paragraph:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
Rockville, Maryland 20852

Mr. Clinton R. Miller, Legislative Advocate
National Health Federation
121 Second Street, N.E.
Washington, D.C. 20002

Dear Mr. Miller:

This is in response to your letter of July 25, 1973, declining to submit names of experts to review the safety and effectiveness of OTC vitamin-mineral drugs.

We regret that you have made this decision. We wish to make certain that you are aware that the Supreme Court has recently ruled that the Food and Drug Administration has the authority to determine the new drug status of products with "administrative finality," and that a United States District Court has recently ruled that one who concludes not to participate in the OTC review does so "at its peril."

We are therefore again providing you with an opportunity to submit nominations, should you wish to do so.

Sincerely yours,
Gary L. Yingling, Esq., Director,
OTC Drug Products Evaluation Staff
Bureau of Drugs

In all this, we cannot help but be reminded of the poem *The Spider and Fly* by Mary Howitt (1799-1888):

"Will you walk into my parlor?" said the Spider to the Fly.
" 'Tis the prettiest little parlor that ever you did spy;
The way into my parlor is up a winding stair,
And I have many curious things to show when you are there."
"Oh, no, no," said the little Fly, "to ask me is in vain;
For who goes up your winding stair can ne'er come down again."

In addition to whatever scientific or other useful value the review panels may have, they serve still another useful function specifically to the FDA. Although the review panels have no final authority and play no actual part in the implementation of their conclusions and recommendations, they do carry the responsibility (and blame) for the actions taken by FDA which are based on the panels' recommendations.

(Continued next page)

If we are to assume, for the moment, that the recently finalized dietary supplement orders will be fully implemented as planned by FDA, it will then be the responsibility of the newly convened review panel to study all the vitamin and mineral supplements providing more than 150% of the Recommended Daily Allowances and thereby are classified as drugs. The panel will be called upon to determine which types of these products should be banned completely, the combinations of ingredients which should be permitted, what claims should be allowed, and at what potency levels a prescription should be required.

If the panel recommendations seem unreasonable to the manufacturers and consumers, there is certain to be loud objections voiced. The FDA can say, in effect, at that time, "This is not of our making. We are merely implementing the recommendations of the review panel composed of experts YOU recommended." We feel certain this is a deliberate, well-planned trap and is another reason why this little fly chooses not to enter the spider's parlor – the peril is greater on the inside than on the outside.

In Memoriam

BRUCE E. BUTT

It is with sadness that we announce the passing of Bruce E. Butt, of Harrisburg, Pennsylvania on July 7th and on behalf of his many friends in NHF, few of whom he ever met, we convey our heartfelt sympathy to his gracious wife.

Mr. Butt was a true American who lived in total honesty and worthiness as a family man and as a citizen. He nobly profiled his dedication to the principles of freedom and justice during a court action in which he was involved and in which these principles were on trial. It was his stand in this trial that won him the admiration, the support and high regard of thousands of NHF members throughout the land though, for the most part, he never had the opportunity to meet these people.

NHF members will recall that it was Mr. Bruce E. Butt who, as the president of a small natural health club, was arrested as a result of his having shown the film, *Nature's Answer To Cancer* (a film about Laetrile) to his fellow club members. His arrest took place in 1970 and the case languished in court for over two years when the charges against him were withdrawn. Early in the case, he was told if he would relinquish the film and plead guilty he would be subjected only to a very small fine. Being the stalwart American he was, he refused to plead guilty when he had committed no crime. His stalwart position and ultimate victory ended a series of similar arrests all over the country. He indeed made a significant contribution to the cause of health freedom.

Adverse Reactions To Medicines

All medicines have a multiplicity of effects. Hopefully, the drug you will use will fulfill the primary function for which it is taken. But some effects from drugs are unexpected or undesirable. Here's what every consumer ought to know about drug reactions.

Whenever you take medicines – whether you buy them with a doctor's prescription, or over the counter in a drugstore without a prescription—you ought to be aware of the possibility that the drug might cause an undesirable or unexpected reaction, known as a "side effect," in addition to the action for which the drug was taken.

It's in your best interests, for health's sake, to be alert to this possibility. Every drug can cause some side effects in some individuals. The more potent the drug—and prescription drugs generally are more potent than those sold over the counter—the greater the potential for an adverse reaction.

Unexpected or undesirable effects can be mild or trivial, such as a slight rash, mild headache, nausea, or drowsiness. They can also be more severe, such as prolonged vomiting, bleeding, fever, marked weakness, or impaired sight or hearing. These symptoms are Nature's way of telling you that the medicine is acting adversely.

If a prescription medicine you are taking causes an unexpected or undesirable effect, call your physician promptly. He will know whether the reaction is expected or not and whether you should continue to take the medicine.

If a side effect is unexpected or unusually severe, your physician will have to decide whether the desirable effects—such as the alleviation of your symptoms or the cure of your disease—outweight the undesirable ones. That's why it's important for you to report the nature and extent of any unexpected effects to your physician as promptly as possible.

Often your physician will tell you when he is writing the prescription that you may have side effects. Listen carefully to what he says so you'll know what to expect.

You may not need to discontinue a prescription drug that has only mild side effects, but this decision is one you should make with your physician. Often your doctor can prescribe another medicine that has fewer or less severe adverse reactions but will still help your condition.

If an unusual or underiable reaction occurs from taking a medicine you purchase over the counter, you should discontinue it right away.

(Continued next page)

Often the expected side effects from over - the - counter drugs are listed on the label. Read the label carefully for this information, as well as for other relevant information. And if there are side effects, use your common sense. If drowsiness occurs, for example, you should not drive or operate any machinery until the drug's effects wear off.

One important fact to remember is that every individual reacts differently to medicines. Just because someone you know had no side effects from a drug, it doesn't mean you won't. For this reason, never take medicine that has been prescribed for someone else.

Your pharmacist and physician are experts in drug actions and should be able to assist you with any questions you may have about side effects or other reactions to drugs. Ask their advice, and heed their warnings.

—Reprinted from FDA Consumer

Much Of Youth's Drug Addiction May Be Due To Bad Diet, Says Doctor

By JAY PATRICK

"Much of the tendency of modern youth toward drug addiction probably can be traced to inadequate diet," says Dr. A. Hoffer of Saskatchewan, Canada.

"'Junk' foods fail to satisfy the body's needs. Many young people are annually consuming nearly their own weight in refined sugar. This alone throws the body so far out of equilibrium that countless metabolic dysfunctions result.

"Symptoms include anxiety, restlessness, depression, memory loss, indolence, fatigue, headaches, and insomnia. In fact, they just about run the gamut of human ailments.

"Should we then wonder that a young person, also beset by the high stress of growing up, or adjusting to a complicated society, often succumbs to the enticement of drugs?—Especially if he finds the family medicine chest already loaded with countless nostrums?

"Accordingly, any real solution of the drug problem rest first, among other things, with elimination from our diet of drugs such as sugar, which would undobutedly be outlawed if subjected to the same clinical evaluation to which calcium cyclamate was subjected."

Dr. Hoffer is an internationally known biochemist, physician and psychiatrist who pioneered in the treatment of mental disease with massive doses of niacin and Vitamin C. He is president of the Huxley Institute of New York, which is organized to advance the new orthomolecular approach to medicine and he is one of the contributors to the recently published book, *Orthomolecular Psychiatry*, edited by Dr. David Hawkins and Dr. Linus Pauling.

Industry's Fluoride Problem

By LEE HARDY

No. 2 In A Series

Fluorine is one of the more plentiful elements in the earth's crust. It emerges in springs and wells in some areas, and is brought to the surface in mining operations. The smelting and refining of minerals releases it into the atmosphere. The toxic nature of fluorine has brought problems to industries which are involved with it in raw material sources. The copper industry is one of these. Cattle around Anaconda, Montana, developed "copper teeth" and other evidences of fluoride poisoning, and it was not to set a record that the copper plant in Anaconda built the world's tallest smokestack, but to disperse the fumes into higher atmosphere to escape damage suits on account of poisoning of livestock and vegetation.

The dangers of fluorine emission have been realized for many years. Before the turn of the century the problem had been under consideration. Francis Wyatt, Ph.D., wrote in 1892 of the dangers of emissions from phosphate plants, listing as their chief substances carbonic acid gas, hydrofluoric acid, silicic tetrafluoride, sulphuric acid and steam. Of these, he says, "... the most dangerous to life and health of the compounds generated by the liberation of fluorine from the fluoride of calcium, the average proportion of which in our phosphates may safely be taken at about three per cent. The quantity of deadly vapor thus becomes very large in some of our big plants ..."[1] Raw phosphate material, he adds, contains 1.22% fluorine.[2]

In 1912 Bartolucci had reported the poisoning of cattle by fluorine near a phosphate plant in Italy.[3] Dr. Floyd DeEds, senior toxicologist with the Department of Agriculture and lecturer on toxicology at Stanford University, stated in 1933 that each year the superphosphate plants were contaminating the atmosphere with 23,000 tons of fluorine and the soil with 90,000 tons.[4]

In 1966 the town of Garrison, Montana, had to fight for its very life against contamination from a phosphate plant in its vicinity. Relief was gained through a court order which temporarily closed the plant and awarded damages. Losses were sustained from crop and livecrippled to the extent that they stock damage. Cattle were reported died of starvation because they were unable to walk to their feeding places.[5] Similar trouble for

(Continued next page)

Lakeland, Florida, was recorded the same year. A newspaper of that state reported, "From the stacks of (phosphate plants) in Polk and eastern Hillsborough Counties belch gaseous fluorides and sulphur dioxide mists that have killed cattle, destroyed pasturelands, burned citrus trees and sickened humans . . ."[6]

Aluminum manufacturers have been beset by the same problem. Fluoride - containing minerals are used to dissolve aluminum ore. In 1896 Joseph W. Richards, Instructor in Metallurgy at Lehigh University, wrote in regard to aluminum manufacture, " . . .aluminum is . . . dissolved only by . . . fluorides. These . . . are the principal salts used at present in aluminum industry."[7] Methods seem to have changed little since that time. Bauxite (aluminum oxide) is still dissolved in molten cryolite (sodium aluminum fluoride) in the reduction process.

Aluminum companies have had their share of damage suits. In 1950 a Washington plant was ordered by a Tacoma Federal Court to pay damages to a cattle raiser whose cattle had been poisoned by eating fluoride - contaminated vegetation. In June, 1958, Blount County, Tennessee, farmers were awarded payment by the U.S. District Court in Knoxville for damages to cattle and crops. A plant at Troutdale, Oregon, had been sued in 1946 by a citizen who claimed and proved damage to the health of his family.

Europe also was in trouble, as evidenced by the Belgian "death fogs" of 1930. Dr. Kaj Roholm, the great Danish scientist, at that time the world's greatest authority on fluoride poisoning, attributed the deaths to acute fluoride intoxication.[8] In a similar disaster in Donora, Pennsylvania, in 1940 fluoride concentrations in the blood of victims were found to be 12 to 25 times higher than in the blood of normal persons.[9]

Dr. Wyatt outlined in 1892 means of scrubbing fluorides and other harmful elements from plant emissions. Industries did decrease such emission considerably, but their problems were not yet solved. They still had in their recovered fluoride residues substances too poisonous to be disposed of by simply throwing them out or by flushing them down the sewer. Research directed toward solving this problem was in process as early as the 1930s. The solution proposed and adopted has led to controversy.

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"Sleep Helps," Says Famed Dr. Paul Dudley White, 87

By JAY PATRICK

"I think that now I've got to recognize the importance of sleep," finally concedes the heart specialist who first gained national attention when he was called in 1955 to treat the late Dwight D. Eisenhower after the President suffered a heart attack.

When he wasn't busy at his active practice, the trim little doctor has chased about the globe for so long that he has become something of a legend, riding his bicycle everywhere and extolling the virtues of an active life to all who would listen.

"But sleep," he often insisted, "is a waste of time."

Since June of this year, though, when Dr. White suffered a slight stroke, the tough but candid physician has taken another look at the idea of sleep—and thinks, finally, that it's worthwhile.

But, unfortunately, many millions of people still share Dr. White's earlier view, probably first popularized in America by the inventor-genius Thomas A. Edison, who bragged that he slept only a few hours nightly.

(But Editon took many, many cat naps during the day!)

Anyway, scientists now know that a good night's sleep, seven to eight hours, is essential for good health. For it is in the night that most of the regeneration of the body occurs, the new cells grow, the liver, the skin, the mind are restored.

There are, indeed, many books on the subject. Perhaps the best is *Sleep* by Gay Gaer Luce and Julius Segal, (Coward-McCann).

This fascinating book stresses the importance of the ritual, the regularity of a good sleep pattern as an enhancement of the circadian (24 hour) rhythm that can help keep man's whole mechanism functioning smoothly and effectively.

Thus man thrives best when following his inner timing, his personal, individual clock that, if it has a chance, will beautifully coordinate the major biochemical interactions of his complex system.

In a study of the sleep habits of more than a million men and women, as reported by Doctors Cheraskin and Ringsdorf (*Predictive Medicine—A Study In Strategy,* Pacific Press), those who lived into their 80's slept seven hours nightly. Those who slept more than seven hours or less than seven hours did not live, on the average, nearly so long.

These statistics do not necessarily mean that any given individual will necessarily shorten his life by regularly sleeping less than seven hours nightly or more than seven hours. However, there is an indication that seven hours is a more healthful period of sleep for most people.

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Dr. A. Hoffer of Canada, famed biochemist and physician who pioneered the use of niacin, says that he finds that he has required only six hours of sleep nightly during the past 10 years, since he started taking three grams of niacin daily.

The doctor ventures that this may be partly because niacin (not niacinamide) imparts a negative charge to the red blood cells, it has recently been learned. This electrical charge breaks up the clumps of red cells, dispersing the cells widely throughout the blood. This dispersion opens up so much more of the cells' surface area that their ability to carry oxygen and other body nutrients is greatly increased. Equally important, says the doctor, the single cells can then travel through the tiny capillaries of the brain, the heart—to all parts of the body, providing essential fuel to areas which might otherwise atrophy.

Along with all the nutrients, especially Vitamins C and E, niacin helps prevent strokes such as Dr. White suffered, says Dr. Hoffer.

Hopefully, fine doctors such as Dr. White will some day come to recognize that exercise, though highly important to good health is still not enough, for, in addition, one's life style must include a good night's sleep and some 43 nutrients.

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(Received July first through mid-August)

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."

Smelly Money

Reprinted from "Letter to the Editor"
in the Gazette Times, Corvalis, Oregon

To the Editor:

California orthodontist Marshall Rothstein, hitherto convinced that children's cavities were caused by high lactose diets, and recommending proper dental hygiene, suddenly reversed himself stating that the only way to control childhood cavities is through fluoride. When asked for proof, he exuded endorsements based on quotes from Sen. Ed Kennedy in *Readers Digest.*

Prof. Yngve Ericsson, with a vast income from fluoride toothpaste in Sweden, labels bone meal for teeth as "quackery." Both he and the World Health Organization which suggested fluoridation be used where practical are being investigated by the Swedish government.

After the Swedish Parliament (1971) revoked the law allowing community fluoridation, health authorities who explored alternatives for tooth and gum health, found bone meal to be the most promising. Its high magnesium stabilizes tooth-surface calcium. Bone meal was endorsed by agronomist Dr. Alfred Aslander, whose children and grandchildren have perfect teeth, having been given effective proper nutrition, including bone meal.

Opposition to bone meal is because children growing up with excellent teeth would leave dentists largely idle, whereas with fluoridation, dentistry would remain a brisk enterprise. Think of the disastrous effects of dental health on a parasitic dental industry—X-ray, dental drill machines, surgical instruments, drugs, prosthetics, filling and cast materials. The Oregon dental politicians are fluoride pushers.

There are no buffalo dentists and none needed for herbivores; there are no cougar and crocodile dentists and none needed for carnivores; there are no gorilla and baboon dentists, and none needed for these omnivores. All these creatures feed on whole, wholesome, unprocessed, unpoisoned, natural foods, and have never endorsed water fluoridation. But the human animal, gluttoning on "profitable" death foods, has rotten teeth, scurvy-gums, and dying peridontal membranes.

Many dentists know these facts, yet by their default of silence, they allow political and fiscal dentistry to put words into their mouths, to engineer their consent for a useless drug remedy giving false assurances via fluoride in lieu of the need for sound nutrition. "Preventive Dentistry" is not preventive, but idly symptomatic. "O tempora, O mores!"

— Dr. Howard H. Hillemann

A Report to the Consumer

LIVER: The Wonder Food

By IDA HONOROF
Consumer Advocate

Liver has often been called a "wonder food." It is rich in the B vitamins, in vitamins A, C, D, iron, calcium, phosphorus, copper, as well as the important amino acids. It has long been known to be both a cure and a preventative of iron deficiency anemia.

In man, as well as in most animals, the liver is considered a vital organ, with remarkable power to grow new cells. It receives blood from the portal vein from the stomach and the intestines. The liver is the detoxifying organ of the body and functions to destroy the poisons we ingest. As blood passes through the liver it is freed of waste matter and poisons. The liver cells take some of the sugar out of the blood and changes it into glycogen. This is stored in the liver cells to be given out again as sugar whenever the blood requires it.

The Journal of Nutrition (July '51) reported experiments done by the Sloan-Kettering Institute for Cancer Research in 1941. Three groups of rats had been put on a diet of rice and butter yellow (butter yellow has been banned from use in the food industry). One group was given 10 percent desiccated liver; and a second group 2 percent, while the control group of 50 animals were fed only rice and butter yellow. (The latter group received no liver.) This group developed cancerous livers within 150 days, while the rats that received liver had smooth and practically normal livers. It was found that the 10 percent liver-ration to offset the disease. Thirty percent of those that received 2 percent liver, had completely healthy livers, while the remaining 70 percent had livers with numerous cancer nodules.

Dr. Kanematsu Sugiura (who contributed a major share of the research) stated "These dietary influences may prove to play a very large part in the causation, prevention and treatment of human cancer." At that time the experimenters had no inkling of what could possibly be present in liver that would have such potent cancer-prevention effect.

In the Journal of Nutrition (3-10-54), Dr. Ershoff pointed out that whole liver, or even fractions of liver in the diet was found to be a very powerful force against the effects of massive doses of industrial pollutants and medical drugs (such as strychnine, sulfanilimide, promin,, atabrine, dinitrophenol, diethylstilbestrol (DES), alpha-estradiol, cortisone, acetate, etc.) apparently because of the protective factor in that part of the liver that is insoluable in water. In his experiments, Dr. Ershoff tested desiccated liver, milk protein and all the known B vitamins, to determine which would offer greater protection to his laboratory animals, from the effects of large doses of thiouracil (the drug that interferes with the thyroid gland function) known that an overdose can have serious effect on the thyroid glands. Dr. Ershoff found that certain batches of desiccated liver protected the rats from ill effects of the drug, while the protective substance was not present in casein or in kelp, or in any or all of the known B vitamins.

Dr. Morton S. Biskind (N.Y.) in *Vitamins and Hormones* reported 450 cases of sex hormone disturbance resulting from an excess of estrogen. The women patients experienced menstrual disorders (painful breasts and acne) while the men had excessive development of the breasts, softening of the testes, loss of hair in the armpits, etc. In both sexes there was infertility. Dr. Biskind reported that the symptoms (sex hormone disturbance and vitamin deficiency) were corrected after treating the patients with desiccated whole liver.

Dr. Bernard Krohn (Long Beach, Calif.) testifying before the Committee to Investigate Chemicals in Foods, pointed to cases of poisoning from insecticides which he treated with injections of liver extract and large amounts of liver given by mouth . . . "treatment of the disease is largely a matter of repairing the damaged tissues . . . high protein and high vitamin diet, especially the B complex of vitamins is useful... injections of crude liver extract speeds the process."

The search for the miraculous, unknown substance in liver took 20 years, until it came to fruition in 1971, when a team of five biochemists with the Department of Biochemistry at the University of Michigan Medical Center, headed by Professor Minor J. Coon, succeeded in isolating and subsequently testing a red protein pigment which was tagged CYTOCHROME P-450. This pigment proved itself able to perform all the mysterious protective functions of liver that had been previously found not attributable to the vitamins and minerals that liver contained. Their findings were reported at the July '71 meeting of the British Biochemical Society.

In a press release Dr. Coon stated "Cytochrome P-450 may prove to be a part of the solution to pollution, drug addiction, alcoholism and even cancer," Harald Taub, Executive Editor of *Prevention*, feels that this statement is rather conservative: "In light of already established knowledge . . . of what we can expect liver to do to help our bodies stay healthy, in spite of a myriad of destructive forces it has to fight." Inasmuch as P-450 is NOT water soluble, the drying process does not remove this remarkably new identified liver factor, but that instead, concentrates it. Desiccated liver is the whole beef liver concentrated by vacuum drying at low heat of about 140°. The scientists are confident that it is only

(Continued next page)

with isolation and testing of P-450 that they can say that the "red protein located in the liver membranes actually changes and renders harmless the chemicals that otherwise would cause cancer." They feel they have a clue indicating that P-450 may both improve the energy production process and also improve the ability of the body to detoxify the fatigue toxins.

In response to a letter from Dr. M. J. Coon, I was informed that "the approach to the problem of CYTOCHROME P-450 is highly basic and far too little information is available to draw conclusions, that the feeding of liver might be beneficial in special cases" that "it is quite likely that CYTOCHROME P-450 is destroyed during digestion, as are other proteins." That "they know too little about the mechanisms by which foreign substances are detoxified in the body, and this is now the subject of research in a number of laboratories . . . an adequate understanding of the events at the molecular level must await the results of ongoing research . . ."

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I certify that the statements made by me above are correct and complete.

R. A. Laurye, Business Administrator

Consumer Affairs Report

By TREESA DRURY

Drugs and Pills Can Kill

It causes about 30,000 deaths a year, hospitalizes more than 3½ million people a year, causes medical costs in excess of three and one-half billion dollars a year . . . WHAT IT IT? It is wrongly prescribed drugs . . . it is the abuse of legally manufactured drugs. Dr. Milton Silverman, a Professor of Pharmacology maintains that some 30,000 deaths are caused each year in the U.S. due to adverse drug reactions. He furthers states that approximately 4½ million hospital admissions annually are due to the same cause. Dr. Silverman says each such patient will stay in the hospital for around 8 days, which figures out to a total yearly cost of 2.6 billion dollars.

The problem is complex and involves the hospital, the doctor, the pharmacist and even the patient. Silverman points out that hospitals often prescribe anti-bacterial drugs whether a patient needs them or not. The incidence of infection is about the same between the hospitals that routinely push these drugs and those that don't. Silverman says that doctors often unknowingly give a patient two or more drugs that interact and cause serious health problems. Blame also must be placed on patients who go to many different doctors and fail to tell the doctor what they are already taking. Silverman also points out that some pharmacists are quilty of refilling prescriptions without first consulting the physician.

Then, of course, there are those people who do not take the drug as prescribed or will use it for something other than prescribed, such as using a barbiturate or tranquilizer to achieve a form of drunkedness or "high." President Nixon has declared an all-out global war on drug menaces. The President mentioned heroin, cocaine and marijuana. But what about the dangerous drugs which originate in America's great pharmaceutical houses? Many advocates feel these drugs, the barbiturates, the amphetamines and the methaqualones should be put under stricter controls . . . but that interferes with profits and may be neglected in the war against the drug menace.

Treesa Drury can be heard nightly in the Los Angeles area, Monday through Friday at 9:30 p.m. with CONSUMER WATCH on KHJ-TV's NEWSWATCH—Channel 9. She also may be heard on a nationally syndicated show — check your local radio station schedules.

WASHINGTON ROUNDUP

Supreme Court Rules In Five FDA Cases

U.S. Supreme Court ruled June 18 on five cases involving FDA's authority to implement the 1962 drug amendments. The justices voted 7 to 0 on all decisions. The court ruled:

- FDA can decide with administrative finality the "new drug," "not new drug" status of a particular drug. A lower court had ruled that such a decision could only be made by the court.
- "Me-too" drugs are not exempt from FDA regulatory decisions. The issue before the court was whether removal of an NDA'ed product from the market included "me-too" products, or whether FDA would be required to take separate legal action against each "me-too" product. The court affirmed FDA's contention that withdrawal of the NDA covers "me-too" products.
- FDA's summary judgment procedures for action against less than effective drugs were ruled to be appropriate. The court ruled that the Agency did not need to grant a hearing when the manufacturer failed to submit any evidence that would satisfy the statutory requirements of adequate and well-controlled clinical studies.

The court also ruled that FDA's regulations to demonstrate effectiveness were appropriate, and that the criteria for general recognition of effectiveness are the same as adequate and well-controlled evidence. However, in one of the cases before the court, the justices ruled that the firm had presented adequate data to justify a hearing before FDA.

Interim Food Additive Regulation Extended for Saccharin

FDA has extended an interim food additive regulation for the use of saccharin in food.

FDA removed saccharin from the GRAS (Generally Recognized As Safe) list of food additives on February 1, 1972, and issued the interim regulation, which is designed to "freeze" use of the artificial sweetener at current levels while additional safety reviews are conducted. Without the extension, the interim regulation would have expired June 30, 1973.

Through product labeling and formulation requirements, the interim order seeks to limit saccharin use to no more than one gram per day for the average adult. One gram of saccharin is equal to seven 12-ounce bottles of the standard diet drink. One gram of saccharin is equal to 60 of the small saccharin tablets. Each tablet is equal to one teaspoon of sugar.

FDA pointed out that saccharin has ben used in the food supply for more than 80 years without evidence of human harm. The only adverse findings in animal tests to date have occurred at levels roughly equivalent to at least 875 bottles of a typical saccharin-sweetened soft drink per day.

FDA Proposes Amendment To Microwave Oven Standard

FDA has proposed a regulation to require microwave cooking ovens to be capable of shutting themselves off in event of safety interlock failure and to remain shut off until repaired.

The requirement incorporated in a proposed amendment to the FDA microwave oven safety performance standard, is aimed at eliminating the possibility that a failure in the interlock system on oven doors might permit operation with the door open. The amendment would make it necessary for ovens to be capable of electrically detecting an interlock failure and automatically disconnecting source of the microwave.

The standard now requires two interlocks to be capable of turning the oven off as the door is opened. The proposed amendment would designate one interlock as primary and the other as secondary.

The primary interlock would have to be capable of preventing a microwave oven, prior to sale, from emitting microwave radiation above one milliwatt per square centimeter as the door is opened.

Both primary and secondary interlocks would be required separately to limit emissions at door opening to no more than five milliwatts per square centimeter after sale and throughout the useful life of the equipment.

No interlock failures have been reported for equipment made in compliance with the present standard. However, a model made before the standard became effective October 6, 1971, was found to be subject to open door operation because of a defective interlock switch. Most units of the model line have been corrected under a program approved by FDA's Bureau of Radiological Health.

FDA Revokes Approval of Violet No. 1 as Color Additive

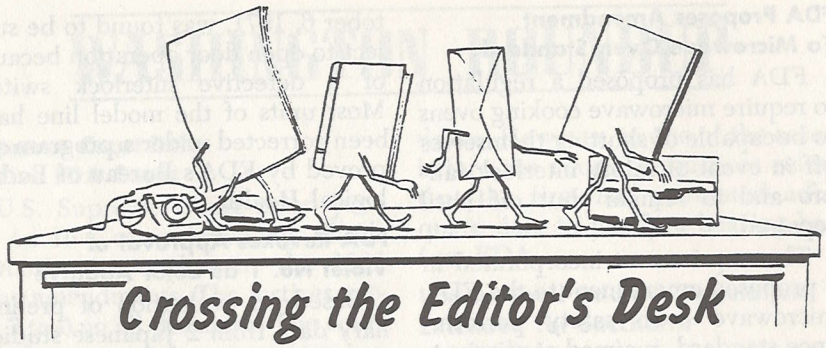
Based on evaluation of preliminary data from 2 Japanese studies, the FDA announced that it is revoking its provisional listing and, therefore, approval for the use of violet No. 1 as a color additive in food, drugs, and cosmetics.

Violet No. 1 has been used for 22 years and has been provisionally listed by FDA since the 1960 Color Additive Amendments to the Food, Drug, and Cosmetic Act. Provisional listing means that additional studies are required to remove all question as to safety.

The order terminating provisional listing and all outstanding certificates for Violet No. 1 was effective April 10. Use of the color in any food, drug, or cosmetic after that date will cause the product to be considered adulerated and subject to regulatory action.

At least 30 percent of all Violet No. 1 is used by the U.S. Department of Agriculture in marking meat for grade and wholesomeness. USDA is providing for alternative methods.

As a food color, Violet No. 1 was widely used in beverages and in other products including candy, bakery goods, ice cream, sherbert, dietary supplements and pet food. It was also used as a coloring agent in some drugs and cosmetics.



Crossing the Editor's Desk

Ralph Nader, in an address given at the convention of the American Society of Preventive Dentistry, urged the dentists to take the lead in coordinating "a national political campaign to do something about the consumption of soft drinks." He claimed that dentists are in a position to show that soft drinks with high sugar content cause cavities. In addition, he said these drinks have little nutritional value and may be injurious to health in general. The Preventive Dentistry Society was established in 1968 because its founders believed that the much larger American Dental Association is too treatment-oriented. The society now has 6000 members.

The American Medical Association, which has been accused by some of its own advisors of being "a captive of the pharmaceutical industry," has invested nearly $10 million from its members retirement fund in drug companies. Under a ruling by the AMA's judicial council, it would be of questionable ethics for an individual physician to invest in drug companies because of the possible appearance of conflict of interest. The AMA last year received $8.6 million, 26 per cent of its total income, from drug company advertising in its various medical journals. The last two chairmen and the vice chairman of the AMA's council on drugs stated before a Senate subcommittee last February that it is this income that makes the AMA "a captive arm and beholden to the pharmaceutical industry."

Speaking of the AMA and its relationship with the pharmaceutical industry, it was believed by many to be significant that the AMA trustees abolished the council on drugs in October of last year after it published its long awaited evaluation of drugs that said the composition of some of the most profitable drugs on pharmacy shelves were "irrational" and that their use was not recommended. The AMA said the council was abolished as an economy move. Two former council chairmen and a vice chairman said the council was abolished because of their harsh words about many drugs.

The rights of non-smokers are gaining in recognition. The Civil Aeronautics Board, in an action taken on May 1, ordered all certified air carriers to provide no smoking areas aboard their flights. The action became effective on July 10 and seems to be in full accord with the spirit and intent of H.R. 1309, the Nonsmokers Relief Act, introduced by Representative C. W. Bill Young, of Florida. The Marriott Hotel chain is doing something also for the non-smokers. As an experiment in three of its Washington, D.C. area facilities, they are reserving large blocks of rooms for use by non-smokers only. The rooms have been repainted and the drapes, bedding and carpets have been thoroughly cleaned to remove all traces of tobacco odor. Even non-smoking maids and housemen have been assigned to service these rooms. If the experiment is successful, the idea will be expanded to all the hotels in the chain.

A government medical researcher, Dr. Robert I. Henkin, estimates that there are probably 500,000 Americans who are undetected sufferers of a disease whose victims lose their sense of taste or smell, or to whom everything tastes or smells awful. Very few physicians, he says, fully appreciate the importance of the problem or what can be done about it. Actually, there is a very simple remedy which has brought about significant improvement in from 40 to 66 per cent of the cases. The treatment consists of the administration of daily doses of zinc sulfate capsules.

Every time a person takes a few drinks of an alcoholic beverage—even a few beers or cocktails at a social function—he permanently damages his brain, and probably his heart and liver also. This is the conclusion of a team of scientists headed by Dr. Melvin H. Knisely, Professor of Anatomy at the University of South Carolina Medical School.

Gallstones are formed from cholesterol in patients who lack enough bile acid to keep the cholesterol suspended says Dr. Leslie J. Schoenfield, of Cedars-Sinai Medical Center in Los Angeles. The hospital has just launched a five-year, $7 million study to assess the use of chenodeoxycholic acid—a naturally occurring bile acid—to redissolve gallstones. Preliminary studies of 90 patients showed gallstones dissolved in from six months to two years. The doctor said that presently, there are about 300,000 gallstone operations performed yearly costing about $1 billion.

A new method has been developed by a scientist at the University of Virginia to kill viruses, bacteria and other organisms in drinking water without chemicals or distillation. It's electrocution. The method involves the use of submerged screens which deliver an alternating electric current. It has been reported that the method and equipment is now ready for use in large cities.

According to the authors of "Jogging," W. J. Bowerman and Dr. W. E. Harris, the most common exercise indulged in by the average middle-aged male is "running down their friends, jumping to conclusions, sidestepping responsibility, and pushing their luck."

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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?

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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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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.

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