National Health Federation BULLETIN

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Update On NHF's Legislative and Legal Activities

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LOW THYROID FUNCTION
Is It Sapping Your Energy?

A remarkably simple temperature test for low thyroid function may give the clue to undue fatigue, skin disorders, infections, headaches and even to a hidden cause of heart attacks. If you have vague, undiagnosed complaints, this test may save you both time and money.

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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Update On NHF Activities . . .

The Hosmer-Proxmire Bills

Progress can be reported in connection with the legislation pending in both the House and the Senate which would block the implementation and, in fact, void most of the sections of FDA's pending dietary supplement regulations. In the Senate (as of April 15th), a total of 37 senators have sponsored or cosponsored such legislation, originally introduced in the Senate by Senator William Proxmire. Intensive lobbying efforts are being directed towards getting additional cosponsors and with the help of NHF members and friends in continuing to write their own U.S. Senators, we could soon have the additional 16 cosponsors needed to give us a clear majority of the Senate committed to the legislation. In the meantime, early hearings on the bills by the Senate Health Subcommittee are imperative. The subcommittee is chaired by Senator Edward Kennedy who has not, so far, been inclined to schedule hearings. In fact, Kennedy has expressed an opinion that the subcommittee should wait until the House acts on the Hosmer bill.

In the House, the Hosmer and related bills are still pending in the House Subcommittee on Public Health and Environment, chaired by Rep. Paul Rogers (Florida), in spite of the fact that seven of the eleven members of the subcommittee and a total of 229 congressmen have either cosponsored the Hosmer bill or have introducd a similar bill on their own. In defense of the subcommittee's delay in reporting out a bill following hearing held in October, 1973, it should be mentioned that Rep. Rogers is not actually opposed to a Hosmer-type bill but that the subcommittee is currently involved with other important and urgent legislation, some of which must be enacted into law before July 1 since it replaces certain environmental legislation previously passed but due to terminate June 30, 1974. However, it is the contention of the supporters of the Hosmer bill that in view of the fact a majority of the subcommittee members are committed to a strong Hosmer-type bill, the subcommittee "mark-up" session should take only a few hours and should be done without further delay.

Winning over a clear majority of the subcommittee members, to the point where they sponsored or cosponsored a Hosmer-type bill, has been the direct result, in some cases, of NHF's most recent strategy of holding one-day public meetings in the home districts of the then uncommitted members of the subcommittee in order to

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enhance the home district grass-roots support for the legislation. NHF engaged the services of Dr. Carlton Fredericks for this project. Dr. Fredericks, of course, is an authority in the field of nutrition and is widely known through his books, lectures and his radio and TV appearances. Dr. Fredericks and Clinton Miller, as a team, have conducted the one-day meetings to tell the NHF story but more particularly to inform their audiences of all the ramifications of the FDA food supplement regulations. The result has been the establishment of solid grass-roots support for the legislation which the members of the audiences conveyed to their respective representatives. In addition to their platform appearances, Dr. Fredericks and Clinton Miller were afforded the opportunity to appear on local radio and TV programs in many of the areas, thus greatly expanding their audience.

NHF's Court Action Against FDA's Vitamins A and D Regulations

Subsequent to the issuance of new regulations by the Food and Drug Administration which became effective on October 1, 1973, NHF filed an action in a Federal District Court in Chicago seeking injunctive relief and asking the court to declare that the regulations were not promulgated in accordance with the law inasmuch as no hearings were held prior to issuance of the regulations and that FDA exceeded its statutory authority in this matter, and to thus declare the regulations null and void until proper hearings are held as required by law.

The regulations in question classified all products containing in excess of 10,000 units of Vitamin A and/or 400 units of Vitamin D, in the daily label-recommended intake, as prescription drugs and thus not available except on prescription by a physician.

On March 22, Judge Parsons dismissed the suit stating the FDA Commissioner Schmidt was merely "interpreting" prescription drug statutes when he arbitrarily limited the amounts of Vitamins A and D available over-the-counter without a prescription. In rendering his decision, Judge Parson largely dodged the issue of our right to hearings. NHF has until April 21 to file a Notice of Appeal.

Court Actions Seeking Judicial Review of FDA's Dietary Supplement Regulations

Within a month or two following the issuance of FDA's **final** dietary supplement Order on August 2, 1973, a number of court actions were initiated in various parts of the country by several individuals, organizations, business firms, and trade organizations. The National Health Federation was one of these, of course. The actions were similar inasmuch as in each case, a petition was filed asking the Federal District Court of Appeals to review the FDA Order to determine, principally, whether or not the FDA has the constitutional authority to promulgate such regulations and whether or not the regulations are based on the best evidence presented during the hearings (1968-1970) on the then proposed regulations.

After a series of legal maneuvers, the cases have been consolidated and will be heard in the Federal District Court of Appeals located in New York City. In one of the early moves of the Court, petitioner's briefs were limited to no more than 50 pages and March 15 was set as the last day for the filing of said briefs. A summary of the brief filed by Kirkpatrick W. Dilling, attorney, on behalf of the National Health Federation is printed on other pages of this issue of the **Bulletin.** The FDA has 60 days to prepare and file its reply. The petitioners then have an additional 30 days to reply to the FDA filing. Chances are, the case will not be scheduled for hearing until at least mid-summer.

FDA Replies To NHF's Fluoride Petition

In January, 1973, Arthur Koch, attorney, acting in behalf of the National Health Federation, prepared and filed with the Food and Drug Administration a "Petition To Have The Food and Drug Administration Classify Fluoridated Water As A Drug Under 21 U.S.C. 321(g) and To Have Fluoridated Water Meet The Rules and Regulations That Apply To All Other Drugs."

The petition noted that the Food, Drug and Cosmetic Act classified as a drug any article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and further noted that the sole intention for fluoridating water is to aid in the *prevention* of tooth decay. Accordingly, therefore, NHF argued that fluoridated water clearly and decisively meets the statutory definition of a drug. This argument was further strengthened by the note that after making some exception, the FDA had previously concluded that "with the exception of certain dentifrices which have been excluded from prescription - dispensing requirements, preparations containing added fluorine compounds should be limited to sale on the prescription of practitioners licensed by law to administer drugs . . ." Accordingly, NHF requested that individual consumers be allowed to follow the implied warning of the Food and Drug Administration that fluoride-containing components may be harmful to human health.

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Drugs are subject to very specific regulations. First, drugs must be shown through exhaustive and controlled tests to be both safe and effective. Further, all drugs are required to be labeled with indications for use (conditions for which the drug has been proved effective), the dosage established generally as being both safe and effective, any contraindications for its use, and any potential hazards incident to its use including the listing of the most common symptoms which may indicate adverse reactions to the drug.

Obviously, the consumers of fluoridated public water are denied the benefits of such labeling. Accordingly, the NHF Petition asked, "... where is the logic of the FDA decision to allow this drug to be freely put into public drinking water? Shouldn't the individual consumer who uses the public water supply, at the very least, have the opportunity to know about the warnings and precautions that currently accompany fluoride products only when they are sold on a prescription basis? It should be noted that each person who takes one of the fluoride prescription products has the opportunity of being warned by his physician—since these drugs are declared not safe 'except under the supervision of a practitioner licensed by law to administer such drug.' The consumer of public water has no such opportunity."

Finally, after the passage of over a year of time, FDA replied to the petition. The reply was in the form of an 11-page single-spaced typed letter bearing the signature of Alexander M. Schmidt, Commissioner of FDA. In short, the petition was denied which came as no particular surprise to NHF. It had been previously assumed that the matter would eventually have to be settled in court.

FDA's position in the matters contained in the petition is fairly well summarized in the following paragraph contained in the 11-page letter:

"The petition erroneously concludes that fluoridated water is a drug under the Federal Food, Drug and Cosmetic Act. It is instead a nutrient, necessary in normal diets to assure good health, and is therefore properly regulated as a food. Moreover, the petition erroneously concludes that additional requirements, such as warnings, would be necessary if fluoridated water were treated as a drug. Actually, the requested changes would result in no difference in requirements. Thus, reclassification would be purely a formality having no practical effect on the distribution of fluoridated water. For these reasons the petition is denied.

MORE SPENT FOR HEALTH

National expenditures on health care rose from $78.35 per person in 1969 to $394.16 per person in 1972. The per capita cost will be $757 by 1980, health economists predict. The changing nature of medical care and inflation are contributing to the expanded medical bill, they say.

NHF Files Brief In Petition For Court Review Of FDA's Vitamin Regulations

Following the issuance of the final dietary supplement regulations on August 2, 1973 by FDA, a number of organizations, firms and individuals filed actions in scattered U.S. Courts of Appeal petitioning the courts to review the Orders and to rule, mainly, on whether or not FDA had exceeded its legal authority in promulgating such regulations and whether or not the FDA Commissioner's findings of fact (based on the testimony presented during the food supplement hearings in 1968-1970) adequately and legally support the regulations contained in the Order.

The scattered cases filed in many parts of the country have been consolidated and will be heard in the U.S. Court of Appeals for the Second District (New York). Although no date has yet been set for oral arguments in the case, in one of the first moves, the court ruled that all briefs submitted must be limited to 50 pages or less. To prepare such an abbreviated brief is in itself a difficult task inasmuch as the briefs submitted by the various petitioners are based primarily on the transcript consisting of over 30,000 pages of testimony given during the two years of hearings.

Working within the 50-page limitation, however, Kirkpatrick W. Dilling and Dennis M. Gronek, attorneys for The National Health Federation, have filed a comprehensive brief, citing that for approximately twelve years the U.S. Food and Drug Administration has sought to promulgate dietary regulations which would bar scores of dietary products sold competitively in the open "marketplace" throughout the United States. These FDA regulations would in effect deny freedom of choice now, and always, exercised by American consumers as to their diets, and arbitrarily bar them from purchasing such products. These procedures are stated to be in excess of any authority granted by Congress and in violation of various provisions of the United States Constitution.

Regulations Deprive Consumers of Unquestioned Rights By Arbitrarily Restricting Nutrients Allowed In Dietary Supplements

These regulations would make it illegal to distribute a special dietary food offering nutrients other than thirteen vitamins and eight minerals. Adoption of the regulations would thus deprive consumers of the unquestioned right which they now have, and have had for decades, to purchase products of composition and nutrient content they desire.

Adoption of such limitations is stated to be arbitrary, capricious, unreasonable, an abuse of discretion, and discriminatory, because as to

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natural foods, Nature, not man, decrees what they shall contain. Also, as to any food for special dietary use, other foods commonly consumed in the United States supply one or more of these nutrients, in quantities either greater or less than those set forth in the regulations.

Application of the Regulations Will Result In Withholding Essential Information Necessary To Fully Inform Purchasers

In the first issue presented in the brief, it is argued that the regulations are in strict derogation of Section 403(j) of the Federal Food, Drug, and Cosmetic Act, the "dietary foods" section, since the application of the regulations results in *withholding*, not *providing* necessary information to "fully informed purchasers."

There is absolutely nothing in the language, states the brief, purposes, or history of this section to support the view that it authorizes *prohibitions* of nutrients as distinguished from affirmative requirements for information. Furthermore, the legislative history contains expressions of belief that full information can "guide" consumers and enable "intellgent use" by them.

The new regulations are stated to constitute an unauthorized usurpation of the legislative function of Congress by decreeing a prohibition against the sale of dietary supplements which vary in content or amounts of nutrients from those prescribed by FDA. Such prohibitions are clearly contrary to the intent of Congress that the consumer shall be fully informed concerning the vitamin, mineral and other dietary properties of foods for special dietary uses, but not barred from consuming foods of his choice.

The second argument presented in the brief directs itself to the FDA's authority to decree what nutrients may be contained in a dietary supplement and in what amounts. Section 401 of the Federal Food, Drug, and Cosmetic Act gives the FDA authority to establish "definitions and standards of identity"; however, such standards must be in "the interest of consumers."

The Regulations Would Attempt To Place All Consumers In the Same Dietary Strait Jacket

Establishing definitions and standards of identity for foods for special dietary use, rather than being beneficial to consumers, is by its restrictive character necessarily injurious to them. Progress will be hindered and consumers denied the benefits of advances in the field of nutrition. Most importantly, such procedures deny to the consumer full dietary freedom, rights and options to which he is entitled. Food choices and habits are personal to each individual, yet the regulations would attempt to place all consumers in the same dietary "strait jacket."

Indeed, if the U.S. Food and Drug Administration can "standardize" individual diets through "definitions and standards of identity" for dietary supplements, what stands in the way of decreeing all the other items which may be included in the American diet? The regulations would form a dangerous precedent and "open the door," so to speak, to further diet dictation.

In Classifying Higher Potency Vitamin Products As Drugs, The Commissioner Arrogates To Himself A Legislative Function Belonging Exclusively To Congress

The third argument contained in the brief discusses the FDA's creation of a definition of a "drug" to include any product containing more than the upper limit of the U.S. RDA (i.e., Recommended Daily Allowance). Thus did the Commissioner arrogate to himself a legislative function which belongs exclusively to Congress. Congress has already defined what is a drug in Section 201(g) of the Federal Food, Drug, and Cosmetic Act.

The next section of the brief discusses how the regulations would censor and ban, under threat of possible civil and/or criminal prosecution, the making of certain statements. For example, one could not truthfully state that special dietary products intended to supplement diets are helpful in any way to prevent, treat, or cure disease; that a given diet of "ordinary foods" would not supply adequate nutrients; that inadequate or insufficient diet is due to or in any way related to the lack of minerals in, or fertility of, the soil in which food is grown; that refining, transportation, storage, preservation or cooking of foods may result in inadequate or deficient diet; or that rutin or other bioflavonoids, para-aminobenzoic acid, inositol and other similar well-known nutrients often desired by the consumer, and present in many common foods, have any nutritive value whatsoever.

The Regulations Infringe Upon Rights Guaranteed By the U.S. Constitution

Examination of the regulations themselves reveals that such statements are to be banned and censored, *regardless of truth.* The right to publish literature which is *truthful and not false or misleading* is absolutely guaranteed under the First Amendment to the U.S. Constitution, notes the brief. The applicable portion of the First Amendment provides:

> "Congress shall make no law . . . abridging the freedom of speech, or of the press."

This argument is supported by numerous decisions cited in the brief, including the following quotation from the landmark case of *Near v. Minnesota:*

> "The liberty deemed to be established was thus described by

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Blackstone: 'The liberty of the press is indeed essential to the nature of a free state; but this consists in laying no previous restraints upon publications and not in freedom from censure for criminal matter when published. Every freeman has an undoubted right to lay what sentiments he pleases before the public; to forbid this, is to destroy the freedom of the press; but if he publishes what is improper, mischievous or illegal, he must take the consequences of his own temerity'."

Selection of Hearing Examiner Was Contrary To Administrative Procedure Act

The next argument contained in the brief discusses how the selection, designation and assignment of David H. Harris to be the Hearing Examiner in the lengthy "vitamin hearings" was contrary to the legislative mandate expressed in the Administrative Procedure Act, was violative of rights of consumers and others opposing the regulations, and constituted a denial of due process of law guaranteed to such parties.

In the proceeding the Commissioner failed to comply with the law in appointing Examiner Harris, the brief charged. Rather than being appointed by the Civil Service Commission from another agency or accepting an appointment in rotation from the agency's staff of examiners, the Commissioner interviewed numerous applicants and then selected his choice.

Thus, FDA, proponent of the regulations to be considered by a presumably impartial examiner, acted precisely as Congress had forbidden, selected its own "hand-picked" examiner for the crucial hearings.

The final issue contained in the brief discusses how the integrity of the hearing was undermined by FDA's repeated interference with Hearing Examiner Harris' conduct of the hearings, illegal action that is clearly contrary to the requirements of the law.

These powers must be exercised independently in any particular case by the examiner properly and legally assigned, and the agency may not intrude into the proceedings, the Federation brief charges.

The record of these hearings, however, demonstrates FDA's repeated efforts to direct and influence the Hearing Examiner's conduct of the hearings and preclude his independent and impartial exercise of the statutory authority vested in him.

The conduct of the Hearing Examiner and FDA demonstrated continuously during the hearing grossly violated due process of law and denied The National Health Federation and others the fair and impartial proceeding to which they were entitled, the brief states finally.

Hearings before the United States Court of Appeals at New York are expected in June.

How Defective Products Are Recalled

By MARGARET MORRISON

Reprinted from FDA CONSUMER

Recalls of consumer products — from cars to foods — have become a common occurrence. This is how recalls of products regulated by FDA are effected.

It seems to crop up often in the news. Another product recalled from the market. The number of recalls has increased to the point where the very word "recall," seldom used in relation to consumer products just a short time ago, is now understood by virtually everyone.

Even though the word is familiar, the actual way in which a recall is carried out may not be so well understood. For example, many people have the impression that a government agency such as FDA conducts the recall. Actually, recalls are conducted by the company that made or distributed the defective or hazardous product.

In the case of products which are regulated by FDA, the Agency may request a company to recall a product, and FDA monitors the recall to make sure it is accomplished. However, in many instances firms decide to recall products without a request from FDA.

FDA can remove hazardous or defective products from the market by seizure, which is undertaken by the courts at FDA's request. However, seizures take time and do not always result in optimum consumer protection. Recall of a defective or hazardous product by the manufacturer or distributor has become the quickest and most practical means of getting an unsafe or unacceptable product off the market.

Use of recall procedures as a means of protecting the public has grown steadily over the years. There were 1,549 recalls monitored by FDA during the last fiscal year. A larger number of actual recalls probably took place, since a company is not required to tell FDA when it is recalling a product.

Companies may have a number of reasons for recalling a defective or hazardous product. If a company —or a consumer or the government —finds something wrong with a product, the company may remove it in the best interest of its customers. Manufacturers and distributors today are very sensitive to consumer demands and their own responsibilities for quality products.

In addition, a company that makes or distributes a defective or

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hazardous product faces a number of less appealing alternatives. The government could seize the product, consumers could file private lawsuits should the product harm someone, there is a chance that company officials could be criminally prosecuted, and there could be adverse publicity due to public warnings by FDA when a company refuses to recall a product.

All actions classed as recalls by FDA appear on the weekly recall list, available from FDA's Office of the Assistant Commissioner for Public Affairs. The publication of this list was begun in 1967, as a further service in the interest of consumer protection.

The recalls of products regulated by FDA range widely in importance and in the amount of time and effort FDA devotes to them. To clarify its role, FDA published a recall policy in 1971 and last year reevaluated it and set forth some new procedures. Four changes in policy are of particular interest.

First, FDA extended its definition of recalls to cover the activities of the Agency's two newest bureaus, Radiological Health and Biologics. Before, neither bureau routinely reported recalls of products to the public.

Second, FDA divided recalls into three classes. Previously there had been two.

Class I recalls are those which pose the most serious threat to health. Examples are botulism found in food, a label mix-up on a life-saving drug, or a defective heart valve.

Class I recalls receive top priority and command the attention of the top Agency officials. The product is removed from the market down to the *consumer* level (to the individual user); a public warning is issued; the recall appears on the weekly recall list; and complete effectiveness checks are carried out to assure adequate removal of the product from the market.

Class II recalls involve products whose hazard is only potential. Examples might be the recall of a drug not used in life-threatening situations, or an X-ray machine giving off unnecessarily high but not acutely hazardous radiation. This also includes recall of a product that is adulterated, represents gross fraud or deception to the consumer, or has a label that is misleading to the point where it might pose a danger of injury or damage to the consumer.

In Class II recalls, the product is removed to the retail level (removed from retail store shelves); it is placed on FDA's weekly recall list; a press release may be issued; and FDA officials check the adequacy of the removal in accordance with the degree of consumer hazard associated with the product.

Class III recalls are those which involve violation of the law but in which a health hazard is remote or nonexistent. An example might be a product labeled to contain 10 ounces which actually contains only 9. Removal is made to the wholesale level, and the product is shown on the weekly recall list, but there is ordinarily no press release.

Class II and Class III recalls, since they deal with situations in which there is no imminent danger, do not require a 100 percent check of all known distributors of the product.

The third major change in FDA recall procedures is to make available to the public more information about regulatory actions, such as seizures, injunctions, and prosecutions. Such information, formerly reported to the public only in FDA CONSUMER, has now been added to the weekly recall list, which can publish the information on a more current basis.

The fourth major change is the modification of FDA's policy of issuing a national press release for every recall which presents a hazard to health. This does not mean that FDA will "withhold" or "keep secret" any recall.

All recalls will continue to be listed as promptly as possible on the weekly recall list. The only change is to provide that in certain rare instances the Commissioner may decide to limit the manner and the degree of publicity the Agency will seek in addition to the weekly list.

For example, a botulism recall involves a high degree of risk and wide distribution of the risk among the population. Obviously, the broadest possible publicity is needed.

On the other hand, suppose that a defective heart-lung machine is distributed to 50 hospital operating rooms. The manufacturer can identify all 50 of the hospitals. A personal visit by FDA and a telegram or personal visit by the manufacturer to those hospitals would notify the affected public promptly and adequately.

Should a recall of this kind be widely publicized before it is conducted, it could cause unnecessary confusion and concern in thousands of other hospitals where similar machines, *not* involved in the recall, may be in use.

Recalls of life-saving products such as pacemakers or heart valves create a special problem. In these cases, FDA will, whenever possible, identify the patients who have the defective devices and notify the physicians who implanted them. The patients will be notified by their physicians. Other patients, thousands of whom may be using similar equipment which is functioning perfectly, will be spared the unnecessary uncertainty and fear that would occur if they heard of a recall of the product on a TV newscast or other public announcement.

In all decisions concerning publicity about recalls, the Commissioner of FDA will determine how much or what kind of publicity is consistent with the nature of the hazard and with the numbers of people involved in possible risk.

To illustrate how a product is actually removed from the market,

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we might follow the coure of a Class II recall. Suppose a report reaches FDA, from a physician or someone else in a health-related field, that a consumer has suffered adverse reactions from an over-the-counter or nonprescription drug. Suppose further that a number of similar complaints are received by FDA, from various parts of the country.

After reviewing information about the adverse reactions suffered by consumers, FDA would then inspect the plant in which the product was manufactured and review all data on the product, including ingredients, production, procedures and containers.

The conditions might show the drug to be a potential hazard to health, and FDA would then recommend to the manufacturer that the product be removed from the market and that the risk to consumers be publicized.

If the company agreed, it would issue a recall letter notifying its distributors that the product must be removed from consumer channels. FDA's consumer safety officers in the District or Field Office usually offer to assist the firm in arranging the text of telephone calls or composing recall telegrams or letters, so the product can be promptly and effectively removed from the market in accordance with FDA requirements.

The appropriate FDA bureau, in this case the Bureau of Drugs, would issue an official recall number, determine the classification of the recall (I, II, or III), and the District or Field Office would send out detailed information (description of the product, dosage, potency, lot number or other identification, reason for the recall, etc.) that would facilitate removal of the product from the market.

In the case of an over-the-counter drug, a news release might go out from FDA with full information about the name of the product, the name of the manufacturer, the potential hazard or problem, and a warning about using the product. At the same time, a message would go out to FDA District and Regional Offices throughout the country, and state and local health officials are also notified of the recall. The action would also be included in FDA's weekly recall list.

If the recall involved a potential consumer hazard, it would be important for the District Office monitoring the recall to assure that stocks of the product were found and recalled as expeditiously as possible. An agreed-upon time when the recall might be expected to be concluded would be established with the firm. Later, the District Office would follow through with the recalling company, to confirm how much of the product had been recovered and the ultimate disposition of it, and to ensure that the unsatisfactory product was indeed removed from the market and either reconditioned or destroyed.

Meanwhile, the FDA District staff and other agencies assisting in monitoring the recall would carry out what the Agency calls "effectiveness checks" to make sure distributors, subdistributors, and retail stores were complying with the recall order. This means making sure distributors are holding up any further shipments of the product to retail outlets and that retail stores are no longer selling the product.

If the company has conducted the recall properly, its distributors all know about the recall and have segregated out the product. They have, presumably, notified the stores that buy the product and they, too, have put the merchandise aside, preparatory to sending it back to the distributor.

However, ideal conditions don't always exist. Recall letters may go out late. They may be delayed in the mails. They may be inadvertently overlooked, in spite of their bright red stamp reading "Urgent: Food (or Drug) Recall." The distributor may put off telling his stores, or they may fail to respond. So the consumer safety officer or other official who performs the effectiveness checks is serving a vital function in keeping potentially dangerous products from consumers.

One important aspect of the recall of a product is that it may trigger the investigation of an entire category of products. When one medicated spray is found to be hazardous, for instance, FDA may begin an investigation of other such spray products, and perhaps find that others also contain ingredients —or are packaged in containers— which pose health hazards. In an actual case of recall of a certain brand of decongestant spray last year, FDA later requested the recall of five other aerosol spray products, all of which contained the solvent 1, 1, 1-trichloroethane, a substance that was present in substantial amounts in the product originally found to be hazardous.

Whenever you hear or read about a recall action, and then see the defective product on store shelves, you can perform a public service by calling it to the attention of the store manager, and by notifying FDA. However, it is important that you be sure of the facts—that you know the exact name, and the lot number, of the product being recalled, since recalls may be of one specific product from a brand line, or one specific lot number of that product.

The fact that recalls are now happening more frequently than in the past should be reassuring to consumers. It means that both industry and government are more alert to consumers' interests and more involved with consumer protection. Whenever a recall takes place, consumers can know it is happening because FDA and the firm making the recall have found evidence that the product is unacceptable and are using the fastest, most efficient method for removing the product from the market.

A remarkably simple temperature test for low thyroid may give the clue to undue fatigue, skin or menstrual disorders, infections, headaches—even to a hidden cause of heart attacks. If you have vague undiagnosed complaints, this test may save you both time and money.

Low Thyroid — *Is It Sapping Your Energy?*

By LAWRENCE GALTON

Reprinted with permission from FAMILY CIRCLE Magazine

Of all the sly, subtle problems that can affect your health—or that of any member of your family, young or old—perhaps none is commoner or oftener overlooked than low thyroid. It can be the cause, often totally unsuspected, of a tremendously broad range of problems—from low energy and undue fatigue to repeated infections, headaches, circulatory disturbances and menstrual difficulties, to name a few. Moreover, it now appears unsuspected thyroid deficiency is a key factor in heart attacks.

Yet, a simple 10-minute thermometer test at home can point clearly to underfunctioning of the thyroid, and the problem is easily enough corrected with thyroid medication.

The thyroid, a small butterfly-shape gland in the neck, weighs less than an ounce, yet its hormone secretions control body metabolism —the way in which the body transforms foods and uses energy.

Too much thyroid hormone—hyperthyroidism—can race body processes and produce strain, weight loss, irritability. Too little—hypothyroidism—can slow the processes, affecting both physical and mental activity.

Possible Effects

From time to time, medical reports tell of new findings about low thyroid's many possibile effects. Recently, poor equilibrium, muscle aches and weakness, some hearing disturbances and nervous - system changes leading to burning and prickling sensations have been found by Mayo Clinic physicians to be due, in some cases, to lowered thyroid activity and respond to thyroid treatment. Recently, too, in University of North Carolina studies, hypothyroidism has been found associated with mental depression, memory loss and difficulties in concentrating.

But a major problem, it now appears, is that many—even most—people with problems traceable to inadequate thyroid function are not being helped, because their thyroid problem is not detected by standard thyroid tests.

BASAL TEMPERATURE TEST FOR LOW THYROID

Because the best time for this test is immediately upon awakening in the morning, shake down a thermometer and place it on the bedside table before going to bed. Immediately upon awakening, place the thermometer snugly in the armpit for 10 minutes—by the clock. The normal basal temperature is between 97.8 and 98.1°. A temperature below 97.8° indicates the possibility of low thyroid activity. WOMEN: As the temperature varies with the phases of the menstrual cycle, the test should be made on the second and third days of menstruation. CHILDREN: In young children, rectal temperature can be taken; two minutes are adequate. Oral temperatures are often misleading, because any respiratory infection, including sinusitis, will elevate the mouth temperature while the rest of the body may be normal.

The basal-metabolism test checks thyroid function by measuring oxygen consumed when the body is at rest, doing nothing but sustaining itself. When hypothyroidism is fairly pronounced, the test may pick it up, but otherwise may not. Other tests, such as protein-bound iodine and radioactive-iodine uptake, may also not always be dependable. In fact, *The Medical Letter*, an independent medical-evaluation bulletin for physicians, recently noted that many commonly used drugs—even shampoo and skin antiseptic compounds—can upset test results.

But more than 30 years ago Dr. Broda O. Barnes, now of Fort Collins, Colorado, found that a subnormal basal temperature (97.8° or lower) could indicate hypothyroidism. The temperature test checked out against the basal-metabolism test when the latter showed low-gland functioning. And it revealed hypothyroidism when the basal-metabolism—and other tests devised later—failed to do so. And when patients with low basal temperature got thyroid treatment, their symptoms disappeared as their temperature returned to normal.

Using the basal temperature test to detect otherwise unsuspected hypothyroidism and then to correct it—starting with very small doses of thyroid extract and increasing them, if necessary, until re-testing shows the temperature has returned to normal range—Dr. Barnes has been able to obtain remarkable results in a variety of disorders:

- *Skin disorders:* Many skin disorders have yielded to thyroid treatment. One of Dr. Barnes' most dramatic cases was a two-year-old boy with *eczema* over his whole body and face. The child had been hospitalized twice, had had competent dermatologists trying to help him, without success. Yet, within a few months after start of therapy, his skin was clear.

About half of patients with *psoriasis* have responded. One, a retired dean at the University of Denver, had had psoriasis for 50 years; it cleared entirely, with thyroid therapy.

About 90 percent of *acne* patients with low basal temperatures —teenagers and adults—have responded to thyroid treatment. And results in those with *chronic boils* are often remarkable, as thyroid

(Continued on next page)

treatment builds resistance to the bacteria that is ever present on the skin.

• *Menstrual disorders:* While these may stem from fibroids, ovarian cysts, cervical polyps and other organic causes, in most cases no such physical problems are found. But many women with menstrual problems run low basal temperatures, and thyroid therapy is often valuable. Dr. Barnes has reported relief of *painful menstruation* in about 90 percent, cure of *irregular cycles* in another 90 percent and an equally high cure rate for *excessive bleeding*.

Dr. Barnes has suggested that basal temperatures be taken in all cases of menstrual irregularities, including girls who have not started by age 14, those who start but are irregular, those who flow excessively and women who tend to miscarry. Not all will be thyroid deficient, "but no harm will result from thyroid therapy for a few months for those who have low temperatures."

• *Infertility:* One of Dr. Barnes' patients had been through seven pregnancies and had produced three babies. She was hypothyroid and knew it and had been treated several times with thyroid and had stopped treatment when she began to feel well. Tracing back, Dr. Barnes found that she had had her babies while on thyroid, her miscarriages while off it.

Sometimes it is the husband rather than the wife who needs treatment in infertility. After trying for 17 years, without success, to have a baby, one couple finally had two children (beginning when the wife was 39) once her husband was placed on thyroid therapy.

• *Infections:* One infection after another is "the story of my life" in many of his thyroid-deficient patients, Dr. Barnes has found. One man, 79 years old when first seen, had had a left ear draining pus since childhood. For 20 years the patient had had a bone infection and had drained pus continually from his left thigh. His temperature was three degrees below normal. Three months after he was started on thyroid treatment, his energy level shot up and his left leg infection cleared; after a year, his ear was clear.

And while many a hypothyroid youngster "with repeated colds" followed by complications such as tonsilitis, sinus infection, draining ears, mastoid infections or rheumatic fever may be treated with antibiotics and his life spared, Dr. Barnes says, "until he is put on thyroid therapy, he will develop another infection in a short time."

• *Fatigue, headache and other problems:* Some of his hypothyroid patients, Dr. Barnes reports, have observed that they seem to have been born tired, never having felt fresh and vigorous; some have complained they were lazy as children and, as adults, have had difficulty getting through daily tasks—and are "tired of being tired."

While *headaches* can have many causes, many hypothyroid people have headaches because of easy fatigue, particularly under stress, and *fatigue* may be related to poor circulation. Because of *poor circulation*, hands and feet may feel cold even in hot weather. *Low energy* in teenagers, *anemia* in teenage girls, and *urinary symptoms*—bedwetting in children, frequent urination in adults—also may sometimes be linked to low thyroid activity.

Hypothyroidism is far from invariably being the cause of *all* such problems, but when it is, and the lowered gland function is detected and treated, the results, so readily and inexpensively obtained, are often gratifying.

Protection Against Heart Attacks

Dr .Barnes has earned a Ph.D. in physiology as well as an M.D. and has taught endocrinology at the University of Chicago in addition to his long time in practice. So he is well-prepared to understand the wide-ranging effects of thyroid deficiency.

In 1950, however, a new problem was suddenly thrust upon him. A friend, who had not been a patient, had a heart attack. In going over his friend's history, Dr. Barnes found the man had for several years suffered symptoms of hypothyroidism but had not sought medical advice. It was then Dr. Barnes realized that in his practice, in which a sizable proportion of patients had problems that could be solved by thyroid therapy, heart attacks had been conspicuously absent—and at a time when they were rising rapidly elsewhere.

Coincidence? Cholesterol was supposed to be a villain, and the thyroid, Dr. Barnes knew, had much to do with controlling blood cholesterol levels. The role of thyroid deficiency in heart disease needed to be investigated. Beginning in 1950, each new adult patient, in addition to the usual screening for hypothyroidism, was questioned about a history of heart disease in the family and received a chest X-ray for heart size, an electrocardiogram and other heart studies. There was no reduction of fats or cholesterol-rich foods in the diet. The only change in daily routine was the taking of thyroid extract for hypothyroidism.

There were 490 women aged 30 to 59; eight cases of heart disease were to be expected. Not one developed. There were 172 high-risk women (with high blood pressure or elevated cholesterol or both); at least seven cases were to be expected. None developed. There were 182 women age 60 and over; eight cases were to be expected. There were none. There were 382 men, age 30 to 59; at least 12 cases were to be expected. There was one. There were 186 high-risk men; 19 cases were to be expected. There were two. There were 157 men age 60 or over; 18 cases were to be expected. Only one developed.

Thus, with 72 cases of heart disease to be expected based on national statistics and with only four actually developing, treatment for hypothyroidism, Dr. Barnes is convinced, produced 94 percent protection in these patients.

(Continued on next page)

How Many Hypothyroids?

Dr. Barnes believes that close to 40 percent of the population may now have the problem of hypothyroidism and that in another decade or so it may be 50 percent.

The rising epidemic of heart attacks is related, he is convinced, to the rising incidence of hypothyroidism, both occurring because of a tremendous, though not well-appreciated, change in people.

Up to this century, he points out, over half of all children died before reaching adulthood. At that time, adults were largely those who were resistant to infectious diseases. Now adults are composed of two groups —those who are resistant to infection and those who, although susceptible, have escaped death as the result of modern medicine. This second group has a proneness not only for infectious diseases but also, because of that, for heart disease and even for such other degenerative diseases as lung cancer and emphysema.

Heart attacks, he notes, were first associated with infectious disease during World War I, when there were 866 such attacks in American servicemen below age 40. Only two important correlations were found: A family history of the disease and a history of previous pneumonia in the men themselves. Pneumonia is an indication of low resistance to infectious diseases.

Incidence of hypothyroidism has further been increasing, Dr. Barnes believes, because hypothyroids tend to marry other hypothyroids and so perpetuate the trait. Pairing off, he says, usually involves individuals with similar amounts of energy.

He tells the story of one patient, a man who had been grossly overweight and had just enough energy to get through a day's work. With thyroid therapy and change of diet, he lost weight, became energetic and then returned nine months later complaining that he couldn't go on with his wife. She was tired, cross, unwilling to go out evenings.

When he was reminded that he used to come home from work, eat, read a paper and go to bed, he realized that the present incompatibility had grown out of the change in his energy level. "Na ture," says Dr. Barnes, "had thrown them together originally and, if they were to enjoy life, the doctor must be called upon to treat both of them in order to maintain a balanced team."

How To Get Help

What can you do if you want to check on yourself or on a member of your family—and get medical help if it is indicated?

You can start with the simple basal temperature test *(see page 15)*. If it indicates a low temperature, you can tell your physician about that. You can report to him, too, any and all symptoms that may be linked with hypothyroidism, many of which have been mentioned here. You can discuss with him the possibility that low thyroid function may be involved.

Dr. Barnes has reported his findings on hypothyroidism in medical journals and at medical meetings and in his recent book, written chiefly for physicians (*Heart Attack Rareness in Thyroid-Treated Patients,* Charles G. Thomas, Publisher, Springfield, Ill.). The number of physicians who are fully aware of the link between low basal temperature and hypothyroidism has been growing, but is still small—perhaps no more than 2,000 across the country have looked into the connection carefully and have begun to work with patients. But there have been results so impressive that they have become strong enthusiasts .

Any physician, Dr. Barnes observes, who is willing to consider the matter and is willing to set out to correct a low basal temperature is capable of doing so. "No physician," Dr. Barnes says, "can afford to deny a patient any help he can give. Only the cost of a thermometer and a willing ear are needed."

Thyroid medication is inexpensive and safe when it is started in small doses and worked up only to the extent needed to bring basal temperature to normal. It must, of course, be prescribed and supervised by a physician.

It may take several months before beneficial results fully take hold. But if your temperature is subnormal now, the chances that you will begin to feel better are good—and, adds Dr. Barnes, "the odds are that some thyroid therapy will not only avoid a premature heart attack but will also prevent many other complications that accompany the aging process."

—From *FAMILY CIRCLE,* October, 1973

Additional information is available in the book, *Heart Attack Rareness In Thyroid-Treated Patients* by Broda O. Barnes, M.D., published by Charles C. Thomas, Springfield, Illinois, $7.25.

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."

NHF Legal Defense Fund Merits Support

It was just one year ago that the NHF Legal Defense Fund was established. Announcement of this move was made to the membership in conjunction with the 1973 NHF Liberty Stamp Drive when it was announced also that all monies received in the drive would be deposited in the newly established fund. Filling a long felt need, the Legal Defense Fund was established in order to assure the availability of funds to provide financial and/or legal assistance in select cases to assure a proper legal defense in certain health-related actions.

Apparently, the membership wholeheartedly approved of the whole idea because the contributions received from the Liberty Stamp drive almost doubled that of any previous year. As a further indication of the membership approval, a Dollar-A-Month Club was established at the suggestion of a member to provide a continuing source of contributions to the fund. Accordingly, it was announced in these pages that anyone could "join" this informal club merely by sending in a dollar, and then, each month, without being billed or reminded, sending in another dollar. These funds also were to be deposited in the Legal Defense Fund. This idea also caught on and a large number of members "joined" —most of them sending in a check for $12.00 for the entire year thus saving the inconvenience of mailing a dollar each month. Hopefully, these club "members" will continue their support through this coming year and that others will be moved to become a Dollar-A-Month member also. Our heartiest appreciation is extended to all those who, in the past, have contributed in one manner or another to the Legal Defense Fund.

It probably should be made very clear at this point that the Legal Defense Fund is not used primarily to defend persons but rather to defend principles, to provide assistance in cases where constitutional issues prevail, where liberties and freedoms guaranteed by the constitution are in danger of being ignored or trampled, where harassment and illegal entrapment has been employed, and in cases where freedom - restricting legal precedents may be established in the event of a decision adverse to the defendant.

Fortunately (thanks to the contributors), funds have been available to enable NHF to intercede or otherwise assist in a number of significant cases throughout the country. Some of these cases are still pending. The extent to which NHF can become involved in similar cases in the future depends upon the contributions to the fund received during the ensuing year and beyond.

The value and importance of NHF's involvement in select cases cannot be overemphasized. It is a simple, but unfortunate, fact that the average attorney is relatively inexperienced and perhaps poorly informed in matters relating to food and drug law. This is not to be construed as criticism of the "average" attorney because food and drug law is a very special field and most lawyers will not encounter a food and drug case during their entire professional career. Consequently, over the years, many important cases have been decided against the defendant merely because the defending attorney was not well enough equipped with background knowledge and the finer ramifications of food and drug law to offer a successful defense for his client.

Fortunately, the National Health Federation has an amicable working arrangement with Kirkpatrick W. Dilling, a Chicago attorney, who has an outstanding reputation in the field of food and drug law. In addition, Mr. Dilling's expertise extends into the field of professional practice rights and constitutional law. Consequently, NHF has available an attorney outstandingly qualified in most of the health rights cases where NHF's assistance is requested.

After a preliminary screening of such cases to determine whether the particular problems of the accused are carelessly and deliberately self-induced and whether or not the case bears any relationship to deprivation of civil rights, NHF then requests its counsel to investigate the case thoroughly to determine how NHF can best serve the interests of the case, if at all. In most instances, NHF counsel offers assistance through the local attorney or party involved without direct legal participation. In the more rare instances, NHF counsel has actively participated in the case. On occasion, NHF has entered a case only as a friend of the court where it seemed that neither the prosecution nor the defense brought forth essential points of law or explored their ramifications.

The administration of the NHF Legal Defense Fund should be recognized as one of the vitally important phases of the work of the National Health Federation. NHF stands for equality of justice but it is only through eternal vigilance that we can hope to attain victory over those forces seeking to destroy the principles of health freedom through harassment, persecution and prosecution of those engaged in or advocating the minority-held health views. Victory in these sometimes small and isolated cases is an integral part of the whole victory.

PRESCRIPTION

Mason: "Your wife used to be so nervous. Now she seems quite cured; what happened?"

Painter: "She is cured. The doctor told her nervousness was a sign of old age."

Nutrition Linked To Learning Disabilities

By DUSTY SKLAR

Walk into almost any elementary school classroom any day of the week and you're bound to find one or two youngsters disrupting the rest of the class so that it cannot function. Teachers will tell you that this is their greatest headache; parents of these children will confess they are beside themselves with grief and guilt.

Until recently, learning disabilities were thought of as a pressing psychological problem, but now they are seen as a medical problem as well. A growing number of scientists and doctors is finding evidence that many abnormalities in the functioning of these children is associated with a biochemical disorder. In some cases the malfunction is caused by actual physical damage to the brain. According to Dr. William Wendle, Director of Research of The New York University Institute of Rehabilitation Medicine, the damage is often too subtle to reveal itself in EEG tests.

Brain damage can occur before, during or after birth. The time between the conception and birth of a child can be much more significant to his later development than has been believed.

Most Susceptible

In that prenatal period, says Dr. Allan Cott, a New York psychiatrist, "A human being is more susceptible to his environment than he will ever be again in his life." What happens to him then "can help sustain normal development or hinder him from ever achieving his full genetic potential. The events which take place before his birth can exert a life-long influence, for part of the child's environment consists of his mother's immediate state of health, her general physical condition, her age at the time of conception and how fatigued she becomes each day."

The Journal of the American Medical Association describes a study conducted by Dr. Benjamin Pasamanick of Ohio State University College of Medicine which compared prenatal and birth records of 372 white boys with reading disorders with a similar number of matched controls. They found that the "children with reading disorders had a significantly larger proportion of premature births and abnormalities of the prenatal and paranatal periods than their control subjects. The toxemias of pregnancy and bleeding during pregnancy constituted those complications largely responsible for the differences found between the two groups.

Cott, who specializes in children with learning disabilities, made similar observations. In hundreds of detailed case histories of parents of these children, he found many mothers who recalled prolonged labor and difficult delivery.

British Study

A long-term British study of more than 17,000 births recently concluded that low birth weight babies were more likely to suffer in areas such as copying ability and reading and number work, and were also more likely to be fidgety and clumsy and to make a poor social adjustment in school. Dr. Nevil Butler, Professor of Child Health at the University of Bristol and Director of the study, said that these babies experienced intrauterine growth retardation or malnutrition in the womb.

In addition to toxemia and cigarette-smoking in pregnancy, poor nutrition is an important cause of low birth weight babies.

Cott points out that often the diet of a pregnant woman is so seriously inadequate that her child is endangered, and yet there will be no recognizable symptoms in the mother to alarm or alert anyone. Many mothers of children who come to him for treatment declare that they were put on a severe diet by their doctors during pregnancy because the obstetrician preferred his patients to have small babies.

Others speak with pride of having delivered a baby of normal weight without themselves gaining a single pound all during pregnancy. Some were prescribed amphetamines to suppress appetite or fight fatigue. Others were given tranquilizers or sedatives. "Anemia during pregnancy is frequently reported," Cott stresses.

Poor nutrition is often responsible, not only for the child's bad beginning, but also for his continued poor development. Dr. Cott has found that many of these problem children suffer also from hypoglycemia, hyperinsulinism or dysinsulinism and therefore should have cane sugar and other rapidly absorbed carbohydrate foods eliminated from their diets. "The removal of offending foods from the diet of disturbed or learning-disabled children can result in dramatic improvement in behavior, attention span and concentration."

Sweetened Drinks

It is usually these very children who have a diet richest in sweet foods. "Most children do not drink milk unless it is sweetened with chocolate syrup or some other syrup additive. All the beverages which they consume every day are spiked with sugar—soda, caffeinated cola drinks, highly sweetened 'fruit juices,' and other concoctions which are sold to them on TV commercials. The child who drinks any water at all is indeed rare. The appalling fact about the constant consumption of these 'junk foods' is the parents' belief that these foods are good for their children."

The usual "nutritious" breakfast for some of Dr. Cott's young patients is "a glass of soda or 'coke' and a portion of chocolate layer cake!"

(Continued on next page)

Cott has become the country's pioneer in using orthomolecular psychiatry with children who have learning disabilities. This treatment seeks to restore the proper balance in the body chemistry through heroic doses of the substances which the individual needs, largely by the use of the right substances in the right concentrations – substances which are normally present in the body.

After several months of large doses of certain vitamin and mineral supplements, depending on the individual child's needs, and with the elimination of "junk foods" from his diet, there are dramatic results in over 50% of the children.

At the present time, there are between five and ten million normal children in our country who cannot learn. Parents and teachers will not deal successfully with this problem, says Dr. Cott, until they "address themselves to the state of the child's nutrition."

The Malpractice Crunch
Its Impact On U.S. Medicine

Millions of Americans are dazzled by television programs depicting medicine as a near-perfect science and physicians as skilled technicians filled with compassion and warmth. But modern medicine is far from a perfect science, and many physicians lack Dr. Welby's bedside manner. The result is a conflict between expectations and actuality.

The conflict has been one major cause of an increasing number of malpractice suits in recent years. Some 14,500 malpractice claims were reported in 1970. But television sagas are hardly the only reason. In the spring of 1971 the Secretary of Health, Education and Welfare appointed a commission of lawyers, doctors, consumers and malpractice insurers to pinpoint other causes. The Secretary's Commission on Medical Malpractice has finally reported its findings. Some were expected. Some are surprises.

A major reason for malpractice suits is a breakdown in communication between physician and patient. Thirty-seven percent of 420 physicians who had been sued or threatened with a suit named "poor communication between physician and patient" as the single most common cause of malpractice suits. "The suit-prone physician," the commission says, is one who cannot admit his own limitations. When he is confronted by a dissatisfied patient, he often neglects the patient by dismissing his complaints as trivial instead of making the patient feel less angry, afraid or depressed.

Another reason for more malpractice suits is Americans' increasing awareness of how they can use the legal process to defend their rights as consumers. In 1970 malpractice insurance carriers judged 46 percent of the claims as meritorious. This indicates, the commission asserts, that "the vast majority of malpractice claims are not entirely baseless, as often alleged."

The commission also probed the effects of malpractice suits on health care. There is no doubt, it says, that a suit destroys the delicate relationship between patient and doctor. Claims have encouraged physicians to practice defensive medicine: to conduct tests that are not medically justified or not to conduct tests that might lead to a suit.

The situation also contributes to rising medical costs. "Medical malpractice," the commission says, "has clearly increased the cost of medical care." As malpractice suits have soared, so has the cost of insurance premiums against suits. The premium costs are reflected in physicians' fees.

The commission has brought home other facts. It verified that the use of allied personnel, however valuable in many respects, increases physicians' chances of being sued. It found groundless physicians' hesitance to give care at the scene of an accident for fear of being sued. Not one court decision has been officially reported in which a person has sued a physician for such care.

Contrary to physicians' accusations, lawyers do not necessarily make a lot of money handling malpractice claims. Survey data showed that half the attorneys who win a malpractice case on a one-third contingent-fee basis earn less than $1,000 for their work. However, the commission points out, "A significant part of the malpractice problem relates to the costs of processing malpractice claims through the system—and defense counsel fees are a major portion of these costs."

The commission prescribes a variety of remedies for the malpractice problem. It calls for a nationwide organization to collect malpractice information and for better education of physicians in handling procedures that often lead to claims. Hospital patient grievance mechanisms should be set up. And medical students should be better prepared.

– From Spears Sanigram

U.S. OPEN TO FOREIGN MDs

While the American Medical Association continues to oppose expansion of medical training facilities in this country, some 50,000 foreign-trained doctors are practicing in the U.S., typically in municiple hospitals. This is one of the findings reported in a study by a Yale University Medical School team under the grant from the DeDepartment of Health, Education and Welfare. There is considerable evidence, the report says, that many of these doctors have inferior medical training. There's also a major problem of communication with patients. (*Prevention*, February, 1974.)

Some Obvious Conclusions

By LEE HARDY

No. 10 In A Series

Just how effective is fluoridation in preventing tooth decay? We have already noted in an earlier installment, "Fluoride and Tooth Structure," reports of impartial dental experts who are not concerned with the disposition of fluoride wastes. Their evidence is conclusive, but other sources of information are of interest as well.

The Newburgh ten-year report notes that Kingston children in the 10- to 12-year-old group "had an 80% higher untreated caries rate than the Newburgh children . . .,"[1] which indicates that increased dental care accompanied the fluoridation in Newburgh, and must receive some credit for any actual improvement. At a time when fluoridation was in effect in Philadelphia (1956-1958) prophylactic treatment was increased from 23% to over 80% of pupils examined. The sale of sweets on school campuses was eliminated and the eating of fruits was encouraged. Still, Philadelphia Health Commissioner Dixon credited all of the reduction in dental decay to fluoridation.[2]

Max Ginns, D.M.D., has quoted from an article in the *Newburgh News* of December 13, 1955, the final year of the Newburgh-Kingston "study," as follows: " 'I still see many children with decay,' said one Newburgh dentist. 'The amazing thing is the number of children in the ages of 2 to 3 years, who have nothing but shells left when they come in.' " Dr. Ginns refers also to the expressed opinion of a prominent member of the Newburgh Dental Society, who commented on fluoridation, "What little effect it might have had was not apparent."

So it is difficult to take seriously the official reports of approximately 60% improvement in dental condition as the result of fluoridation. This appears to be a standard promise to communities who may be prospects for fluoridation programs, regardless of the condition of the teeth in the subject community.

Fluoridationists have made much of the idea that Hereford, Texas, with two parts per million of natural fluoride in the water (3.2 ppm, according to a tabulation by F. J. McClure in *Fluoride Domestic Waters and Systemic Effect*, Public Health Report No. 48, Vol. 59, December 1, 1944, Table 1, P. 1548), was "a town without a toothache." Only one dentist plied his trade there. However, Ellendale, North Dakota, with less than one-third the population of Hereford, and with so much fluoride in the water that its health officer warned against drinking it, supported two dentists.

Dr. G. W. Heard, Hereford's dentist, denied that the town was "without a toothache." He explained, however, that originally the incidence of tooth decay was very low, but as the consumption of highly processed foods increased, "tooth decay increased by leaps and bounds."[3] Still, the inhabitants of Hereford were drinking the same water as before, with the same two (3.2) parts per million of fluoride.

The case for fluoride in water as a preventive of dental caries becomes less convincing when these facts are considered. The secret of good teeth appears to be other than fluoride intake. It is known that Deaf Smith County, in which Hereford is located, is blessed with more than ordinarily good soil, and this is the most probable answer. A. W. Erickson, of the Crop Reporting Service of Minneapolis, Minnesota, in a report dated September 8, 1945, explains the richness of these soils, and how it is maintained. The prevailing winds in the Hereford area, he says, keep the soils constantly enriched by dropping particles from the calcium-rich plains as they rise over the "Map Rock" plateau, on which most of the county lies.[4]

This affords a very plausible explanation for the former dental excellence of the area, since calcium is the chief mineral constituent of tooth structure. Later, however, when food produced on these rich soils was sent away for processing and highly processed imported food became the mainstay of diet, the advantage was largely lost. It is evident that the fluoride content of the water is not the determining factor for sound teeth, else there would have been no change. We must look to other factors for relief from the curse of tooth decay among our children.

1. Ast, D. B., Smith, D. J., Wachs, B., Cantwell, K. T., *Newburgh-Kingston caries fluorine study XIV, Combined clinical and roentgenographic dental findings after ten years of fluoride experience,* JADA 52:314, Mar. 1956.
2. Report of the Third Medical - Dental Conference on Evaluation of Fluoridation, Mar. 7, 1959.
3. Quoted by Rorty, J., Intro to *The American Fluoridation Experiment* (Exner and Waldbott), Devin-Adair, N. Y., 1961, PP. 5-6.
4. Erickson, A. W., *Deaf Smith's Secret,* Lee Foundation for Nutritional Research, Milwaukee 5, Wis., PP. 6-7.

NEW LIFE MEMBERS

Mrs. L. B. Rippy
Harry Towne
Ernst Anrig, D.C.
Neil B. Purdy
Richard K. and Edith Hurt
Dr. and Mrs. D. R. LiaBraaten
Dr. Frank B. Hamilton
Eric Erickson
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Mrs. Lillian Share
Ms. Pam Warner
Mrs. Antoinette Edwards
Mrs. Clara Zweifel
Mrs. Eileen Collins
Mr. Bernard Hoffenberg
Mrs. Adeline G. Perdew

(With apologies for previous misspelling)

(Received mid-March through mid-April)

The Politics Of Cancer

By IDA HONOROF

The United States has spent over $2 billion on cancer studies in the past 20 years, and according to Lucy Eisenberg, (writing in Nov. '71 *Harpers*) at least one prominent scientist believes that "little would be lost if most of this were burned."

In the magazine, *The Macrobiotic*, Thomas Klaber writes that "most distinguished cancer researchers admit that they know little or nothing about cancer." Dr. Peyton Rous, (winner of 1966 Nobel Prize for Cancer Research, done 50 years prior) in his acceptance speech stated, "We have no inkling of what happens when a cell becomes neoplastic, nor of how its power is passed on when it divides." Klaber goes on to say that "the blame for this ignorance cannot be put on shortage of funds. The reasons behind most modern scientific cancer research's failure to cure cancer are found in the basic attitudes, ways of thinking and methodology of modern scientists – mechanistic, materialistic and dualistic—concerned only with repressing or destroying symptoms and not going to the root causes of disease. Official medicine's first mistake is to think that cancer can be cured by destroying the cancerous, or neoplastic cells, which is done through surgery, chemicals and radiation, at the cost of also destroying healthy cells and severely weakening the vitality and natural curative powers of the body, which doctors are supposed to support, not destroy."

Thomas Klaber quotes Dr. Wilhelm Reich (German psychologist) that, "Cancer is not a disease separate from all other disease, but the ultimate expression of the systemic biological disease based on a disintegrative process in the total organism. The cancer tumor is no more than a symptom of the cancer disease, therefore local treatment of the tumor, be it operation or irradiation with radium or X-ray, affects not the cancer disease as such, but only one of its visible symptoms."

Afer two decades and $2 billion, the 5-year survival rate of cancer patients has increased from 1 out of 5 in 1930, to almost 2 out of 5. Medicine claims that early detection increases the survival rates, yet according to Thomas Klaber, more cancer cures were effected through natural foods, medications and exercises, through faith and spontaneous recoveries, than there were through the efficacy of modern medicine.

Thomas Klaber further contends, "Modern science attempts to investigate life by analyzing, naming, measuring and describing isolated parts of the total life process using extremely artificial methods. Scientists take small pieces of tissue, stain it in order to enable it to be looked at under a microscope, or examine organisms cultured in test tubes. They think that the "life processes" they observe in a test tube are the same as found in the living organism. This kind of "analytical" thinking defies all "common sense."

Dr. Henry Bergson criticizes this analytical mechanistic research. "The most striking characteristic of modern Western science is its complete ignorance of life." Dr. Wilhelm Reich states, "Mechanistic bacteriology colors certain cocci and bacteria with biologically effective stains in order to make them more visible. In the gram stain, staphylococci appear blue, tubercle bacilli appears red in eosin. The bacteriologist then speaks of special color reactions of bacteria, as if they were specific biological qualities of these creatures. This is wrong, for the staining is an artificial measure for the presentation of the object, and not a specific quality of the creature . . . the cancer researcher of mechanistic direction constantly overlooks the true qualities of cancer cells because he is stuck in the secondary, artificial properties which the cancer cells acquire in the process of investigation."

The Conquest of Cancer Act, enacted over two years ago, was the product of a high powered public relations campaign, and a rather deceptive one at that. The proponents claim that a cancer breakthrough is imminent, and that given enough money and the proper management techniques, man can conquer cancer, just as he split the atom and landed on the moon. Scientists continue to dispute this assumption, and maintain that new bureaucratic arrangements will not shed any light on the difficult problems of cancer research, and to suggest that we are on "the threshold of a new breakthrough" is a cruel and dangerous deception. Many scientists view the National Cancer Institute (that body that has responsibility for administering all monies in this research field) as being run more like a business than any other institute. Huge amounts of money go out in contracts to universities and drug companies, to think-tanks and companies like Life Sciences Inc. and Flow Labs . . . The crash-programs of Conquest of Cancer Act, were opposed by virtually every group of research scientists in the country. The only large group, besides the American Cancer Society, that supported the Conquest of Cancer Act, was the American Heart Association, and its Director, Dr. Campbell Moses made quite clear his reason for support. "Congress," he said, "ought to consider a similar agency to study the heart."

Lucy Eisenberg thinks that "Congress was bewitched by words, whipped into a rhetorical frenzy with talk of universal anguish and suffering, and of overcoming an implacable foe, that it overlooked the great areas of ignorance about

cancer that still remain . . . NCI seems to have embraced a General Motors approach to science. The Director of NCI, Carl Baker, (M.A. in chemistry) thinks more like a businessman or a general than a scientist, and compares cancer research to the Battle of Britain, claiming that the basic knowledge needed to find a cure for cancer is available, and what is now needed is management, planning and administrative expertise. Drs. Baker, Huebner and other members of the cancer establishment think that cancer can be cured with a massive infusion of funds."

Cancer has political implications, not only because Congressmen, like the rest of us, have a special dread of cancer, but because Congress must allocate the money that supports most cancer research, a most difficult and controversial task. "The Conquest of Cancer Act is cancer on a social level," writes Klaber. "It is the result of a way of thinking which is not only incapable of curing cancer, but is the basic cause of cancer, and other disease, mental illness, allergies, etc., or on the social level, such as crime, war and conflict. This act will not cure cancer, but will feed it."

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Straws In the Wind - -

FTC Preparing Food Advertising Regulations

The Federal Trade Commission, it has been reported, has begun work on proposed, industry-wide trade regulations that would change the way thousands of food products are advertised by setting strict limits on what can and cannot be said about ingredients, additives and the nutritional value of a huge variety of products ranging from health foods to those with high sugar content. The staff proposals, now in the hands of the commissioners for final determination, have been more than two years in the making.

It is anticipated that the staff proposals will be given early consideration by the Commission particularly since the FTC has been sharply criticized over the past year for not moving faster to implement rules covering nutritional claims made by food advertisers. It is impossible to predict now whether or not the Commission will adopt all or nearly all the proposals submitted by the staff but it is expected that the final draft of the proposed trade rule will be comprehensive and will lay down strict limits on advertising claims. In the meantime, it is reported that the staff proposals offer a wide variety of suggestions, for example –

- It is proposed that any food product containing more than 50% sugar or a sugar-like substance would have to clearly reveal this fact to the public and that it shall not be advertised to an audience which may reasonably be expected to include a majority of persons under 13 years of age.
- The term, *health food,* would be totally eliminated from all printed and broadcast advertising.
- There probably will be restrictions on the use of the terms, *natural* and *organic.*
- Severe limitations on the advertising of comparisons of the nutritional benefits of one food as compared to another, for instance, the statement that a specific breakfast drink is equivalent nutritionally to an egg, bacon and toast.
- A prohibition of such terms as wholesome, complete, or nutritionally perfect.
- Strict provisions governing disclosure of cholesterol and fatty acid content of food products both on the label as well as in advertising.

Once the proposed trade rule is approved by the Commission, it will be made public and will become the subject of hearings by the FTC, which will ask for comment from all interested parties.

When the final version of the proposed rule is released by FTC, the National Health Federation will, of course, give the proposal detailed study and will file comment opposing or supporting its various sections.

Abbott Laboratories Petitions FDA To Remove Ban On Cyclamates

When it found that a significant percentage of rats fed cyclamates developed bladder cancer, the FDA was compelled to impose a ban, a few years ago, on the use of the artificial sweetener. FDA's action was made mandatory by the "Delaney Amendment" to the Food, Drug and Cosmetic Act, enacted in 1958 which prohibits the use of any additive in foods which has been shown capable of producing cancer in man or animals. In the intervening years, there has been a more less constant, though subtle, move by the affected industry aimed at the eventual removal of the ban and re-clearing cyclamates for use as a food additive.

The latest positive move in this direction was a petition submitted by Abbott Laboratories requesting FDA to re-clear the artificial sweetener. The petition, presumably, is based on later findings. Since the ban became effective, laboratories outside the government have reported that they have duplicated the tests conducted by the government which resulted in the development of the bladder cancers but that in these later tests, the rats did not develop cancer.

In acting on the petition, the FDA has indicated that the matter will be referred to the National Academy of Sciences' Food Protection Committee following an initial review by FDA's scientists. On learning this, Anita Johnson, an attorney with the Ralph Nader Health Group filed a letter with FDA Commissioner Alexander Schmidt objecting to sending the data to the Food Protection Committee charging that the committee is "an industry - oriented group

(Continued on next page)

which has belittled environmental chemical hazards for many years" and that the group "is financed in part by the food, packaging and chemical industries." Johnson said "FDA employees, perhaps with the advice from individual specialized consultants, should assess and decide the cyclamate question."

MAJORITY OF DRUGGISTS SEE THEIR DOCTORS REGULARLY

In a recent survey on the health of the pharmacist, it was reported in the November issue of *American Druggist Merchandising*, that pharmacists tend to visit doctors and dentists with some frequency. The survey found that 76.1% said they have regular dental examinations; 57.9% regular medical checkups. Only 3.5% go to podiatrists on a regular basis, and chiropractors are consulted by 17.4%.

SURGEON WORKING ON NUCLEAR HEART

Dr. George A. Magovern, director of surgery at Allegheny General Hospital in Pittsburgh, Pa., has been given $100,000 by the Western Pennsylvania Heart Association to develop a nuclear heart.

It is the largest grant ever given by an affiliate of the American Heart Association, but Dr. Magovern said it is only one-tenth of what he will need.

The surgeon hopes eventually to replace 40 percent of the pumping chambers of the heart with a nuclear pump, "a very miniaturized version of a conventional nuclear reactor."

If successful, the nuclear heart may replace heart transplants, since it eliminates problems of rejection.

— From Heartland News

Your Invitation To Join THE NATIONAL HEALTH FEDERATION

Name (Print).....

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☐ 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.

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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.

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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: 121 2nd Street N. E., Washington, D.C. 20002
Phone: (202) 547-2547

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.

NATIONAL HEALTH FEDERATION
P.O. Box 688
212 West Foothill Boulevard
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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.

NOTE: If the last numbers in the code appearing under your name and address above read 7-74 (or any earlier date), your membership dues are now due.

COMING NHF CONVENTIONS

San Francisco — Jack Tar Hotel ..... **June 29-30**
Portland — Sheraton Motor Inn ..... **July 13-14**
Chicago — Pick Congress Hotel ..... **Sept. 6-8**
Las Vegas — MGM Hotel ..... **Sept. 14**
San Bernardino — S. B. Conv. Center....**Oct. 12-13**
New York — Statler-Hilton Hotel ..... **Nov. 16-17**

HELP SAVE OUR HEALTH FREEDOMS