National Health Federation BULLETIN

OCTOBER, 1974

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New Light On the THERAPEUTIC USEFULNESS of NATURAL VITAMIN D

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Dedicated to the Protection of Health Freedoms

THE
NATIONAL HEALTH FEDERATION BULLETIN

Protection of Health Freedoms — *Published Monthly*

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

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Now Who's Getting Into the Act?

Many people have wondered what's really behind the Food and Drug Administration's eagerness to establish the pending dietary supplement regulations—a move which will remove from the marketplace about 80% of the products now sold as dietary supplements. Why is FDA so dead set on a course which so deeply invades the basic freedom of people to determine what kind and how much food they desire to ingest? Many people firmly believe there is a powerful force (or forces) behind and outside the FDA which is responsible for the vigor with which FDA has persued its course including an apparent, deliberate course of harassment of the health food industry in general.

The Food and Drug Administration would have us believe their actions are necessary and justified in order to prevent the American people from wasting money on vitamins they don't need, claiming that the ordinary, balanced American diet supplies all the vitamins and minerals needed by humans under ordinary circumstances. FDA notes that the cereal grains which lose most of their vitamins in the milling process are mostly all "enriched" and thus are no longer deficient foods but rather a source of essential vitamins and minerals.

Supposedly, we should be grateful to FDA for being so solicitious concerning our pocketbook. However, the constitutional role of government does not include protecting us from our own harmless dietary whims—if that is what excessive vitamin-taking is. If FDA was really honest and sincere on this score, soda pop, cokes, most candy and a great many other items under FDA jurisdiction would have been removed from the marketplace long ago.

Now, contrary to the previous pronouncements of FDA, the federal government's chief independent scientific research arm, The National Research Council of the National Academy of Sciences, has concluded that significant numbers of Americans suffer a variety of vitamin and mineral deficiencies, and has recommended that all foods made of wheat, corn and rice be enriched with 10 essential nutrients.

At present, wheat flour and bread are enriched with vitamins B-1, B-2, niacin and iron. The Council recommends that the list be broadened to include also vitamin A, vitamin B-6, folic acid, calcium, magnesium, and zinc and that the enrichment program be extended to include all products made from wheat, corn and rice. The Council's report also

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urged millers to reduce the amount of "refining" they do to wheat to make white fluor.

The billionaire food production and processing companies, collectively called agribusiness, have the frightening and unique capacity to greatly affect the nutritional health of the American people by controlling the type and nutritional quality of the foods generally available to us. Their operations are aimed primarily towards greater production and higher profits rather than greater nutritional values. However, as long as their foods of poor nutritional quality can be "enriched" by adding a few vitamins and minerals, they can continue to ignore and cover-up the real reason for the need for the enrichment and still represent their foods as having high vitamin and mineral content. Naturally, we know that no enrichment program replaces either all or the same kind of nutrients lost in the refining processes.

With this background, it would seem a logical step for agribusiness to extend their business into the vitamin and mineral field and even into the health food industry itself which has traditionally been a vocal foe of the food processors. During the past two years especially, a goodly number of long established and well-known health food manufacturing and distributing firms have been purchased by huge conglomerates.

Is agribusiness involved, behind the scenes, in a move against consumers and companies that have pioneered the food supplement and health food business, and now wish to take over the exclusive right to all profits by adding these same nutrients to their depleted food products? Are we looking at another bit of evidence showing monopoly at its worst?

In Memoriam

Dr. Fred D. Miller, of Altoona, Pennsylvania, a nationally known dentist and nutritionist, died August 12 in a London hospital. He became ill at the London Airport while enroute home from a month's vacation in France and Switzerland.

Dr. Miller was a rare jewel of a man and an even greater and rarer man in his chosen field, the dental profession. He advocated preventive dentistry long years ago when the term was scarcely used. He was noted for his writings and lectures in both the fields of nutrition and preventive and restorative dentistry. His motion picture on preventive dentistry, "Gateway To Health" has been shown to professional and lay groups all over the world, and his book, "Open Door To Health" has been read the world around.

Dr. Miller firmly believed in the principles advocated by the National Health Federation and was a staunch supporter and true friend of NHF.

U.S. Court of Appeals Renders Decision In Vitamin Regulations Case

The United States Court of Appeals for the Second Circuit (located in New York City) has rendered a decision in the actions initiated by several individuals, firms and organizations (including the National Health Federation) which earlier had petitioned the court to review the pending dietary supplement regulations issued in final form by FDA on August 2, 1973. The petitions, originally filed in scattered parts of the country, were consolidated early this year and the Second Circuit Court of Appeals heard oral arguments in the consolidated case on June 19, 1974. Ten attorneys were present representing their respective petitioner. Kirkpatrick W. Dilling represented the National Health Federation. Four government attorneys were present to represent the FDA's position.

The decision, consisting of about 100 pages, is complex and will require detailed study by counsel before all the implications inherent in the decision may be realized. While the court certainly did not void the regulations in toto, as many of us might have hoped it would do, the decision does provide a definite and distinct victory for the opponents of the regulations on several important points. Admittedly, however, it is only a partial victory.

Pending the completion of a detailed analysis of the decision by Mr. Dilling, and in order to meet the printer's deadline for this issue of the **Bulletin,** we offer at this time only the following very brief summary of some of the highpoints contained in the decision:

1. The court upheld the legal authority of FDA to issue the regulations, thus ruling against the charge of some of the petitioners that the FDA had exceeded its statutory authority in issuing such sweeping regulations.

2. The court issued a stay of the effective date preventing FDA from implementing and enforcing any part of the regulations until after June 30, 1975.

3. The court recognized the fact that the level of the various nutrients, especially vitamins, needed by humans vary greatly from

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individual to individual and that probably many persons require an intake of certain food factors in excess of the upper limits permitted in dietary supplements under the regulations. The court further took note of a point emphasized by Mr. Dilling during the oral arguments, namely, that an ordinary serving of many foods provides a higher intake of certain specific vitamins than would be permitted in the daily recommended dosage of vitamin supplements under the regulations. Accordingly, the court expressed the opinion that the maximum levels permitted (150% of the RDAs) in dietary supplements were too low and too rigidly fixed. The court referred this matter back to the FDA with at least the implied command that FDA modify the regulations or establish some procedure whereby a manufacturer, possibly through he submission of an application, might continue to make and distribute a product which does not fully comply with the pending regulations.

4. The court took note of the fact that FDA's pending regulations permit the inclusion, in a multivitamin-mineral supplement, of only 21 of the essential vitamins and minerals, thus prohibiting the inclusion of other nutrients also recognized as essential in human nutrition. On this point the court holds the opinion that all essential vitamins and minerals should be permitted in a dietary supplement and remanded this matter also back to FDA for modification of the regulations.

5. The court upheld that portion of the regulations prohibiting the inclusion, in dietary supplements, of substances deemed not to be essential in human nutrition along with essential nutrients. Examples of such substances are rutin, bioflavonoids, choline, etc. The court observed that the regulations permit these substances to be marketed as single ingredient products thus permitting those consumers desiring these substances the privilege of purchasing them.

6. The court took note of certain irregularities in the hearings held 1968-1970 on the then proposed regulations, particularly the refusal of the hearing examiner to permit cross-examination of certain witnesses. Specifically, the court noted the hearing examiner's refusal to permit Dr. Miles Robinson, NHF's representative at the hearings, to cross-examine Dr. Sebrell whose testimony FDA used extensively as justification for some parts of the regulations. The court "suggested" that the FDA should do something about this matter even at this late date four years after the close of the hearings.

7. The court gave the FDA until June 30, 1975 to constructively act on those matters referred back to the agency.

House Health Subcommittee Reports Out Vitamin Regulations Bill

Following nine months after the conclusion of hearings on the Hosmer and related bills, the House Subcommittee on Public Health and Environment has reported out a bill following a "mark-up" session which continued over four days.

When hearings were held on the bills in October, 1973, a majority of members of the House of Representatives had already sponsored or cosponsored the Hosmer or similar bills. Though the bills varied in minor details, all were similar in that they would restrict the authority of the Food and Drug Administration to limit the potency of vitamins and minerals and the combination of ingredients in dietary supplements except when proved to be harmful to health. In addition, the Hosmer and other similar bills were short and concise and the intent of the bills was precisely stated. The bills were actually very simple in concept and consisted of two principle provisions, namely: (1) a definition of "food supplements" or "foods for special dietary uses" taking verbatim the definition prepared by FDA itself in 1955 and used by FDA as a working definition ever snce, and (2) adding the following provision to the Food, Drug and Cosmetic Act applying to such foods:

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

The bill introduced in the Senate by Senator Proxmire (S. 2801) and now cosponsored by 44 other senators has the same intent and purpose as the Hosmer bill and is equally brief and concise.

Subcommittee Bill Unnecessarily Complicated and Vague

The bill which came out of the House Subcommittee following the "mark-up" session is, however, unnecessarily complicated according, even to counsel specializing in the field of food and drug law. Furthermore, it seems vague on a number of points thus opening the door for FDA to draft enforcement regulations based upon the interpretation most desired by FDA. The bill is no longer the "Hosmer bill" because an entirely new bill has been drawn which is now known as H.R. 16317. Though the new bill does reflect some of the original purposes of the Hosmer bill, some of these provisons are now clouded by qualifications and limitations.. In

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addition, the Subcommittee has seen fit to draft into the bill, new provisions not originally included in the Hosmer or related bills.

It can be assumed that the subcommittee staff actually drafted the detailed bill *presumably* reflecting the desires of the majority of the committee members. Many features of the bill strongly suggest that the staff worked closely with FDA in drafting the final version. Some of the proponents of the original Hosmer bill who have since had an opportunity to discuss the new bill with some of the Subcommittee members are of the opinion that at least some of the members do not grasp the full significance of some of the changes in terminology, etc. which, on the surface, may seem insignificant. In simply reading the bill alone without any knowledge of how it relates to the entire Food, Drug and Cosmetic Act, one might well conclude that the bill is acceptable. However, it cannot be judged in this manner; it must be read in context with the whole Act and when done so, many of the simple provisions of the bill take on new meaning.

New Bill Defeats Principle Intent Of Hosmer Bill

After giving the Subcommittee bill careful study in context with the entire Act, Attorney Kirkpatrick W. Dilling, who has represented NHF in matters relating to the pending food supplement regulations, observed that the bill would, in effect, limit its scope to vitamins and minerals, eliminating other essential nutrients such as protein, unsaturated fatty acids, and the like, and also eliminating foods for special dietary use in powder form such as are widely available at the present time. He further noted that even the limited number of products which would be permitted could be classified as "food additives" or "prescription drugs" almost at the whim of the FDA, and without the usual due process protection otherwise available. For example, without a hearing, the FDA Commissioner could classify a vitamin or mineral product as a "prescription drug" based only upon his presumed "expertise," such as was the case concerning vitamins A and D last year.

Bill Grants FDA Authority To Control Advertising

The Subcommittee bill grants very broad and extensive authority to the Food and Drug Administration with respect to advertising of dietary supplements. No provision of this type appeared in the Hosmer bill and none seemed necessary inasmuch as the Federal Trade Commission has traditionally had control over this matter. However, the Subcommittee chairman, Rep. Paul Rogers, made it clearly known beginning at the hearings last October that he favored giving FDA the authority to regulate advertising. The advertising provision was included in the Subcommittee bill presumably at the insistence of the chairman even though FDA went on record as stating it did not need the authority. During the hearings, Mr. Hutt, FDA Counsel, stated in reply to a question by Rep. Rogers on the matter, "Mr. Rogers, I think we should state for the record because we believe it quite firmly that we have no quarrel with the ability of the Federal Trade Commission in this matter. They have done an excellent job." At another point in the record, FDA further stated, "With respect to authority to deal with pamphlets, mail-outs, radio advertisements, etc., we feel the present authority vested in the Postal Service, Federal Trade Commission and the FDA is adequate."

Milton A. Bass, counsel representing the National Nutritional Foods Association, noted that the Subcommittee bill gives FDA power over advertising under Section 403(a) — i.e., with respect to any false or misleading claims in any particular and, in addition, grants advertising power to the FDA under Section 403(j) which gives the FDA the power to dictate the language which must actually be included in advertising material. This unprecedented broad and extensive grant of power raises many questions. For example, he said, "The nature of the power could be very destructive in effectively preventing many forms of advertising, such as television, radio, magazines, window streamers in a store, etc., merely by the requirement of extensive language which must be included in such advertisement." Mr. Bass further noted that by granting FDA jurisdiction over advertising, it automatically brings it under the extensive criminal provisions in the Food, Drug and Cosmetic Act under which criminal liability attaches without FDA having to prove intent or knowledge of the alleged wrong.

Basic Intent Of Legislation Weakened By Exceptions

Bass also pointed out a number of exceptions in the Subcommittee bill which FDA could use to circumvent the intent of the legislation to prohibit limitations of potencies and combinations of food ingredients. The prescription provision in the bill provides a method by which the FDA can limit potencies and combinations almost at will. The food additive provision provides another method by which the FDA can limit potencies and combinations of food products. Also, there is still another provision in the bill providing another exception with respect to potencies and combinations where the product is also intended for children under 12 years of age and for pregnant or lactating women. "There is no reason for this exception," Bass said, "and the product, in effect, would have to represent that it is not to be used by children under 12 years of age where there may be no reason for such caution or warning."

Bill Is A Dangerous Distortion Of the Hosmer-Proxmire Type Bills

The Subcommittee bill, H.R. 16317, has been called a "compromise bill" by some of the committee members and it was reported out of the House Health Subcommittee with 10 of the 11 members of the subcommittee as cosponsors. Clinton Miller, NHF's legislative advo-

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cate, said, "The bill is a radical departure from, and a distortion of, the Hosmer - Proxmire type bills which have been introduced by a majority of the House (234) and a near majority of the Senate (45). It is my personal opinion that H.R. 61317 would dismantle the health food and food supplement industry more surely and permanently than FDA's new vitamin regulations."

Can anything be done to change the bill at this time? It's possible but not probable before voted on in the House. As the bill leaves the Subcommittee on Health, it must go before the full committee, the House Interstate Commerce Committee, before being reported out onto the floor of the House. The bill could be amended by a majority vote of the members of the full committee, however this is not likely because the ten members of the subcommittee, including its chairman, Rep. Paul Rogers, who voted for H.R. 16317 are members also of the full committee. The bill could be amended also on the floor of the House prior to the vote on the bill.

Undoubtedly, the most probable hope lies in getting the Proxmire bill (S. 2801) through the Senate intact. This, then, would probably result in a compromise bill worked out in a conference between the House and the Senate. Hopefully, such a compromise bill would be less objectionable than the present House bill.

In any event, unless drastically amended, the National Health Federation is strongly opposed to H.R. 16317 in its present form.

H.R. 16317

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish certain limitations respecting the authority of the Secretary of Health, Education, and Welfare to regulate certain foods for special dietary use under that Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Section 1. (a) Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding after section 409 (21 U.S.C. 348) the following new section:

VITAMINS AND MINERALS

Sec. 410. (a) (1) Except as provided in subsection (b)—

(A) the Secretary may not establish maximum limits on the potency of any synthetic or natural vitamin or mineral within a food for special dietary use which is intended for ingestion in tablet. capsule, or liquid form;

(B) the Secretary may not classify any vitamin or mineral as a drug solely on the basis of the potency of the vitamin or mineral; and

(C) the Secretary may not limit the combination or number of any synthetic or natural—

(i) vitamin,
(ii) mineral, or
(iii) other ingredient of food,

within a food for special dietary use which is intended for ingestion in capsule, tablet, or liquid form

For purposes of this subsection and section 403, a food for special dietary use shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

(2) A food for special dietary use which is intended for ingestion in tablet, capsule, or liquid form shall not be deemed under section 403 to be misbranded solely because its label bears, in accordance with section 403 (i) (2), all the ingredients in the food. The labeling and advertising for any food for special dietary use which is intended for ingestion in tablet, capsule, or liquid form may not (A) list its ingredients which are not vitamins or minerals unless such ingredients (i) are listed in a list of all the ingredients of such food, or (ii) are subject to a regulation promulgated under section 403 (j), or (B) give prominence or emphasize the list of ingredients.

(b) (1) Subsection (a) (1) shall not apply in the case of a vitamin, mineral, or other ingredient of food which is (A) deemed adulterated under section 402, or (B) represented for a use with respect to which the vitamin, mineral, or other ingredient is an unsafe food additive under section 409.

(2) Subsection (a) (1) (B) or (a) (1) (C) shall not apply in the case of a vitamin, mineral, or other ingredient of food which—

(A) the Secretary requires by regulations promulgated under section 503 (b) (1) to be dispensed only upon prescription, or

(B) the Secretary determines is represented for use by children or pregnant or lactating women.

For purposes of subparagraph (B), the term 'children' means individuals who are under the age of twelve years.

(c) (1) Vitamins, minerals, and other ingredients of food shall be subject to all other provisions of this Act according to their terms, except as specifically provided by this section.

(2) A food for special dietary use which under section 201 (g) is also a drug shall be subject to the provisions of chapter V according to its terms.

(3) Subsection (a) (1) (A) shall not be construed to limit the authority of the Secretary to establish maximum limits on the potency of a synthetic or natural vitamin or mineral if such limits are prescribed in a regulation promulgated under section 503 (b) (1) requiring the vitamin or mineral to be dispensed only upon a prescription.

(d) For purposes of this section, the term 'special dietary use' as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

(1) Supplying a special dietary need that exists by reason of a physical, physiological, or other condition, including but not limited to the conditions convalescence, pregnancy, lactation, infancy, allergic hypersensivity to food, underweight, overweight, diabetes mellitus, or the need to control the intake of sodium.

(2) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

(3) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

(b) The Secretary of Health, Education, and Welfare shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act which is inconsistent with section 410 of such Act (as added by subsection (a)) and such amendments shall be promulgated in accordance with section 553 or title 5, United States Code.

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Sec. 2. (a) (1) Section 403 (a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343 (a)) is amended by inserting before the period at the end the following: "or, in the case of a food for special dietary use (as defined in section 410 (d)) which in intended for ingestion in tablet, capsule, or liquid form, its advertising is false or mis leading in any particular."

(2) Section 403 (j) of such Act is amended by inserting after "label" the following: "(or in the case of a food for special dietary use (as defined in section 410 (d)) which is intended for ingestion in tablet, capsule, or liquid form, its advertising)".

(b) Chapter VII of such Act is amended by adding after section 706 (21 U.S.C. 376) the following new section:

ADVERTISING OF A FOOD FOR SPECIAL DIETARY USE

Sec. 707. Before initiating any action under chapter III with respect to any food for special dietary use which is deemed to be misbranded under section 403 (a) or 403 (j) because of its advertising the Secretary shall consult with the Federal Trade Commission and, for the purpose of avoiding unnecessary duplication, coordinate such action with any action taken or proposed to be taken by the Commission under the Federal Trade Commission Act.

(c) The amendments made by subsection (a) shall take effect one hundred and eighty days after the date of the enactment of this Act.

NEW LIFE AND PERPETUAL MEMBERS

Perpetual

Roy A. Fellars, R. Ph.
Marjorie Robba
V. Fern Norton

Life

Florence Claffey
Mr. and Mrs. B. G. Devore
Daisy L. Mante, Ph.D.
Ruben Tamamian
Edna Schalebaum
Clara Badertscher
Mrs. Elizabeth Ann Lee
Georgia L. Brown
Ruth P. Lundquist
Kay Anderson
Kathleen A. Fischer
Earl B. Lively
Olga Benyo
Jim Beck
Rolland L. Waters
Jerry Hayes
Frederick and Eva Geiger
Mrs. Loretta M. Shearer
Mrs. Elva-May Brooks
Frances M. Miller
Ruby F. Williams
Helen Hoyer
Doris A. Mintonye
Mr. and Mrs. John P. Jones
Glenn S. Berg
Harold Eilts
Mrs. Marian D. Royle
Doris Blair
James P. Mosser and
Cynthia A. Ream
John V. Loudon
Julie Bellan
Jean Soich
Sandra Mattey
Charles R. Waters II
Caroline A. Sudduth

(Received mid-July through mid-August

Senate Health Subcommittee Holds Hearings On Proxmire Bill

Proponents and opponents of S. 2801, introduced by Senator Proxmire, presented their clashing testimony during two days of hearings before the Senate Labor and Public Welfare Health Subcommittee. The hearings, held on August 14 and 22, were called by Senator Edward Kennedy (D-Mass.), subcommittee chairman.

In opening the first of two days of hearings, Senator Kennedy said, "At issue is not only the important question of the responsibility of the federal government to safeguard the safety of marketed foods, but also its responsibility to assure that vitamins, minerals and food additives are not marketed in such a way as to lead the consumer to expect benefits for which no evidence exists. It is the delicate balance between that protection and infringement upon the rights of individuals to purchase and consume whatever foods they wish that we hope will be examined during these hearings." Kennedy made it clear he believes the FDA "has the responsibility to protect the American consumer against economic fraud. It must make certain that Americans are not led to believe that dietary products are therapeutic or in some other ways beneficial, when, in fact, they may be worthless and a waste of money."

The Real Issue: Is FDA Going To Play God?

Senator Proxmire (D-Wis.), who is the sponsor of S. 2801 with 44 other Senators, said, "The real issue is whether the Food and Drug Administration is going to play 'God'." He and other proponent witnesses challenged the classification of vitamins as "drugs" and also the concept of the RDAs. "If vitamins are to be called drugs and labelled and regulated as drugs on the grounds of toxicity," Proxmire said, "the FDA should logically regulate an entire group of other foods as drugs, including sugar, salt, coffee, tea, alcohol, and water."

Proxmire pointed out that vitamin or mineral products with potencies greater than 150% of the RDAs would be classified as a drug under FDA's regulation. This would mean, he said, that these products would have to state on their label the diseases or symptoms which the recommended dosage would prevent, cure or mitigate, in order to comply with present law applicable to all drugs. "This requirement for vitamins and minerals," Proxmire said, "is not only onerous but it is impossible."

Sen. Kennedy Hints Favor of FDA Control Over Advertising

Senator Kennedy has indicated that he, like Rep. Paul Rogers, favors strict control over advertis-

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ing of dietary supplements. Early in the hearings, Kennedy held up a copy of *Prevention* magazine and drew attention to an article on zinc in the magazine. He then drew attention to an advertisement for a zinc supplement. He asked Proxmire what he thought about this "problem." Proxmire replied with a very correct and well considered reply saying that if the ad was false, fraudulent or misleading, the FTC could act against it, but the First Amendment protected the article.

Though the matter was not persued further at the hearings, Kennedy's question is very significant and portrays the handwriting on the wall. If Congress gives FDA adequate authority to regulate advertising, it will, many believe, eventually rule that articles in a magazine are a part of the advertisement if the advertised product contains ingredients discussed in articles and will then declare that the product is fraudulently and misleadingly advertised. This is not far-fetched. Long ago FDA attempted to link the contents of certain books with the labels of certain products when they were both sold in the same store. Specifically, FDA declared a book advocating the use of brewers yeast and black strap molasses to be a part of the label of the yeast and molasses sold in the same store.

FDA Commissioner Strongly Defends Regulations

FDA Commissioner Schmidt presented a strong case for not approving the proposed legislation. He denied that the FDA was against all vitamins or any particular segment of the industry dealing with these products. He further declared that FDA has no intention of depriving people of any substance they wish to ingest unless there would be some hazard associated with that consumption. He warned that passage of the legislation would jeopardize consumer safety, give special and unlimited privileges to a select section of industry, and encourage consumer deception and fraud.

Sen. Schweiker Questions FDA's Ultimate Motives

Senator Schweiker (R-Pa.), a member of the subcommittee, challenged the FDA Commissioner frequently during the Commissioner's testimony. Schweiker wanted to know if FDA doesn't have enough authority now to deal with vitamins and minerals. Schmidt admitted that FDA does presently have the authority, but it would have to be used on a case-by-case, product-by-product basis and this would not be a wise expenditure. Schweiker also wanted to know why FDA thinks vitamins and minerals are more dangerous than sugar and liquor, especially since "everyone knows" that sugar can cause cavities. Schmidt replied that FDA has authority over sugar in cereals and liquor only so far as they make therapeutic claims. Schweiker expressed his concern that the FDA regulations would become more and more restrictive as time goes on and that the situation outlined by FDA now would change in the future.

Attending the hearings to support the FDA position and oppose the legislation under consideration, were representative members of the National Nutrition Consortium, composed of the American Society of Clinical Nutrition, the Institute of Food Technologists, American Institute of Nutrition, and the American Dietetic Association. Annie Galbraith, a registered dietition representing the latter organization, said many commercial enterprises in the "health" food industry are frequently not based on scientific knowledge and "appeal more to fad than fact." She said, "Enactment of the bill would seriously erode FDA's control of false and misleading health claims and would encourage the indiscriminate supplementation and/or fortification of foods with vitamins, minerals, and other substances which have no known benefit to health."

Dr. C. E. Butterworth, Chairman of AMA's Council on Foods and Nutrition, testified in opposition to the proposed legislation and said, among other things, that "the mere classification of a chemical compound as a 'vitamin' does not guarantee total safety at any level."

Panel of Eminent Scientists Support S. 2801

A panel present on August 14 to give testimony in support of S. 2801 consisted of Linus Pauling, Director of the Institute of Orthomolecular Medicine, Menlo Park, California; Roger J. Williams, University of Texas; Richard O. Brennan, International Academy of Preventive Medicine, Houston; Dr. George H. Mitchell, a family physician; Paul Buck, Assistant Professor of Food Sciences, Cornell University; and Unabelle Blackwood. The panel appearing on August 22 in support of the bill consisted of attorneys including Kirkpatrick W. Dilling representing the National Health Federation.

Linus Pauling discussed the "Recommended Daily Allowance" levels in considerable detail. He pointed out that "there is a general misunderstanding about these allowances." He explained that they are the amounts that, for most people, would prevent death or serious illness by vitamin deficiency disease, but are not the amounts that lead to the best health.

Roger Williams said the regulation of foods and drugs is two different things and the regulations suitable for one are not suitable for for the other. He emphasized that a nutrient is not a drug, regardless of potency or claims made for it, because of the difference in physiological actions of the two. Drugs, he said, are specific in their actions and work alone. Nutrients, on the other hand, he said, invariably work only in conjunction with other nutrients.

Brennan was strongly critical of the FDA. He said, "the American consumer has been so propogandized by the powerful interests that

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dominate and control the agri-food/chemical hierarchy, that he feels he cannot begin to think in simple terms regarding his food and his health." The average American, he said, "is so overwhelmed by the misinformation generated by this hierarchy, with the assistance of the FDA, that he no longer believes he has any right or ability to think for himself." He continued saying, "if the FDA is allowed to continue and strengthen its despotic attitude, it can only lead to grave consequences including more illnesses and earlier death for the American consumers."

Brennan further charged that the FDA was not aware that the removal of nutrients through overprocessing and cooking, and the addition of many additives to our foods, compound the toxic effects of poor food on the quality of health. "And to top it all off," he said, "the FDA is going to make it a crime to tell the truth about our food and our health status."

Kirkpatrick W. Dilling Testifies On Behalf of NHF

In his testimony on August 22, Kirkpatrick W. Dilling stressed that the bills under consideration simply define food supplements, employing verbatim the language of regulations enacted by FDA and in effect since 1955. Beyond that, he said that the pending bills pose but one issue, namely, the preservation of the consumers' freedom of choice to purchase safe food supplement products, honestly labeled, without dictation as to their nutritional composition.

Dilling further told the subcommittee members that contrary to what certain officials of FDA may have told the members of the Senate in an attempt to deter support for the bills, the enactment of the bills would in no way alter or lessen FDA's present authority to bar unsafe products or to control false or misleading labeling.

In criticizing the regulations, Dilling said, "The regulations in effect make it illegal, civilly and criminally, to distribute a special dietary food offering nutrients other than the thirteen vitamins and seven minerals listed in the regulations, and these arbitrarily limited as to quantity and as to combinations with any other nutrients commonly occurring together in ordinary foods. The regulations thus deprive consumers of the unquestioned right which they have had for more than 30 years to purchase products of composition and nutrient content they desire."

Dilling continued, saying, "The thirteen vitamins and seven minerals listed in the regulations do not consist of essential nutrients, but comprise only a minor proportion of the total number of nutrients known to be vital for human health. The regulations would cause at least thirty or more concedely vital and essential nutrients now available in special dietary foods to be arbitrarily and capriciously barred from inclusion."

FDA Staff Members Report Harassment and Suppression

Again evidence has come to the surface indicating that the drug companies supposedly being regulated by the FDA are, in fact, able to exert tremendous influence on highly placed officials within the Food and Drug Administration with the result that unfavorable reports on new drugs, under study for safety and efficacy, are frequently ignored or suppressed.

Recently, testifying under oath before a joint meeting of the Senate Judiciary and Labor-Welfare Committees, eleven FDA staff doctors told the Senate panel the FDA frequently suppresses unfavorable reports on new drugs and disciplines those who draft the reports. They cited numerous instances in which adverse reports on drugs were overturned by higher FDA officials. Some said that after making such reports, they were taken off the case and their drug study assigned to another doctor who subsequently recommended approval.

Six of the FDA staff doctors who testified said they were transferred to less important jobs and away from their field of expertise after speaking out against certain drugs or against FDA procedures. Dr. J. Marion Bryant, a cardiologist with the FDA said he was severely reprimanded by his bosses for speaking out on a drug he felt was exceedingly dangerous. He further said that after being harassed and reprimanded, he was transferred out of the agency's cardiology section after devoting more than 30 years to cardiology.

Another FDA staff member, Dr. B. L. Appleton, told how he was constantly harassed in the way he was trying to do his work and said that he finally discovered that his superior, at that time, was giving his findings to the drug company sponsor of the drug being reviewed.

Several of the witnesses said their unfavorable reports on drugs were later changed to reflect a more favorable finding. Obviously, this would be more favorable to the drug company seeking approval for the marketing of the drug. Others testified they were pressured by FDA officials to change or modify their recommendations to pave the way towards FDA approval of drugs they felt should not be marketed.

Dr. Carol Kennedy, a specialist on psychiatric drugs, said, "I've had significant portion of some of my reviews deleted" and then told of how she was transferred to a section that checked contact lenses after she voiced her criticism of FDA procedures.

(Continued on next page)

The joint meeting of the two Senate committees was held to investigate the nation's pharmaceutical industry and the government agencies that regulate it. Senator Edward Kennedy, D-Mass., who served as chairman, warned FDA officials against attempting to take "any administrative action" against the employees because of their testimony.

These latest revelations remind us of two earlier incidents which were reported in the June, 1972 issue of the *NHF Bulletin*. The earlier incidents involved two conscientious, dedicated FDA staff doctors who had just felt the retalitory muscles of the FDA high-ups.

Dr. John Nestor is a name which will long be remembered in connection with *Thalidomide* and *MER/29*, especially, because it was Dr. Nestor's honesty and determination which saved the public from inestimable harm from these two drugs. Thalidomine is a drug which caused hundreds of babies to be born with horrible deformities in Europe. Had it not been for Dr. Nestor's alertness and initiative, the drug probably would have been marketed in this country with a resulting repetition of the European disaster in this country.

MER/29 was a highly toxic drug manufactured by the drug firm, Richardson-Merrell, and was widely prescribed to lower blood cholesterol. Before Dr. Nestor was assigned to a study of the drug, it had been on the market for 15 months despite one study (made known before marketing) showing it caused cataracts in humans. Shortly after being assigned to the drug, Dr. Nestor found reason to doubt the drug's therapeutic effectiveness in addition to the cataract hazard. On the basis of problems of both safety and efficacy, Dr. Nestor urged FDA to halt the marketing of the drug, but, for reasons best known to the higher FDA officials, the drug was permitted to remain on the market, exposing thousands of people to the risk of cataracts. About a year later, Dr. Nestor traveled to the Richardson-Merrell Laboratory in Cincinnati. At the end of a two-day investigation, it became clear to Dr. Nestor that Richardson-Merrell had falsified data on animal studies of *MER/29*. Two days after that, Richardson-Merrell offered to remove *MER/29* from the market. Subsequently, 338 million dollars in suits for damages were filed against the Laboratory and grand jury indictments were returned against company officials for withholding information which led to varying degrees of blindness in an unknown number of Americans.

It would be logical to presume that Dr. Nestor's superiors would have high praise for his remarkable record of public service and possibly reward him with a promotion. Not so, however. On March 14, 1972, Dr. Nestor was abruptly informed that he was being transferred to the Office of Compliance. In the process, he was demoted from a medical specialist to a general medical officer.

Dr. John Winkler was the Acting Director of the Cardiopulmonary-Renal Division in which Dr. Nestor worked. Under the leadership of Dr. Winkler, augmented by the outstanding work of Dr. John Nestor, Dr. J. Marion Bryant, and many others, the Division developed the reputation of being extremely effective in performing a surveillance function over the drug industry to prevent drugs which can cause cancer, blindness, birth defects, etc. from being marketed.

Despite this excellent record, on March 3, 1972, Dr. Winkler was told he was being removed from his job and was offered the option of a supervisory job in another division (Surgical and Dental) without loss of rank, or of staying in the Cardiopulmonary - Renal Division and acepting the demotion to a nonsupervisory medical officer.

The Commisioner of the Food and Drug Administration, Dr. Alexander M. Schmidt, was called to testify also before the Senate panel where the eleven FDA staff doctors had previously testified. Schmidt acknowledge that while there may have been implied pressure on FDA employees from the drug industry in the past, there is no longer a 'dual standard" and that now, all recommendations against approval of new drugs are closely examined. Faced with the charges of retalitory transfers of certain staff doctors, he admitted that medical officers may have been transferred because they were needed in other areas, or because of "incompetence or unwillingness to do a job." This explanation falls rather flat however when the circumstances of Dr. Nestor's transfer are considered as an example. Dr. Nestor is a board-certified Pediatric Cardiologist. His expertise was being utilized in the Cardiopulmonary-Renal Division where he did the outstanding work mentioned above. Dr. Nestor testified before the panel that since his transfer two years ago, he hasn't done any work to earn his $36,000-a-year salary.

Schmidt testified further that he knows of no pattern of harassment of FDA employees and that the reported alterations or destructions of documents relating to the approval of medicinal drugs is contrary to agency policy. However, in all of his testimony at the Senate hearing, Dr. Schmidt left unrefuted the charges by 14 present and past employees and consultants that intimidation of subordinates and suppression of important data are commonplace in FDA.

The manipulated workings of the "vitamin hearings" held in 1968-1970, out of which came the currently pending dietary supplement regulations, are set forth in a Brief submitted to the U.S. Court of Appeals by Karl B. Lutz, et al. Copies of this Brief are available from NHF Headquarters for $2.00 per copy, postpaid. California residents add 12c sales tax.

New Light On the Therapeutic Usefulness Of Vitamin D

A Report of the Committee for Re-evaluation of Irradiated Ergosterol In Human Pathology

Prepared by J. YOGAMUNDI MOON

The work of two Canadian physicians in more than ten thousand cases, has shown the high intake of the natural form of Vitamin D to be both safe and therapeutically useful in a variety of conditions.

Most of the recognized essential nutritional factors have been associated with a specific deficiency syndrome resulting in humans and laboratory animals as a result of insufficient dietary consumption of that specific factor. Thus, vitamin C is generally thought of as the anti-scorbutic factor, thiamine is the specific remedy for beri-beri, niacin for pellagra, vitamin D for rickets, etc.

Such a limited point of view was acceptable during the early decades of the development of the nutritional sciences. It gave rise to important public health measures which have resulted in the virtual elimination of many of the classical nutritional deficiency diseases.

On the other hand, increasing knowledge concerning the mode of activity of these essential nutritional factors clearly demonstrates that every known vitamin factor *and* essential mineral and trace element performs an important function in *every living cell* in our bodies. It is no longer accurate to think that vitamin D is necessary only to build perfect skeletal structures.

Is There More Than One Form Of Vitamin D?

Although we have referred to "vitamin D" above as if it were a single, specific chemical compound, there are, in reality, a large number of chemical substances which, following irradiation with ultra-violet light, develop anti-rachitic properties—the properties which cause the substances to promote the absorption and utilization of calcium and thus prevent rickets. Thus, the term "vitamin D" is rather meaningless inasmuch as some of the forms are highly toxic in spite of having anti-rachitic properties.

The natural form of the vitamin (though it acts more like a hormone) is referred to as *vitamin D-3*. It is the form of the vitamin produced in the subcutaneous layers of the skin when we are exposed to sunshine. It is the form also that is found in certain fish liver oil although it is not understood how these deep sea fish synthesize such a rich supply of "D-3" without exposure to ultra violet light.

Though "D-3" is the only really natural form of the vitamin, there are over twenty different plant sterols which may be "activated" by exposure to ultra-violet light or by chemical reaction to have "vitamin D activity." Ergosterol is one such plant sterol and is the one most frequently irradiated to develop "vitamin D activity" but this should be regarded as a synthetic form. Technically, this form is referred to as *vitamin D-2* or irridiated ergosterol, the name printed on every container of milk sold in this country today. It is the form presently used to "fortify" a variety of foodstuffs in this country, i.e. dairy milk, canned milk, powdered milk, cocoa, ready-to-eat breakfast cereals, margarine, and many multi-vitamin supplements. In this writer's opinion, the term *toxisterol* most accurately describes this hormonal imposter of vitamin D-3. Vitamin D-2 should be more accurately referred to as a growth-promoting, age-inducing, *un*natural synthetic steroid hormone, a sister compound to diethylstilbestrol (DES). Vitamin D-2 is the subject of a future article in this *Bulletin*.

Unfortunately, the calcifying properties of vitamin D-3 are so spectacular that the involvement in muscular and nervous excitability has remained virtually unexplored. If it were not for the brave and continuous efforts of two great Canadian orthomolecular physicians, Drs. Carl Reich and John Bennett, this information would have been lost for decades to come. The price, in terms of human health, is incalculable.

Vitamin D-3 More Than A Calcifying Hormone

Classically, vitamin D-3 has been thought of as the calcifying vitamin. More recent research has indicated that the calcifying properties of vitamin D-3 are mediated via *hormonal* mechanisms, and consequently the lay press has tended to refer to vitamin D-3 as the *calcifying hormone*. This again, is a very limited point of view.

Vitamin D-3 is the parent chemical which gives rise to a number of hormonal derivatives which control blood calcium to phosphorus balance. All muscular activity is directly dependent upon calcium transfer, and, in fact, the presence of appropriate levels of calcium in the bathing medium of *every cell* is essential for appropriate cellular function.

"Spastic Conduit Diseases" The Reich Therapy

There is a relatively large group of common illnesses which is characterized by spasmodic contractions of involuntary smooth muscle encircling highly functional body conduits. Major examples of body conduits ("pipes") are: the arteries and arterioles, the intestine, and the bronchi of the lungs. Under healthful conditions and appropriate mineral balance, the smooth muscles encircling these body conduits are in continuous rhythmic motion, performing their vital body

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functions of transporting blood, oxygen, food and waste. Inappropriate mineral balance may cause healthful rhythmic contractions to give way to uncontrolled spastic contractions. Dr. Reich appropriately refers to this broad spectrum of illnesses as the "Spastic Conduit Diseases." (Table III)

Table I
Some Functions of
The Solar Generated Vitamin and Master Hormone D-3

Regulates calcium to phosphorous balance by:
- a) Intestinal calcium absorption.
- b) Bone calcium resorption.
- c) Renal calcium re-absorption.

Active in synthesis of:
- a) Brush border "calcium ATPase-alkaline phosphatase" complex.
- b) Calcium-binding protein.
- c) Vitamin D-binding protein (?).
- d) Proteins involved in bone calcium mobilization.

Utilized in formation of:
- a) 25-hydroxyvitamin D-3.
- b) 1, 25-dihydroxyvitamin D-3.
- c) 24, 25-dihydroxyvitamin D-3.
- d) 25, 26-dihydroxyfitamin D-3.
- e) Others (?).

Regulates function of:
- a) Parathyroid Hormone.
- b) Calcitonin.

Aids in maintenance of:
- a) Corticosteroid balance.
- b) Optimal blood cholesterol levels.
- c) Integrity of cardiovascular, nervous, and skeletal systems through maintenance of bone, nerve, blood, and muscle calcium to phosphorus balance.

In his study of the spastic conduit diseases, Dr. Reich has concentrated his efforts on bronchial asthma, a primary manifestation of this broad spectrum of illnesses. Using primarily vitamin D-3 in combination with vitamin A and bone meal, Dr. Reich has treated approximately 10,000 chronic asthmatics with results that exceed those of orthodox therapy with drugs. Complete blood profiles taken on approximately 50% of these patients during treatment that has been carried on continuously for up to six years has failed to reveal excessive blood calcium levels in one instance. Not one case of kidney stones or other pathology has yet been noted or brought to his attention by his associates. Dr. Reich now employs an initial dosage of approximately 7,000 I.U. of natural vitamin D-3 for adults. This dosage is reduced to 50% or less if beneficial results are attained or not attained. Patients are also encouraged to enjoy the beneficial effects of exposure to the healing rays of the sun.

Bennett Modification Of the Hoffer-Osmond Therapy

It is well-known to readers of the *Bulletin* that the orthomolecular approach to senility and various mental illnesses as introduced by Drs. Hoffer and Osmond in Canada is highly effective. This regime employs relatively large amounts of niacin, vitamin C, and other of the B-vitamins. Dr. J. B. Bennett in Sherwood Park, Alberta, Canada, recognizing the efficacy of the Hoffer-Osmond therapy, and also recognizing the frequent association between mental illnes and lack of exposure to sunshine, utilizes a combined Hoffer - Osmond - Reich regime with excellent results for the treatment of some forms of schizophrenia.

Mode of Activity and Functions Of Vitamin D-3

Prior to 1970 it was commonly believed that vitamin D-3 exerted its physiological functions directly, as do other vitamins. Since that time, however, it has been demonstrated that vitamin D must first be metabolized to other chemical entities which are the true active forms of the vitamin. These newly-discovered forms of vitamin D are produced in one particular organ of the body and poured into the blood stream to be carried to their site of activity elsewhere in the body. This is clearly a characteristic of hormones, not vitamins, and vitamin D has consequently been reclassified as a *steroid hormone.*

In its hormonal capacity, vitamin D-3 performs a number of very important functions. It regulates virtually all phases of calcium and phosphorus metabolism in the human body, thereby maintaining the integrity of the cardiovascular system, and promoting the perfect functioning of the neuro-muscular system. In order to accomplish this, vitamin D-3 induces the synthesis of a number of very important proteins, controls the function of other hormones (parathyroid hormone and calcitonin), and maintains corticosteroid hormone balance and cholesterol levels. Some of the many known functions of the solar-generated vitamin and master hormone D-3 are listed in Table I.

Table II
Some Illnesses
Reported to Respond to Vitamin D-3

Organs Involved	Illnesses
Joints	Osteoarthritis*
	Rheumatoid arthritis*
	Bursitis*
Bones	Rickets
	Osteomalacia
Lungs	Bronchial asthma**
	Pulmonary tuberculosis**
	Pulmonary Pneumonia**
Eyes	Myopia**
	Cataract**
Heart	Coronary Spasms
Skin*,**	Eczema, Psoriasis, Acne, Burns, Wounds
Blood, Nerves, Muscle	Nervous and muscular hyper-excitability
	Spasmophilia (Infantile Tetany)
	Convulsions
	Some forms of Schizophrenia

*Fish liver oil both topically applied and orally ingested.

**Optimal response depends on presence of vitamin A. Vitamin A occurs in all natural vitamin D-3 sources and preparations, where it effectively prevents toxic manifestations and has beneficial effects above and beyond those of Vitamin D-3 alone.

Vitamin D-3 Deficiency In Human Pathology

Since vitamin D-3 has so many documented important functions in

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human physiology, it should not be surprising that a deficiency of this solar - generated vitamin/hormone might give rise to a broad spectrum of human illnesses. Illnesses which are reported in the medical literature to respond to vitamin D-3 are listed in Table II. Table III lists and classifies those illnesses which are believed to be a direct result of vitamin D-3 deficiency.

Table III
Classification of the Vitamin D-3 Deficiency Diseases

A. Mineral Transfer Diseases:
- Rickets
- Osteomalacia
- Infantile Tetany
- Osteoporosis
- Rheumatoid Arthritis
- Pre-senile Osteoarthritis

B. Spastic Conduit Diseases*
- Bronchiolar Spasms (Asthma)
- Coronary Spasms (Coronary heart Attack)
- Peripheral Artery Spasms (Hypertension)
- Gastrointestinal Spasm
  - —stomach (gastric spasms and gastric ulcer)
  - —duodenum (duodenal ulcer)
  - —ileum (ileitis)
  - —colon (colitis, constipation)
- Cerebral spasm
  - —large temporal artery (migrane)
- Genitourinary spasm
  - —bladder (enuresis)

*The Spastic Conduit Diseases may be further classified as direct or indirect vitamin D-3 and mineral deficiency diseases. The direct diseases are due to deficiency influences causing ionic misproportion in the conduits themselves, while the indirect effect is mediated via the autonomic nervous system.

The classical vitamin D-3 defiency diseases, rickets, osteomalacia, and infantile tetany, are mineral transfer diseases indirectly attributable to a deficiency of solar ultraviolet radiation which results from the many influences of industrialization, i.e., smog, big city shade, better clothing and transportation, etc.

As these factors which decrease availability of the healing rays of the sun—the source of all physical life on this planet—become more prevalent, and with no common food to supply this important nutrient, the liklihood exists that vitamin D-3 deficiency diseases are among the most prevalent illnesses in this and other industrial societies.

STATUS OF DES

DES (diethylstilbestrol) is a growth stimulant used for years by cattle feeders to fatten their animals. However, DES was banned last year because the hormone is known to be cancer-causing and traces of it were showing up in the liver of some slaughtered animals. The ban was ruled illegal last January by a federal court because the FDA hadn't held public hearings on the matter.

Legally, cattle feeders can now use the hormone but few are doing so because they don't know what FDA might do and anyway DES is scarce and expensive because only one DES maker has resumed production.

Mass Harm From Fluoridation

By LEE HARDY

No. 13 In A Series

On March 24, 1952, Dr. A. L. Miller, Congressman from Nebraska and formerly State Health Director, apologized to the members of Congress for having introduced legislation which led to the fluoridation of the water supply of the District of Columbia. He had been led to believe, he said, that the U.S. Public Health Service had researched all aspects of fluoridation before they had recommended it to the people of this nation. Hearings before the Special Commission on Chemicals in Foods had opened his eyes to things he had not known. "I was mislead," he said, "by the United States Public Health Service."[1]

In extension of his remarks in the Congressional Record Appendix Dr. Miller questioned the effect of fluoridated water on children or adults who were acutely or chronically ill. He also produced figures to justify his concern. "A check of vital statistics of Grand Rapids, Mich.,—which is the only city of any size that has had artificial fluoridation for more than four years—shows that the death rate from heart disease in the year 1944 numbered 585. Four years later, after fluoridation had started (in 1945), there were 1,059 deaths. There was an increase of 50 per cent in the deaths from nephritis. There was an increase of 50 percent, over a period of four years, in the deaths from intercranial lesions. These figures are contained in the Vital Statistics of the United States published annually by the United States Public Health Service."[2]

There was a prompt attempt at refutation, with claims that Dr. Miller's figures were erroneous. However, there appears to be no mistake of major import in the figures given. An editorial in the Grand Rapids *Herald*, August 7, 1955, stated: "The City - County Health Department has been allotted $5,000.00 in federal funds to learn why the death rate from major diseases is higher in Grand Rapids than throughout Michigan." the editorial quotes Dr. W. B. Prothro, Health Officer, as admitting that in 1950 deaths per 100,000 population due to heart ailments were 403.9 for Grand Rapids, as compared with 322.1 for the whole of Michigan; deaths from cancer, 189.2 for Grand Rapids, 136.6 state-

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wide; from intercranial lesions (stroke), 149.6 for Grand Rapids, 100.1 for the entire state.

Dr. Miller admitted error in one figure he had given.[3] The 1.059 deaths from heart disease were for the whole of Kent County, which totaled 28 more than the city of Grand Rapids figure. "The Bureau of Vital Statistics tells me," he said, "there has been some revision of the classification in recording deaths in 1949 . . . The deaths from heart disease under the new classification for Grand Rapids show an increase from 585 deaths in 1944 to 1.031 in 1949." The additional 446 deaths above the 1944 figure amount to an increase of 76% in the four years of fluoridation. The increase in population of Grand Rapids during that period was approximately eight per cent.

An editorial in the Newburgh, New York, *News*, January 27, 1954, after nine years of fluoridation, states: "According to statistics now being released by the Government, heart disease, our leading menace, is responsible for a larger proportion of deaths in Newburgh than in most other sections of the United States. The 283 heart deaths in Newburgh in the (designated) year were equal to a rate of 882 deaths per 100,000 population. This was more than the rate for the nation as a whole, 507 per 100,000 population. It was also higher than the Middle Atlantic States rate, 590 heart deaths per 100,000." By these figures, heart deaths in Newburgh were 73.9% higher than the national rate.

Not only have human lives been lost on account of fluoridation. Philadelphia's water supply was fluoridated in 1954. In an article by H. L. Ratcliffe, published in the Annals of New York Academy of Sciences in 1965,[4] graphs were given to show that roughly 70% of the birds on exhibition in the Philadelphia Zoological Garden in the period 1959-1963 developed coronary artery disease as compared with 16% in the period 1940-1944. For mammals the figures were approximately 93%, as compared with 13%.

Among more recently revealed mortality figures for humans from fluoridation are those from Antigo, Wisconsin. Antigo water was fluoridated in 1949. Deaths from heart disease were compiled from death certificates for Antigo residents by Isabel Jansen, R.N., and compared with heart deaths for the entire nation. The compilation shows that during the five-year period 1946-50 Antigo heart deaths were 86.4 per 100,000 lower than the national rate (244.5, compared with 330.9). By the 1960-64 five-year period Antigo heart deaths had increased to exceed the national rate by 110.7 per 100,000. Fluoridation was terminated in 1960. Still, by the 1963-67 period the excess over the national rate had increased to 186.7 per 100,000 before a leveling off began. It is apparent that harm from fluoridation does not cease immediately when fluoridation is stopped.

In the examples given here a pattern emerges which cannot be disregarded. As indicated by the Grand Rapids mortality data, the increase in deaths in fluoridated areas is not limited to heart fatalities. These are data which communities contemplating fluoridation would do well to consider.

1. Miller, A. L., Extension of Remarks, Cong. Record Appendix, Vol. 98, Part 9, P. 1833.
2. Ibid., P. 1834.
3. Ibid., P. 2791.
4. Radcliffe, H. L., *Age and Environment as Factors in the Nature and Frequency of Cardiovascular Lesions of Mammals and Birds in the Philadelphia Zoological Garden,* Annals of the New York Acad. of Sciences, 127:715-735, 1965.

Heart Deaths per 100,000, Antigo, Wisconsin—United States

Period covered	Antigo, Wis.	U.S.	Diff. per 100,000
*1946-50	244.5	330.9	—(86.4)
7-51	282.4	340.8	(58.4)
8-52	283.9	347.8	(63.9)
9-53	275.7	355.3	(79.6)
1950-54	296.2	355.2	(59.0)
1-55	337.5	355.4	(17.9)
2-56	352.6	356.5	(3.9)
3-57	359.4	359.1	+ .3
4-58	409.3	360.6	48.7
1955-59	410.0	363.6	46.4
6-60	398.5	366.1	32.4
7-61	412.4	366.3	46.1
8-62	430.7	366.5	64.2
9-63	449.8	368.1	81.7
1960-64	479.4	368.6	110.8
1-65	539.8	368.2	171.6
2-66	541.5	370.0	171.5
3-67	555.6	368.9	186.7
4-68	547.5	368.3	179.2
1965-69	544.0	368.0	176.0
6-70	542.7	366.2	176.5
20-year increase per 100,000	298.2	35.3	262.9

—( ) U.S. in excess over Antigo, Wis. per 100,000

— Antigo, Wis. in excess over U.S. per 100,000

* Five-year moving average

Records from State of Wisconsin and Langlade County, Wis. vital statistics, U.S.P.H.S. and U.S. Census Bureau.

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TWO KEY QUESTIONS ABOUT FLUORIDATION

By JOHN YIAMOUYIANNIS

Is fluoride at 1 part per million in the drinking water an optimal level or an overdose?

Optimal nutritional levels of fluoride appear to be in the range of 0.1 to 0.3 parts per million fluoride and certainly no more than 0.4 ppm. At levels greater than 0.4 ppm mottling occurs[1] whereas at levels below 0.3 ppm mottling is virtually nonexistent. While fluoride at 0.1 to 0.3 ppm appears to be of value, it has never been shown to be essential to human life or any other for that matter. In other words, fluoride is not an essential nutrient.

MODE OF ACTION

There have been a number of reports disputing the contention that fluoride is associated with harder teeth or that it protects teeth against dissolution by weak acids.[2]

Much evidence points to the conclusion that whatever decay preventative effect 1 ppm fluoride has, it is by virtue of its effect on oral bacteria.[3] Fluoride decreases the amount of lactic acid formation of oral bacteria which are digesting residual food particles on the teeth, thereby reducing the acid formed, resulting in a lower incidence of caries.[4]

Fluoride inhibits the enzyme *enolase*, one of the enzymes responsible for the formation of lactic acid from glucose (glycolysis). Another inhibitor of enolase, Ca *a*-glycerol phosphate, also decreases the frequency of dental caries and is twice as effective as fluoride and yet completely safe since, unlike fluoride, it can be metabolized by intestinal bacteria[5] via *a*-glycerol-phosphate dehydrogenase.

Is fluoride at 1 ppm safe and effective?

Two studies from the laboratories of A. A. Petina conclude that in areas of fluoride pollution, water fluoride levels should not exceed 0.5 ppm and in areas of no fluoride pollution, water fluoride levels should not exceed 0.8 ppm. Toxic effects of fluoride were found when water fluoride levels were 1.0 and 1.5 ppm.[6]

A number of studies have shown that oral bacteria are becoming resistant to fluoride.[7] This would result in a loss in the effectiveness of 1 ppm fluoride in caries prevention. In a recent study, the optimal level for decay prevention was shown between 0.2 and 0.4 ppm fluoride in the drinking water and that at 1 ppm in the drinking water, decay rate increased.[8] In a study by R. Ziegelbecker, it was found that after a certain time, fluoridated teeth became carious faster.[9]

Fluoride (at 1 ppm) causes an increase in calculus formation.[10] Fluoridation has also been associated with gum resorption.[11]

Since the Food and Drug Administration has allowed the following statement to be made, it must concur with Colgate when it states, "Only your dentist can give teeth a better fluoride treatment than Colgate." This would imply that whatever the value of drinking fluoridated water would be to teeth, it would have to be less than getting a topical fluoride treatment from the dentist or brushing with Colgate. However, N. C. Cons. et al. of the Bureau of Dental Health of the New York Department of Health showed that topical fluoride, as applied by dentists, is practically ineffective in reducing the incidence of caries.[12] Thus, one would have to conclude that fluoridated water is even less than practically ineffective in reducing the incidence of caries.

When fluoridated water (1 ppm) is taken internally, as with oral bacterial metabolism, intestinal metabolism is also disturbed leading to chronic gastrointestinal disorders.

When fluoride is absorbed into the blood, it produces erratic blood levels of glucose, lactic acid, pyruvic acid, enzymes, etc.[13] There it also mimicks the effects of hormones such as adrenaline and the thyroid-stimulating hormone (TSH), by stimulating adenyl cyclase.[14]

Further, fluoride accumulates[15] in bones[16] and interferes with RBC formation and metabolism, in teeth leading to mottling, in kidneys leading to nephrotoxicity,[17] in thyroid leading to metabolic disturbances,[18] in reproductive organs leading to mongolism,[19] and in liver where it causes changes in the peripheral areas of the liver lobule[20] and alters its metabolism.[21] In addition, specific allergies to fluoride have been reported.[22]

1. Y. Imai, *Koku Eisei Gakkali Zasshi* 22(2) 285-284 (1972) and R. S. Nahda, *Ind. J. Med. Res.* 60 (10) 1470-82 (1972).
2. Masaaki Sato, *Koku Eisei Gakkai Zasshi* 21 (4) 279-285- (1971); F. Marci, et al., *Ann Fac. Med. Chir. Univ. Studi Perugia* 59 (2) 363-71 (1967).
3. Hsueh-Wan Kwan. *J. Dent. Res.* 50 (2) (Pt. 2) 331-3 (1971).
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THE FAMILY CIRCLE

By CHARLES I. CRECELIUS
President of the National Health Federation

We have just passed three milestones in connection with our legal and legislative efforts to block the implementation of FDA's pending dietary supplement regulations against which we have battled so diligently. All within the space of two weeks, the U.S. Court of Appeals rendered its decision following its review of the regulations—an action initiated by a petition filed by NHF and independently by a number of other groups, firms and individuals. Also the House Subcommittee on Health and Environment held its long awaited "mark-up" session on the Hosmer bill, and, at about the same time, the Senate Health Subcommittee held hearings on the Proxmire bill (S. 2801), a bill, which like that introduced by Rep. Hosmer, would virtually nullify the FDA regulations. Each of these three events is extremely important to every nutrition-oriented American. The outcome of this current battle will determine the extent to which a government bureau will be able to dictate and control your nutritional program and your quest for health. Needless to say, NHF has in the past, and will continue in the future, to throw all its force and resources into this battle.

Our Washington, D.C. office has moved. We outgrew the former office long ago but continued on in that location because of its convenience to the capitol complex—practically across the street. Office space is virtually unavailable in that same area so after much searching and prayerful thought on the matter, we finally settled on adequate and desirable office space in Arlington, Virginia.

Speaking of moving, members who plan to move should send their change of address to the Monrovia headquarters just as soon as the new address has been determined. We don't want you to miss a single copy of the **Bulletin** or any other important announcement we may mail to you. Ordinarily the post office will not forward second or third class mail unless the individual has indicated a willingness to pay forwarding postage.

The response to our annual Liberty Stamp Drive this year has been somewhat below that of the previous years, chiefly because fewer members have responded. This has been unfortunate because we are more desperately in need of these funds this year than ever before because of the heavy costs involved in the legal and legislative fight against the vitamin regulations. We would like to remind our members that it is never too late to send in a contribution—so if you are one of those who had good intentions but somehow just failed to get your contribution into the mail, it will be just as gratefully received now.

FOOD - *Green Grow the Profits*

How billionaire companies collectively identified as *Agribusiness* dominate food production and distribution in the United States is revealed in a startling fashion in a new booklet reproduced and being made available by the National Health Federation. The booklet presents transcribed interviews conducted in 1973 on an ABC network TV program, *Food – Green Grow the Profits.* The booklet reveals the changes underway in these vital food production and processing industries that so directly affect the health of the nation's people. The following excerpts (portions of interviews) will give you an idea of how valuable this booklet can be as an educational tool:

"Del Monte and Hunt and Heinz and the giant processors wanted to mechanically harvest tomatoes because they wanted to eliminate labor in the fields. And the land grant colleges said Yes, we'll do that for you. So they genetically redesigned the tomato. But then they had to harvest the tomatoes green because they still aren't hard enough. So they developed a system of applying ethylene gas to tomatoes, which turns them red, uniformly and at the same time. They're chemically ripened. Now they've isolated 70 chemicals that cause flavor in tomatoes and they are going to artificially inject those back into that tomato."

As to special treatment scheduled for chickens of the future, the report continues:

"This chicken that I am holding is called a "naked neck"—obviously because of the fact that it has no feathers on its neck. I am looking into the possibility of developing this into a commercial strain because in processing, one of the processing problems is the fact that when the chicken is killed, and the head cut off, there is usually a ring of feathers in this area that has to be removed by hand, and it is very difficult to remove. There is another mutation called "naked" in which the entire bird may have a total of three or four feathers. If you think this is a weird looking bird then you should see the naked bird."

"The instruments in this room are all being used to attempt to solve the problem of chicken flavor and what compounds or materials are responsible for what we call chicken flavor. This problem arose be-

(Continued on next page)

cause certain people questioned whether a modern chicken is equal to the chicken that grew up on grandpa's farm. So we trap the small amounts of material such as this, and this is equivalent to about ten pounds of chicken. What we hope to do is find that maybe five or six or seven major or minor components will reproduce the odor of chicken, and help the feed formulators decide on a diet that would produce the superior flavor chickens."

Again we are reminded that "the feed is heavily laced with arsenic."

Growing and processing changes are being planned for many of the foods processed by AGRICULTURE including peaches and cantaloupes. From direct statements and reading between the lines, one can clearly see the new holy alliance between government and Agribusiness companies. You will read *Food—Green Grow the Profits* with great interest and find that skeptical friends and neighbors may be more impressed with the message than from any other piece of literature you might share with them.

We are adding it to our Reprint List. Single copies 50c; 3 for $1.

NHF's reproduction of the booklet, *Food—Green Grow the Profits,* has just come off the press and is now available from NHF Headquarters, P.O. Box 688, Monrovia, California 91016. Single copies, 50c or three copies for $1.00, mailed postpaid all to one address. California residents should add 6% sales tax.

JUVENILE DIPLOMAT

Billy had been to a birthday party and, knowing his weakness, his mother looked him straight in the eye and said, "I hope you didn't ask Mrs. Parker to give you a second piece of cake?"

"No," replied Billy, "I told Mrs. Parker I wanted the recipe so you could make some more like it, and she gave me two more piece without my asking."

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."

Book Reviews

THE HERB MASTER'S INDEX—Part I consisting of 30 5x8 inch durable cards, printed two sides, $2.00. Part II consisting of 28 5x8 cards, printed two sides, $2.00. Parts I and II ordered together, $3.75. Published by The Herb Master, Camp Wood Route, Prescott, Arizona 86301.

The total of 58 cards contained in the two parts of this unique publication may sound somewhat unimpressive but on these 58 cards is a wealth of practical information so concisely stated, there is not a wasted word.

Part I deals with 21 common disorders, alphabetically arranged beginning with Alcoholism and ending with Worms. The causes, symptoms, general rules to follow, and the specific herbal treatments are concisely listed for each of the 21 disorders. In addition, the set also provides a glossary of terms necesary for the implementation of treatments, and a list of the herbs used, giving botanical names and uses.

Part II provides an amazing amount of information on a number of subjects with more than half being devoted to pregnancy and the

(Continued on next page)

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

R. A. Laurye, Business Administrator

care of infants and small children. Offered are general rules to follow during pregnancy with specific suggestions for diet and here we find some interesting recipes. There are sections dealing with breastfeeding, formulas for the bottle-fed baby, and numerous suggestions for the preparation of foods and drinks for the baby. Included also in Part II is a section dealing with poultices using herbs or other natural substances which may be worth the cost of the entire set.

* * *

THE COMPLETE HERBAL GUIDE TO NATURAL HEALTH AND BEAUTY. Dian Dincin Buchman (Garden City, New York: Doubleday & Company, Inc.; 1973). 221 pages, paperback, $2.95. Index. Chart for Botanical, Pharmaceutical and Food Usage.

This book is unusually complete; it tells one how to collect and dry herbs, or if this is not possible, where to purchase them; then there are instructions for how, when, and where they are to be used.

Dian Buchman's *Complete Herbal Guide To Natural Health And Beauty* is a sort of "encyclopedia" for the use of herbs for skin, bathing, hair, eyes, mouth and teeth, hands, feet, sleep, and perfumes. She gives recipes for skin cleansers, creams, natural deodorants, hair conditioners, mouthwashes, and aids to sleeping, etc. Since herbs are not readily available to everyone, she has also included sources where one may purchase herbs by mail. The Botanical, Pharmaceutical, Food Usage Chart in the back of the book lists approximately 250 herbs and the how and what of their use.

—Marilyn Ramsey

Your Invitation To Join
THE NATIONAL HEALTH FEDERATION

Name (Print).....

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City..... State..... Zip.....

☐ I wish to become a REGULAR MEMBER of the NHF and am enclosing $5.00 as yearly dues. $1.50 of which is for a subscription to the BULLETIN for the current year.

☐ New subscription. ☐ Renewal subscription.

☐ I wish to become a SUSTAINING MEMBER and am enclosing $.....(minimum fee, $25.00) as membership dues for the current year. $1.50 of which is for a subscription to the BULLETIN.

☐ I wish to become a LIFE MEMBER and will pay the sum of $.....each month until the sum of $100.00 is reached.

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☐ Enclosed please find a donation of $.....for the Washington Office.

☐ Enclosed is a donation of $.....for the NHF Legal Defense Fund.

☐ Enclosed in a donation of $.....to be used for.....

☐ I wish to pledge $.....per month/per quarter/per year (check which applicable) in support of NHF.

Mail to: The National Health Federation, P.O. Box 688, Monrovia, California 91016

THIS IS THE
NATIONAL HEALTH FEDERATION

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

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

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

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

Will you join us in this worthy effort?

ELECTED FEDERATION OFFICERS

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

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

Betty Lee Morales — Secretary

Dorothy B. Hart — Treasurer

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

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

PAID FEDERATION STAFF AND THEIR FIELDS OF ACTIVITY

Clinton R. Miller — Vice President in charge of the Washington Office, which includes Legislation and Regulations.
Address: 4600 Lee Highway, Arlington, Virginia 22207

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

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

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

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

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

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

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

COMING NHF CONVENTIONS

San Bernardino — S. B. Conv. Center....**Oct. 12-13**
Salt Lake City — Salt Palace ..... **Oct. 25-26**
New York — Statler-Hilton Hotel ..... **Nov. 16-17**
Annual West Coast NHF Convention
Anaheim Convention Center.....January 15-18

HELP SAVE OUR HEALTH FREEDOMS