National Health Federation BULLETIN

NOVEMBER, 1973

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CAN WE FORESTALL HEART ATTACK, STROKE and SENILITY?

An exclusive interview with DR. ABRAM HOFFER

AMA-HEW formula for second-class health care

PSRO

(Professional Standards Review Organization)

Public Law 72-603, enacted last year and to be implemented next year, establishes a Professional Standards Review Organization under HEW with countless regional PSROs under direct control of HEW which will police the health care of all beneficiaries of Social Security programs (80 million persons) by denying doctors their free exercise of experienced judgment in case management and compelling doctors and hospitals to conform to standardized procedures in care, diagnosis and treatment as outlined in government rulebooks; and opening doctors' patient records to government "snoopers."

FDA OVERRULES MOTHER NATURE

FDA says a product containing the same ingredients as naturally found in two oranges cannot be legally labeled or sold as either a dietary supplement or a drug under new regulations.

— See page 7 —

Dedicated to the Protection of Health Freedoms

THE
NATIONAL HEALTH FEDERATION BULLETIN

Protection of Health Freedoms — *Published Monthly*

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CONTENTS

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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An Issue Of Urgent National Import

There are no words more fitting for our Editorial Commentary, or which more fittingly also expresses NHF's viewpoint, than the words of Representative Wendell Wyatt, of Oregon, as they appeared in the Congressional Record of September 10, 1973. We are pleased to reprint his remarks here:

Mr. Speaker, I rise today to urge immediate hearings and prompt action on legislation which would once and for all prevent the Food and Drug Administration from infringing on the rights of consumers to purchase safe food supplements for their own consumption without hinderance or restriction. Such legislation, in the form of H.R. 643, has been languishing before the Interstate and Foreign Commerce Committee for months, without receiving even an initial hearing.

The past decade has witnessed a veritable explosion of freeze-dried, fabricated, frozen and "fast" foods. While most of these products are high in polyunsaturated convenience, many are woefully low in real nutritional quality. We are experiencing the strange phenomenon in the United States of a standard of living which has soared to the highest level in the world, while the quality of our diets has steadily deteriorated.

Americans consume 8½ billion gallons of soft drinks yearly, and triple that amount of coffee. We eat more than 8½ billion hot dogs a year, and each man, woman and child swallows on the average of 10 pounds of potato chips. Hamburger and french fries establishments have proliferated along our highways and become a way of life. Cookbooks are regular bestsellers in the United States, fad diets make millionaires of their inventors and losing weight is the No. 1 American preoccupation. We have reached the point where many of our eating habits are determined more by expensive advertising campaigns and enticing packaging than by taste or nutritional value.

The food products on our grocery shelves have been stabilized, colored, emulsified, preserved, canned, frozen, freeze-dried, engineered, gas ripened, reconstituted, bleached, refined, and additive-filled. The route traveled by our food from the field or farm to its final destination on the table is a long and arduous one, often consisting of hundreds or thousands of miles, with a serious and significant loss of nutrients along the way.

We have little control over the distance our food must travel before it reaches the grocery shelves, and little control over the treatment and

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processing most of our foodstuffs must undergo before we buy them. We do have the opportunity to insure that the American consumer is guaranteed the privilege of replacing these lost vitamins and nutrients if he so desires. H.R. 643 would insure the availability of vitamins and food supplements for those nutritionally aware consumers who seek to overcome the widespread deficiencies in our food.

It is quite clear in my mind that the FDA should not make a regulation that interferes with the proper nutrition of the American people. It is our obligation to stop the FDA from limiting our freedoms without justification.

Mr. Speaker, we are talking today about vitamins, minerals and food supplements – not drugs. We are discussing the lack of vital nutrients in American diets which we have little power to control. In short, Mr. Speaker, we are discussing an issue of urgent national import which deserves the promptest attention of Congress.

Orange Overdosing Illegal?

The Food and Drug Administration's war on vitamins continues with its latest ruling that drugstores next year may not sell vitamin C tablets without prescription if they contain more than 90 milligrams. (Those who believe the vitamin has cold-fighting capabilities, including Nobel Prize-winner Linus Pauling of Stanford, take up to 6,000 milligrams daily.) I refuse to quibble with the FDA's attempt to preserve the common cold, but I'm wondering if I'll be able to adhere to the letter of the law. Like many Arizona residents, it's just possible (I'm not admitting anything) that I have an orange tree in my back yard. And this fruit, of course, is a dangerous source of vitamin C – the average specimen containing an almost lethal 40 milligrams.

Now, if I should throw caution to the winds and decide to consume more than two oranges on a given day (assuming I have an orange tree, which I don't admit), will I need a prescription from my doctor?

Or would written permission from FDA be sufficient?

Most important, if permission is impossible to obtain, will I have enough moral character to keep from sneaking out to my tree in the dead of night and over-dosing on three or four oranges in one frenzied sitting?

The only solution, I'm afraid, is for the government to order every private orange-tree owner in America to dig up his source of supply and turn it in to the nearest police station.

I'd rather be sickly than a fugitive from justice.

– Jim Fiebig
in the Sacramento Union

PSRO
(Professional Standards Review Organization)

An AMA-conceived plan, adopted by HEW and enacted into law, introduces a new, foreign philosophy of health care in America in which government bureaucrats will dictate standardized procedures in care, diagnosis and treatment which must be followed by providers of health care services; and which will make doctors' patient records available to government bureaucrats.

By WILLADEAN VANCE

"Rigid federal government controls on private medical records starting next January, 1974, will destroy personal doctor-patient relationships," says Dr. James R. Privitera, of Covina, California, in an interview with John Steinbacher, managing editor of *Health Gazette*, and myself.

"The thing that hurts most," moans Dr. Privitera, "is we were sold out by the American Medical Association without even a chance of being heard when they had their legal department draw up this PSRO bill that sold us out!"

The PSRO referred to by Dr. Privitera stands for Professional Standards Review Organization to be administered and controlled by the Department of Health, Education and Welfare under the Secretary of HEW, Casper Weinberger who may become known as the first American Health Czar.

Professional Standards Review Organizations were established as legally - recognized, government - related agencies by Public Law 92-603 passed by the 92nd Congress and signed by the President on October 30, 1972. The law establishing regional PSROs as well as a national PSRO within HEW was crowded into the very complex Social Security bill which had been before Congress for at least two years. But the PSRO section, at the last minute, was pushed into the bill consisting of 989 pages and consequently, was not given proper study or hearings and was given practically no publicity. Even the senator who introduced the PSRO bill had no idea of how far-reaching it was or the influence it would have on the practice of medicine. It has been said by one responsible member of the medical profession that this single act forms a basis for greater changes in the practice of medicine than had been provided by any health legislation in the history of this country.

A Professional Standards Review Organization is, basically, a peer review committee and there is nothing new in the concept of peer review committees in the medical community. Most hospitals, for example, have long had one or more

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peer review committees. For instance, there may be a tissue review committee composed of a few qualified members of the hospital's medical staff, having the responsibility of examining tissues removed surgically. This serves to deter unnecessary surgeries, encourage greater surgical competence, and to protect the patient's welfare. Peer review committees whether within hospitals or within a local medical society have thus served well and have undoubtedly enhanced the quality of care available. However, these peer review committees have been voluntary and private, have come from within the profession itself, and is a demonstration of the efforts of the profession to police itself.

Now, with the enactment of the PSRO legislation, however, the Department of Health, Education and Welfare must set up a national review panel to be known as the Professional Standards Review Organization which, in turn, will contract with regional review panels or peer review committees to become official, government-associated PSROs. Under the terms of the law, if the HEW PSRO feels that the regional PSRO is not doing an effective job in carrying out the dictates of the national organization, the contract can be terminated and the national PSRO will take over.

The basic concept of PSRO is that the government should assume authority over what has been a private function of a private professional medical society. The concept originated with the AMA legal department and was introduced into Congress as the Peer Review Organization section of the AMA-sponsored Medicredit bill (AMA's brand of national health insurance) and was done so without approval of the AMA House of Delegates.

The controls which the PSRO law imposes upon the providers of health care services are beyond belief and cannot be covered in detail in this article but will be explored in depth in future articles. The excuse given for imposing controls is that "the costs of the Medicare and Medicaid programs have skyrocketed far beyond early estimates" and thus the government must step in to reduce these costs. Politicians justify the interference on the premise that the federal government is subsidizing health care and government can properly control anything it subsidizes. Their excuse based on "too much fraud in medical charges have been uncovered" falls rather flat when the records show a total of only 16 doctors have been convicted in all fifty states in the six years since Medicare-Medicaid began under Social Security. This averages three physicians per year for the entire country—a threat?

At present, the law is applicable only to care which may be paid for in whole or in part under the Social Security Act. This is the health care presently given some 80 million aged, poor and disabled persons. In addition, if (or when) a national health insurance plan is enacted which probably will cover everybody, the PSRO rules and regulations will be applicable to every doctor in his care of every patient.

Under the PSRO take-over, doctors can be suspended from practice and fined up to $5,000 for failure to comply with the stiff rules laid down by the PSRO under which he practices or the federal PSRO in HEW. This is the reason why some physicians have already notified their patients they no longer will treat patients whose fees will be paid directly or indirectly, in part or in whole, by Social Security. They have done this not because of dissatisfaction over a fee schedule, but rather, because they feel they can no longer practice "good" medicine and give the patients the type of care the patients deserve when the government dictates the type of treatment to be rendered, the laboratory procedures which may be done, the length of hospital stay, etc. Further, these physicians violently oppose the loss of the customary confidentiality between doctor and patient since all the physicians records must be made available to the bureaucracy and ultimately ALL records relating to the patients will be fed into a master computer presumably to be available only to the PSRO staff members and another doctor who may later see the patient. Under this arrangement, there would be no necessity for the government to send a "Plumber's Unit" to burglarize a doctors office to obtain medical records because the information would be readily available in the government's computer.

The PSRO law requires also that "profiles" be prepared and maintained on each health care provider as well as the patients. Though the law itself does not go into detail, this apparently is a device to computerize, for instant recall, a short, vivid biography giving the most outstanding characteristics of every act of every physician in diagnosing, prescribing, treating, discharging and charging every patient.

The PSRO law further provides for the standardization of treatment of every disease. One of the responsibilities of each regional PSRO is to prepare a schedule of "norms" covering the care, diagnosis and treatment based on typical patterns of practice in its region including typical lengths of stay for institutional care by age and diagnosis. For example, if you were suffering from a cold, you may be permitted to see the doctor only once or perhaps twice, the drugs he may use must be selected from the "approved" list, the doctor possibly will not be permitted to x-ray your chest unless he is prepared to furnish justifiable evidence of why he suspects you may be developing a complication such as bronchopneumonia, and the schedule of "norms" may limit your professional care to a period not to exceed five days.

All this began when the chairman of the powerful Ways and Means Committee asked the AMA to prepare guidelines to help control excessive health care costs and a plan whereby the profession could effectively police itself — or

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face the possibility the government would do the policing. Probably, Mr. Mills never thought his request would lead to the bureaucratic dream of socialized medicine openly promoted by the physicians' so-called protector, the American Medical Association.

Congressman Mills should feel fortunate that his slipped disc required treatment this year, because when the medical bureaucrats take over, the so-called "norms" will not permit a physician to use his experience and judgement in treatment, and waiting for the central data bank to send instructions could be uncomfortable—especially when the government seemingly can't even answer a letter in less than ten days.

Readers of the *National Health Gazette* recently read the shocking story broke by managing editor John Steinbacher from a novel he unearthed by John Spivak called, *The Medical Trust Unmasked*, a story of the gigantic AMA conspiracy. Author Spivak had written how the AMA was a dead giveaway in 1897 when he read their original Incorporation papers stating their purpose THEN, as a society, was to "Federate into one compact organization the medical profession, of safeguarding the material interests of the medical profession, of securing enactment and enforcement of medical laws . . . and of directing medical opinion in regard to state medicine" . . .enough said!

When the Sherman anti-trust act came along a couple years later, the AMA quietly changed the papers to read, "To promote the science and art of medicine" to avoid embarrassment, without changing their original plans one wit. The seed planted in 1897 is to be harvested in 1974 in spite of Spivak's early warning, "The time will come, and soon, when the laymen who dare to consult a practitioner not approved by organized medical societies will be arrested and prosecuted!"

The Association of American Physicians and Surgeons which Dr. Privitera belongs, joined by three physicians, has filed suit in U.S. District Court in Chicago challenging the constitutionality of the Professional Standards Review Organization Law. This will be a significant case and one we will be watching.

Doctors all over the country are beginning to inform their patients of the evils contained in the PSRO Law. Doctors reading this article may wish to use it, and others to follow in future issues, to tell the the story. The article may be reproduced without permission if credit is given its source. Also, doctors will find articles in the *National Health Gazette* (1110 South Pomona Ave., Fullerton, Calif. 92632) telling the story. The Gazette may be purchased for 25c per copy in lots for distribution to patients. John Steinbacher, the managing editor, is a fighter from way back with the largest number of Freedom Awards in both the field of news reporting and books dealing with the sell-out of American freedom in health, education, etc.

Washington Report

By CLINTON R. MILLER, NHF Legislative Advocate

Mother Nature would be in deep trouble with the Food and Drug Administration if FDA's latest dietary supplement regulations were to be made applicable to raw agricultural products. This was dramatically brought out recently when NHF submitted to the FDA, proposed label copy for a fictitious product requesting that FDA reply with a note of approval, disapproval or other comments.

The label which we submitted was for an imaginary product supplying approximately the same ingredients found in two medium sized oranges — 100 milligrams of vitamin C and 25 milligrams of bioflavonoids. FDA's regulations prohibit, in dietary supplements, more than 90 mg. of vitamin C in the recommended daily intake and prohibit the inclusion of bioflavonoids in any amount in a product containing "essential" nutrients contending that the bioflavonoids are completely without nutritional or therapeutic value and that the [ignorant] public would believe that they had value if combined with nutritionally useful ingredients even though the label might bear a clearly written statement disclaiming any nutritional value.

FDA arrived at their contention regarding the bioflavonoids in spite of voluminous evidence attesting to the contrary and the experience of untold thousands of persons who have discovered that when they use bioflavonoids, they no longer bruise easily and rarely, if ever, have those spontaneous appearing black and blue spots on their skin caused by subcutaneous hemorrhages. Inasmuch as these spontaneous subcutaneous hemorrhages are an outward, visible manifestation of what could occur also in the brain, the heart or some other vital organ, who can say how many persons have been saved from strokes or heart attacks by using bioflavonoids?

We believe that the correspondence between NHF and the FDA regarding our fictitious label contains information which is both significant and enlightening and for this reason, in spite of being lengthy, is presented here so that our members and other readers may give it due study. Peter Barton Hutt's lengthy reply provides an insight to the track upon which the FDA bureaucratic mind operates and ceraintly it would be less than fair not to give exposure to the concepts, the viewpoints and the legal position of the Food and Drug Administration.

As indicated in the first letter which follows, this correspondence and the submission of the fictitious label grew out of a meeting which was instigated by Representative Paul Rogers, chairman of the House subcommittee which has the responsibility of holding hearings on the Hosmer

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bill. The meeting, held in the Congressman's office, was attended by Peter Barton Hutt, General Counsel for the FDA, as well as representatives of the National Health Federation and the National Nutritional Foods Association. In the course of the discussion which ensued at the meeting, it was pointed out that under the new regulations, it would be impossible to write a legally acceptable label for a product which provided merely the same ingredients found in a glass of orange juice. Representative Rogers took note of this point and intimated that surely there must be some common ground of understanding in such problems and suggested that NHF get together with FDA in an effort to resolve some of these problems. It was on the basis of this suggestion that we prepared the fictitious label and submitted it to Mr. Hutt for his comments.

And now, with this explanatory preface, we reprint the letters without further comment.

THE NATIONAL HEALTH FEDERATION
Washington Office
121 2nd Street, N.E.
Washington, D.C. 20002

The Honorable Peter Barton Hutt, General Counsel
Food and Drug Administration
Rockville, Maryland 20852

Dear Mr. Hutt:

In pursuance of our conference yesterday with Congressman Paul Rogers herewith delivered is a pro forma suggested label for a dietary product, which should meet the labeling criteria concerning which the Congressman desired discussion and possible agreement.

Please note that the product in question would contain 100 milligrams of vitamin C, in association with 25 milligrams of bioflavonoids. Please note that the suggested label would set forth correctly, we believe, the attitude of your agency, as indicated during our conference yesterday.

Incidentally, according to official government food tables, one glass of Florida orange juice would supply 127 milligrams of vitamin C, or 127% of the vitamin C supplied by the product in question, whereas, according to the same tables, two large navel oranges would supply 166 milligrams of this essential nutrient, or 166% of the vitamin C supplied by the product in question. Of course, it is fundamental that either the orange juice or the oranges, as the case may be, would contain citrus bioflavonoids naturally associated with the vitamin C so supplied.

Needless to say, we are most anxious to determine, at the earliest possible time, whether or not the labeling approach mentioned by Congressman Rogers would be acceptable, the label delivered herewith merely being illustrative thereof.

The undersigned stands ready to discuss this matter with you at your earliest convenience.

Sincerely,
Clinton R. Miller

The following proposed label was included with the above letter:

(Trade Name of Product)

DIETARY SUPPLEMENT

Each tablet provides

Vitamin C — 100 mg.*

Citrus Bioflavonoids — 25 mg.**

CONTENTS: 100 TABLETS

Recommendation: One tablet per day, as directed for dietary supplementation.

Distributed by
X-Y-Z Company
Anywhere, U.S.A.

*One tablet contains Vitamin C — 100 mg., which is 10 mg. more than the maximum amount considered appropriate, or of value, for dietary supplementation by the U.S. Food and Drug Administration.

**The U.S. Food and Drug Administration does not consider citrus bioflavonoids of nutritional value for any purpose whatsoever.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
ROCKVILLE, MARYLAND 20852

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

Dear Mr. Miller:

This is in response to your letter of July 13, 1973, enclosing a "pro forma suggested label for a dietary product." This label was sent at the suggestion of Congressman Rogers that an attempt should be made to determine whether some agreement on an appropriate label could be obtained.

I might first mention that the label you submitted does not conform to the concepts discussed by Congressman Rogers. His first suggestion was that the same label might be used for both food and drug use. As I will discuss below, this concept is entirely acceptable to the Food and Drug Administration, and indeed requires no change in current regulations. His second suggestion related to the use of a clear affirmative disclosure to the effect that any representation of a food product for medicinal or therapeutic uses would be fraudulent. Not only is no such disclosure included

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Although the National Health Federation does not promote nor advocate any specific therapeutic approaches or methods of treatment, we do occasionally pass on to our readers, through these pages, information relating to newer trends in the field of therapeutics. We are privileged here to present a report by Mr. Jay Patrick of an exclusive interview with Dr. Abram Hoffer, a distinguished biochemist, physician and psychiatrist. We believe the information revealed by Dr. Hoffer in this interview to be so significant, it is printed in its entirety in spite of its length. The general acceptance and application of Dr. Hoffer's findings may well add several years to the average life span of our people.

Transforming society's major loss to a major gain —

Can We Forestall Heart Attack, Stroke, and Senility?

By JAY PATRICK

Nearly everyone spends most of his life learning his profession. This takes a lot of time, a lot of effort, and a lot of money. Then, in most cases, just as he is rising to the peak of his effectiveness — comes the fall.

Often it's death, as some 800,000 will succumb this year to heart disease. Sometimes it's much less obvious — an imperceptible stroke, a decline in memory, an inability to collect one's thoughts, a loss of energy, a tendency to slur words, a growing frustration with the complexities of life.

Our society is thus robbed of the cream of each generation.

But what if we could reverse this course? — if we could add 10 or more years to man's productive life?

Indeed, the major loss of our society might then be converted to a major gain, it seems, if we could just utilize the health knowledge now available to us.

This could add a new peak to each man's career, research indicates, as the cumulative effect of all his knowledge and experience is brought together in synergistic accomplishment. Thus 2 plus 2 might equal 5 or 6, and the world could be enriched by the full utilization of its best brains and most experienced citizens.

This is the way it looks from my seat in the arena. Thus, it was one of the real pleasures of my life to sit down and talk at great length with Dr. Abram Hoffer, distinguished biochemist, physician, and psychiatrist, and to ask him, *"CAN WE FORESTALL HEART ATTACK, STROKES, AND SENILITY?"*

DR. ABRAM HOFFER (l.) — MR. JAY PATRICK (rt.)

"Yes, we can . . . in most cases," said this famed biochemist, physician, and psychiatrist, Dr. Abram Hoffer.

The internationally known researcher had flown down from his native Saskatchewan, Canada, to keep numerous TV and lecture engagements in California.

But he had set aside a week for writing while sunning himself in Palm Springs, and it was there that I managed to catch him for many hours of fascinating discussion of a wide range of man's health problems.

At first we talked primarily about his astounding successes in bringing countless schizophrenics, alcoholics, and mentally disturbed people back to reality and joy of living. — His chief tools, Niacin and Vitamin C, massive doses of them.

"What is the usual treatment for schizophrenics?" I asked.

"Each case is different. Many times, though, a daily intake of 3 to 5 grams of vitamin C, up to about 20 grams of niacin, the right diet, and good vitamin and mineral supplementation will within a few weeks or months bring most acute schizophrenics around to what we call normalcy. Other cases may involve, until the megavitamin therapy is well under way, the addition of some of the commonly accepted tranquilizers and anti-depressants, plus even electro convulsive (shock) therapy, if the disorder is far advanced."

"Do you perform this work as a psychiatrist?"

"I think of myself as a physician and a biochemist, don't even have a couch in my office. I don't spend a lot of time going into the patient's childhood. I don't care if his parents toilet trained him early or late, if he over-loved his mother and hated his father, whether he learned

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about sex at 5 or 25 years. I *do* have a series of written questions which tells me if he is suffering from schizophrenia. Dr. Humphry Osmond was closely associated with me in the early work in Saskatchewan. He and I developed this questionnaire which is known as the Hoffer-Osmond Diagnostic Test or HOD. It reveals the kind and degree of perceptual distortions experienced by the patient, and, when repeated, helps us determine his degree of recovery."

"Tell me, doctor, about how many people have schizophrenia?"

"About 3%, which would be over 6 million people in the United States."

"Well, doctor, it's wonderful what you have accomplished with these unfortunate people who have often been shuffled about from one mental hospital to another. Of course, we need thousands of doctors who believe in your biochemical procedures. However, 100% of the people face, with advancing years, the specter of heart attack, stroke or senility. I understand that your work has lead you to important discoveries. How did these discoveries come about?"

"In 1954, just before I was given a Rockefeller Foundation Grant, they attached one condition to it: They said, 'We will not give you the money until you go to Europe for three months as a Rockefeller Fellow.' It was a very easy condition to follow; so my wife and I started off to Europe to visit the research centers of England, France and Germany.

"Just before we left I went to see my mother and father. My mother was very ill. She complained that she had arthritis. She was going blind in one eye, her fingers were getting crippled up, and her memory was gone. She was under a good deal of pressure, as my dad was suffering from cancer of the prostate, and he had only a year or two left to live.

"I didn't know what to do about my mother because, like every other doctor, I *knew* that there is no treatment for senility. Every doctor *knows* this, so I *knew* that I couldn't do anything for my mother. But I thought: 'What can I give her that will be very dramatic, will not hurt her, but will lead her to think she is getting something, the placebo effect?'

"So I started her on niacin, because I knew a good deal about it by then, since I had been using it for some years for schizophrenia cases. I knew it wouldn't hurt her, and it has a dramatic flush when you first start taking it. So I put my mother on 3 grams of niacin daily in 1954.

"Then we went to Europe, and six weeks later I got a letter from my mother at my mail point in London. It was a very enthusiastic letter. She said: 'My vision is okay, my arthritis is gone, those little bumps on my fingers are going away,' and she described herself as feeling marvelous. Well, I laughed! I said, 'It couldn't possibly be true, it's just the placebo effect.'

"So I came back home three months later, in July of that year, and we went down to see mother and dad. She was a different woman; there was no doubt about it. Now my dad *did* die, but my mother is still living."

"How old is she now?"

"She's 86 now; her mind today is just as keen as it ever was, and she spends her time writing her memoirs."

"Have you kept her on niacin?"

"She's been on it ever since – 3 grams a day. This started me thinking. I said to myself: 'Well, here I always *knew* that senility was irreversible, but I have to believe what I see, not what I am told. And here is my mother, whose senility apparently *was* reversible, and she has done so well ever since.'

"So this started me on other tests and pretty soon with the Professor of Anatomy, Dr. Mark C. Altschule, we did a study on niacin in lowering cholesterol levels and we found that it would. We published a paper in the Archives of Biochemistry in 1955 where we claimed that niacin lowered blood cholesterol, and within the year that was confirmed by the Mayo Research Foundation. Since then there have seen a thousand papers published on it, all confirming, and now niacin is one of the standard agents used."

"But this technique does not appear to be widely used. How many doctors are using niacin this way?"

"Not all, but many doctors. Sharp internists are now using it."

"Maybe 2% of the doctors?"

"I can't guess, but certainly not enough – except in certain areas, where a lot more doctors are using it. It is recognized by the American government. It is now the one use for niacin in these megavitamin doses which they recognize."

"But what vitamins and minerals do you think one should take?"

"Well, I think every man and woman has a responsibility to be healthy. He has the responsibility to be so healthy that he won't ever have to see a doctor. When you go to a doctor it means you have failed somehow."

"Well, it's a good point of view, but we need more knowledges as to how to take care of ourselves and certainly, just as much, the will to follow the right life style – is that not so?"

"Yes, it certainly is."

"But, how do we do it?" I asked.

"Well, you do it first of all by insuring that your nutrition is not just adequate but *optimum* – the best you can figure out. To me that means no 'junk.' No sugar, no caffeine, no white flour. If you follow these three simple rules, and then have three meals a day, you can't go too far wrong. That's the first principle of good nutrition.

"The second principle is that this may not be enough for many people since we are all very much different, in the same way that we don't look alike, don't act alike, we are different people. We are different chemical organisms. We have to tailor our own needs. So that I would say the next thing is to go on to what is most probably wrong

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– that within our culture most of us have been eating badly for a long time.

"The most likely thing that we need is niacin – and there the minimum dose is probably around 3 grams a day. That is, 1 gram taken after each meal. The new timed release, buffered tablets, just going on the market, offer the best solution to the problem. They produce little or no flushing and distribute the water soluble vitamin more evenly through the day.

"If you take the conventional tablets, which are not timed release, you must watch very carefully because the flushing action can be quite extreme. It will not harm you, but it could be very disconcerting while driving a car, for instance. The flush starts in your forehead, and works down. It lasts maybe an hour, is accompanied by itching of the skin and some chilling effects. The next thing is, I don't say which is more important – but a combination of nutrients. The next vitamin is vitamin C, and there I think that the minimum is 3 grams. That's minimum, but when you are under stress, have a cold, an infection, or are working too hard, not sleeping well, you need more. Some people have gone up to 10 or 20 grams of vitamin C. There again, timed release 'C' is far more effective, since it is assimilated in the body over something like an 8-hour period, and tends to maintain a more steady level of this vital substance in the body."

"Doctor, what causes the flushing?"

"The flushing is due to the fact that the niacin causes the release of histamine. We have certain cells in the body that store histamine. These are called the mast cells, and the histamine is locked in these cells and held there. Now when you take niacin it sort of opens the gates and histamine floods into the blood, causing the flushing action, itching and temporary discomfort. If you go on this kind of program, it reduces the chances of developing coronary disease or brain strokes."

"Well, doctor, this discovery of yours seems to be of enormous importance."

"Yes, when you consider that some 25 million people in the United States are over 65 years of age, nearly all of them facing senility, heart attack or strokes . . ."

"Well," I commented, "I have been writing for some time that the major loss to our society is that these people, just when they have acquired the knowledge and experience to make them our most effective citizens, find that they slump into senility or die of heart disease. As a consequence, our whole country suffers in countless ways from the loss of this talent and expertise, and finds, instead, that it must contribute greatly to the support of people who would, otherwise, in good health, be supporting themselves."

"Yes, that's certainly true."

Doctor, you are talking about the use of a vitamin, niacin, or B-3. Most of our population has now been so brain-washed by the AMA, the FDA and some voluble followers of the medical establishment that they cannot comprehend that a vitamin could do so much good. They have been told that a 'well-balanced diet' is all that the average person needs, and have been led to believe that such a 'well-balanced diet' is easily obtained."

"I can agree that a well-balanced diet is often all that most people need, especially if they start on it early, but getting that 'well-balanced diet' is no easy task.

"Most people, for instance, overload themselves with sugar. The analysis of one American's diet showed, for instance, that he was getting about 400 pounds of sugar annually in his diet. The average in the United States is approximately 115 pounds. This highly refined carbohydrate, completely devoid of all the other nutrients present in the cane or beet from which it originates, is held chiefly responsible for the death, in the United States, of approximately 800,000 persons annually of heart disease. Actually, it is responsible for the death and ill health of millions and millions more. Dr. John Yudkin has discussed this subject more effectively in his excellent book, 'Sweet and Dangerous.'

"Researchers have found that if dogs are deprived of their normal requirements of niacin for a *short* time and are then soon given the proper amounts, their bodies are easily restored to normalcy. On the other hand, dogs deprived of their basic requirements of niacin for six months, which is equivalent to some 10 or more years of a man's life, cannot then be brought back to good health without the steady use of niacin in quantities far in excess of their usual requirements.

"This is what happens, we find, with any man who has gone for a long period of time without the volume of niacin his particular body needs. We find that he cannot regain his health without a dosage way in excess of the so-called normal requirements. In fact, we do not know for sure just how much of any vitamin or mineral each specific, unique persons requires.

"Dr. Roger Williams has written several interesting books emphasizing that each person varies enormously from the other in size, shape, and effectiveness of his internal organs. In addition, these substantial variations, far greater internally than the differences in our outward appearance, are accentuated by the radical differences in our life style, the foods we eat, the localities in which we live, the minerals present or not present in the soil from which our vegetables are grown, the individual stress, racial and familial eating habits, and so on.

"Since the human body is so intricate, we accordingly cannot know for sure just what any, specific person requires nutritionally. Thus, we must resort to a certain amount of trial and error. This is called the pragmatic approach: 'It's good if it works'."

"But about a million people die

(Continued next page)

annually in the United States from heart disease, three times as many as die of cancer. Can you help them?"

"Perhaps 65% can, I believe, postpone or prevent such an attack, maybe extending their lives 10 to 20 years."

"Fabulous! How does niacin do this?"

"There are two major ways in which this action seems to occur. The first one is that, by lowering the quantity of cholesterol and triglycerides in the blood stream there is less pressure exerted by the blood on the vessels.

"The other factor is that niacin has anti-sludging properties. Sludging occurs in the blood when the red cells stick to each other. Instead of flowing smoothly and freely in the liquid media, they clump together; and when they are clumped together, the cells cannot pass through the small capilaries. Capilaries, minute blood vessels, are so small that in some cases, the blood cells must go through, one after the other, in single file. Thus, when they are clumped together, they cannot pass through, and so, nutrients, including oxygen, which are essential to the life of the tissue, heart muscle, the brain, any area of the body, are not transported to all points where they are needed. Accordingly, various sections of the body are reduced in efficiency, may malfunction, atrophy, or die."

"I guess most people tend to think almost entirely about major arteries in the body, ignoring the millions of small blood vessels."

"Yes, that's so. All the vessels, large and small, must be working in the really healthy person. Now, niacin prevents sludging. In the presence of adequate niacin the red blood cells disperse from each other. There seems to be an increase of the electro-negative charge in the cells, so that they separate more readily from one another."

"But, doctor, what about strokes and the senility that comes with old age, that even strikes many in their late 50's?"

"Well, the word 'stroke' is, of course, the common term for impairment of the flow of blood in some area of the brain – clotting, clots, or hemorrhaging. Now, if sluding can be prevented, the small capilaries in the brain are not going to get clogged, the tissues are not going to get softened, and, therefore, there is less chance that a hemorrhage will occur.

"So, generally, niacin acts by improving the circulation of all areas of the body, including the brain. But there is another important factor. Since niacin is a component of one of the major respiratory enzymes, NAD, it has been established that an increase in the quantity of niacin in the body results in an increase of this enzyme, which seems to step up the efficiency of the brain, which, also, is very helpful.

"I have had some elderly people who were becoming senile, who, after being on a good level of niacin and other vitamins for one or two months, fully regained their normal mental activity."

"Wonderful!"

"... And in my own practice, any time a patient comes to me in a pre-senile state, who follows this program faithfully, usually, just about in every case, comes out pretty quickly."

"But how does anyone know he is in a pre-senile state?"

"When the general clarity of his mind is reduced, when he has to grope for words, when he finds that he is repeating with great frequency the stories he may tell friends, when he frequently forgets the subject he was discussing.

"But it is my ambition to bring every man to such a state of good mental health that until he dies, as some time happens to us all, he will be in full possession of his faculties."

"Then you don't feel, Dr. Hoffer, that each of us must face steady deterioration of his brain power as he gets older? You know we are told that we lose 100,000 brain cells every day of our lives."

"Well, we may lose a lot of brain cells daily, surely less if we have the best possible nutrition, but we seem to have enough left to last for 100 years anyway. There is no theoretical reason why the brain should be the first organ to go. The brain should the the *last* organ to go.

"But of course this therapy, this really good eating program, this commitment to follow the right life style must come before the brain deteriorates to any substantial extent – because, once a person has lost part of his brain, nothing will bring it back."

"Dr. Hoffer, your work and the work of your associates, your findings, your brilliant conclusions stand out like a beacon in the lives of nearly 4 billion people who grope in semi-darkness, rarely ever realizing any good measure of their potential. In behalf of all humanity, I thank you."

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."

Industry's Fluoride Solution

By LEE HARDY

No. 3 In A Series

Desperate situations require desperate remedies. The solution eventually adopted for disposing of fluoride wastes from industrial processes was to put them into public water supplies for people to drink. The argument for such a procedure was based upon the theory that fluorides would combine with the calcium in the teeth of children and produce a harder tooth tissue which would be more resistant to decay.

The proponent of this idea was Dr. Gerald J. Cox, a research fellow at the Mellon Institute. He presented the idea in November 1939 in a dissertation published in the Journal of the American Water Works Association.[1] The idea is ingenious, to say the least. Tooth decay is such a curse in America and other "civilized" countries that any means of abating it should be welcomed, and the welfare of our children is so dear to us all that fluoridation should be accepted by everyone without question.

Dr. Cox gleaned his idea from a Public Health Report of a survey conducted by Dr. H. Trendley Dean, director of the National Institute of Dental Research, issued in May 1939.[2] Dr. Dean and four associates had investigated the dental condition of children in four Illinois cities: Galesburg, Monmouth, Macomb and Quincy. In the water in Galesburg and Monmouth they had found concentrations of 1.9 and 1.6 parts per million of fluoride respectively, and had correlated these figures with respective findings of 194 and 208 carious permanent teeth per 100 children, while Macomb and Quincy, with only 0.2 ppm of fluoride in their water, had dental decay rates respectively of 369 and 628 per 100 children. From this comparison they came to the conclusion that the presence of the fluorides in the water had resulted in 50% to 67% less dental decay.[2]

Dr. Dean and his coworkers discovered also that calcium, the chief mineral constituent of tooth structure, was present in the Galesburg and Monmouth water at 62.2 ppm and 65.0 ppm respectively, and in Macomb and Quincy water at respective rates of 47.1 ppm and 28.2 ppm. Their report stated that ". . . the possibility that the composition of the water in other respects (than fluoride) may also be a factor should not be overlooked."[2]

Dr. Cox chose to disregard the idea that the calcium content could be responsible for the difference in dental condition. By a simple mathematical process either Dr. Cox or Dr. Dean could have determined that the condition of children's teeth in Macomb and Quincy varied inversely in almost identical relation with the calcium content of the water, but did not vary directly as the fluoride content, since fluoride content was identical in both cities. Dr. Cox did remark, "They (Dr. Dean and associates) did not cite evidence of varieties of dietary habits. But, of course, marked differences in food usage would not be expected. One would suppose, for example, that the per capita consumption of fermentable carbohydrates would be about the same for each of the four cities."[1]

Dr. Cox may be exactly right in his assumption, but it is hardly the type of evidence required for scientific conclusions. However, he was willing to overlook important dietary factors and base his solution of the fluoride problem upon the Dean report. Boldly defying earlier U.S. Public Health Service policy, Dr. Cox wrote ". . . the present trend toward the removal of fluorine from food and water may need some reversal."[1]

On such flimsy premises is the fluoridation of public water supplies based. Dr. Dean, who became known as the "father of fluoridation," might well have remembered his survey of 1938 in which he found 37% of teeth examined in Pueblo, Colorado, caries-free with 0.6 ppm of fluoride in the water in contrast with only 11% caries-free in East Moline, Illinois, with 1.5 ppm of fluoride.[3] However, human nature is such that one finds most readily that which he is seeking.

It is charitable to presume that industry's purpose in its research which led to fluoridation was to rid itself of its burden of unwanted residue rather than add to corporate profits. However, it appears that both results were accomplished. Rises in fluoride price suggest that a drug on the market soon became a commodity in considerable demand. Also a fair business in supplying equipment for the insertion of fluoride into the water has developed, along with other related services.

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1. Cox, G. J., *New Knowledge of Fluorine in Relation to Dental Caries,* JAWWA, 31:1926-1950, 1939.
2. Dean, H. T., Jay, P., Arnold, F. A., Jr., McClure, F. J. Elvove, E., *Domestic Water and Dental Caries, Including Certain Epidemiological Aspects of Oral L. Acidophilus,* Public Health Report, 54:862-888, May 1939.
3. Dean, H. T., *Endemic Fluorosis in Its Relation to Dental Caries,* Pub. Health Report 53:1441-1555, Aug. 19, 1938.

TEN YEARS TO RECOVER

A Canadian cancer expert claims it takes at least ten years for a person's lungs to recover after he stops smoking. Dr. Robert Taylor stated, "Only after 10 years would an ex-smoker's chances of developing cancer be reduced to those of a person who never smoked." He stated that about 90 percent of lung cancer was due to smoking.

THE FAMILY CIRCLE

By FRED J. HART
Chairman of the Board of Governors

Judging from the number of suits which already have been filed in federal courts around the country, and the suits which are still being planned, all aimed at blocking FDA's dietary supplement regulations, the FDA legal staff undoubtedly will be busy in courts for many months to come. NHF filed a petition in the 2nd Circuit Court of Appeals within days after the FDA published their final order which will limit the potency number and combinations of vitamins and minerals in dietary supplements. There is nothing else the FDA could have done which would have aroused more people to the realization of the extent of the bureaucratic encroachment upon their liberties.

The promulgation of the vitamin and mineral regulations was no surprise to those who have followed FDA's actions in this field for the past ten years. Inasmuch as court action was not possible until the FDA actually issued and finalized the regulations, NHF, several years ago, saw the need for legislation to block any attempts of the FDA to even propose such regulations. Consequently, it was NHF which wrote the bill introduced by Representative Hosmer during the past several sessions. But because the FDA had not yet issued the anticipated regulations, it seemed impossible to gather sufficient popular or congressional support to move the bill. It seems to be human nature not to get excited about an enemy until he is at the front door.

It is gratifying to those of us within the National Health Federation, however, to acknowledge that we now have the support of many organizations and groups of people completely outside of our own organization.

It has recently become very evident that there is a decided step-up in a campaign to intimidate and harass people engaged in the health food business. Several arrests have been made on the flimziest of charges. This emphasizes the need to bolster our **Legal Defense Fund** either through sizable (or small) one-time contribution to the fund or through more members in our **Dollar-A-Month Club** — people who contribute one dollar each month, without being billed for it, to the Legal Defense Fund. Many who have already joined have sent a check for $12.00 for the entire year. The money in this fund will be used to provide financial and/or legal help to some of these victims when constitutional issues are involved or where the case is one clearly of harassment.

In the meantime, it gives me pleasure to announce that the NHF headquarters is now housed in our new home located at 212 West Foothill Boulevard in Monrovia. We outgrew our former building long ago. Our new home, a very attractive, five-year-old building, provides us with over 20,000 square feet of floor space which should fill our needs for some time to come.

A wonderful program is being planned for our Annual West Coast Convention to be held at the Anaheim (California) Convention Center where our last year's successful convention was staged. Watch the **Bulletin** and your mail for more details about the coming convention but, in the meantime, begin making plans to attend. The dates are January 17-18-19-20. We are going all out in planning the program and we can promise you it will be an event to be long remembered. A better seating arrangement is being planned which will provide more good seats as well as seats on the ground floor to eliminate the necessity of climbing stairs for those who find this a difficulty. All of the exhibits will be completely apart from the lecture area. Look for the details concerning the convention in the December **NHF Bulletin.**

Your Invitation To Join
THE NATIONAL HEALTH FEDERATION

Name (Print).....

Street.....

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.

☐ I wish to become a PERPETUAL MEMBER ($1,000.00 payable in cash or convenient terms).

☐ 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

A REPORT TO CONSUMERS

The Story On Red Dye No. 2

By IDA HONOROF
Consumer Advocate

On April 15th of this year, the Food and Drug Administration (FDA) banned the food color dye, Violet No. 1, which had been used in drugs, cosmetics, beverages, bakery goods, ice cream - sherbet, pet foods, drugs and cosmetics. 20% of this dye had been used by the U.S. Department of Agriculture (USDA) in their federal meat inspection program, which stamps the "USDA Inspected and Passed — Choice, Prime, Good" etc., the stamp is familiar to meat buyers.

The FDA stated that their decision to ban Violet No. 1 was based on two unpublished Japanese studies, in which the dye had been proven to conclusively cause cancer. For once the FDA (after 22 years of use) had acted correctly, despite the fact that early this year the National Academy of Science (NAS) had given their assurance that Violet No. 1 was safe. The FDA stated that the Japanese studies *caused them to do a re-evaluation.* The ban on Violet No. 1 became effective on April 10, 1973, but the FDA stated that they will not recall any products presently on the market that contain this dye. Neither do they plan to stop the use of the dye that was manufactured prior to April 10th.

However, the sales of Violet No. 1 in no way can compare to that of Red No. 2, the most widely used dye in foods of all kinds, in drugs, lipstick, etc. It is so ubiquitous, that according to one FDA official, "If Red No. 2 would self destruct tomorrow, a lot of people would starve." Alone, or blended with other dyes, Red No. 2 colors ice cream, bakery goods, hot dogs, processed cheese, luncheon meats, dry cereals, pickles, canned fruits, pet foods, jellies, jams, candies, gelatins, salad dressings, non-cola soft drinks, etc., etc.

In 1970, the FDA was advised that two Russian studies had reported that Red No. 2 caused cancer, birth defects and fetal deaths in laboratory animals. These reports were translated and by January 1971, FDA scientists felt that an immediate study should be undertaken to determine the authenticity of the Russian findings. On March 11, 1971 the FDA began their own tests. Within 6 months, the FDA findings revealed conclusively that a possible hazard did exist.

True to their past performance, the FDA became petrified when the food industry was challenged. On July 3, 1972, they proposed a restriction on Red No. 2, stating that it could be used only in amounts not to exceed 30 ppm. In beverages, where approximately 50% of current production is used, the average levels would be cut in half. In lipstick, it could be used at levels up to 1,000 ppm. In pet food it could be used in amounts up to 30 ppm. (This means a reduction of only 30%.)

On September 21, 1972, Anita Johnson, an attorney with the Health Research Group, testifying before the Senate Select Committee on Nutrition and Human Needs, pointed out that "In 1960, Congress passed a law which required that color additives be tested for safety before being added to our food supply. Today, 12 years after Congress demanded proof of safety, dyes are still on the provisional list, without proof that their use is safe. The FDA has granted extensions of time for testing with routine abandon, ignoring the law it is supposed to enforce. Nowhere are the consequences more alarming than in the case of the coal-tar dye, FD&C Red No. 2.

Instead of acting in accordance with his own FDA scientists, Charles Edwards referred the question of safety (of Red No. 2) to the National Academy of Sciences Food Protection Committee, who at first refused to consider the matter, but on the insistence of the industry liason committee (composed of scientists in food industry employ) NAS took the case. The Food Protection Committee is well known for its bias for industry affairs at the expense of consumer protection, being heavily influenced by its industry liason group and consistently receiving financial support from the food, packaging and chemical industries. The Food Protection Committee will never recommend action which would significantly inhibit the industry. It has long been dominated by scientists with close industry ties, some of them openly deride concern for long term effects such as cancer, genetic damage and birth defects.

It was no surprise that the Food Protection Committee issued a report that whitewashed Red No. 2 hazards. It discarded studies showing toxicity, without specifying any fault with them. It instead accepted studies produced by the industry which concluded that there were no adverse effects. In spite of their conclusions, the actual data of these tests, as analyzed by a Health Research Group biochemist showed significant adverse effects. Julius Coon who headed the Food Protection Committee "study of Red No. 2," also heads many Academy Studies of FDA food matters, made his position clear when he stated, "There is not a shred of evidence or even a basis of reasonable suspicion that any such damaging effects (cancer, birth deformities, or genetic defects) have ever been caused by the additives or pesticides in food consumed in North America" (Industrial Medicine, vol. 39, no. 10, October 1970, p. 31). After an FDA scientist presented evidence that the dye caused birth defects in chicks, Coon stated "We

(Continued next page)

all appreciate your coming over here and entertaining us this afternoon."

The FDA embraced the Food Protection Committee report and completely abandoned the FDA traditional 100-fold safety margin in setting permissible uses of the dye (37 F.R. 129, 13181) . . . "A safety factor in applying animal experimentation data to man of 100 to 1 will be used; that is, a food additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum amount demonstrated to be without harm to experimental animals." —(21-C.F.R. s. 121.5)

The 100-fold safety factor is used to compensate for the insensitivity of animals as indicators of human adverse effects and for widely varying consumed diets. FDA's regulations gives the agency some discretion in choice of a safety margin from the no-effect dose in animals, but the choice of a safety margin 9/10 below the 100-fold prescription is utterly beyond discretionary bounds. IN AN UNPRECEDENTED MOVE, THE FDA USED A *10-FOLD SAFETY MARGIN INSTEAD OF A 100-FOLD.*

The reason that the FDA adopted the 10-fold safety factor for Red No. 2 is revealed by Dr. Virgil Wodicka (FDA Bureau of Foods) in his statement in Medical World News (September 8, 1972) . . . "We're stuck with Red No. 2; if we went to a 0.15 mg limit, we'd wipe out its use." The 0.15 limit is that dictated by the traditional 100-fold safety margin. A 110 lb. woman drinking one can of cherry soda a day would exceed the "safe" limit. Said limit would prohibit the use of Red No. 2, and therefore the FDA invented a new concept—a "safety" factor that allows the industry to continue using its favorite additives, "public be damned" as Anita Johnson testified.

Anita Johnson sums it up: "The American public would rise up in terror if Congress imposed a law requiring compulsory birth control . . . Totalitarian, we would all cry. Yet the FDA in effect does exactly the same thing in allowing this dye on the market. In the name of retaining the 'market profile' of fake red food products. Further, the FDA has ignored the indications of birth defects and of cancer that Red No. 2 has raised. In short, in the case of Red No. 2, FDA has subscribed to the theory, 'sell now, test later.' As tests later start rolling in, and they raise doubts of safety, FDA then waives the safety margin its own regulations demand. In so doing, FDA *waives its legal responsibility to protect consumer health."*

The foregoing, reproduced with permission, has been excerpted from "A Report to the Consumer," a highly informative bulletin published bi-monthly by Ida Honorof, P.O. Box 5449, Sherman Oaks, CA 91503. Subscriptions $7.00 per year.

"Two things are bad for the heart," noted Bernard Baruch, "running up stairs and running down people."

Consumer Affairs Report

By TREESA DRURY

The Cereal Controversy Continues

The cereal controversy has been with us since 1971. At that time, congressional subcommittees listened to testimony . . . that many if not most of the leading cold cereals not only contained very little in the way of nutrition but they contained sugar, artificial coloring and antioxidants which made them unwholesome. The debate still continues. In the last several years, many cereals have begun to fortify their products with vitamins and minerals in addition to the free toys, sugar frostings, and preservatives. However, consumer advocates feel that this approach also has evil overtones.

Michael Jacobson is co-director of the Center For Science in the Public Interest, holds a Ph.D. in microbiology and is an advisor to the Consumer's Institute for Food Research. Jacobson in testimony before the Senate Subcommittee, pointed out that the consumer is paying much too much for cereals that are vitamin fortified. He said that the wholesale cost of 100% of the adult minimum daily requirement of eight vitamins is less than 1/20th of a cent. He gave as a concrete example, General Mills Wheaties and Total. The lists of ingredients are identical except that Total contains 100% of the minimum daily requirement of nine vitamins and one mineral. He said as far as he could tell, these two products look, smell and taste the same.

The major difference of course, is that Total is much more nutritious and much more expensive. According to Jacobson, the industry price lists show that the wholesale costs of the added vitamins in a 12 ounce box of Total was 6/10th of a cent . . . yet the consumer generally pays 18c more for a box of Total than for Wheaties . . . which amounts to around 3000% mark-up. In carrying those figures out, Jacobson estimates that the Consumer is paying $7.3 million a year in overcharges. He said this unwholesomeness is not cancelled out by the addition of nutrients. "Our goal should be to have nutritious foods that are also wholesome."

Saccharin Removal In the Wind

Diabetics and dieters were distressed with the removal of cyclamates and will be equally upset, probably, should saccharin be removed. However, don't despair. It seems when pushed to give up what an agency may consider harmful to your health, industry manages to find a substitute. In this case a natural protein said to be 3000 times as sweet as sugar has been extracted from a type of West African berry and is now under study as the "perfect sweetner."

Health Freedom Rally Planned In San Francisco

A giant rally has been planned for the San Francisco area for the purpose of bringing together concerned citizens to protest against the Food and Drug Administration's new regulations limiting vitamin and mineral potencies in dietary supplements and eliminating the freedom of choice in building better health.

The rally has been scheduled for Sunday, November 11 from 1:00 to 4:30 p.m. at the famous Cow Palace near San Francisco. The Cow Palace has a seating capacity of 14,500 and a full house is anticipated.

The Health Freedom Rally is being sponsored by Consumers for Health Freedom, which was formed in response to citizen concern for their health freedom. It is aimed at bringing to the attention of the entire country the misleading information promulgated by certain FDA proposals and the dangers these proposals give rise to. The purpose of the rally is to harness the power of the people in gaining nationwide support for H.R. 643 (the Hosmer bill) which would prevent the FDA from limiting the potency, number and combination of vitamins and minerals unless they can first prove that they are harmful.

Many notables have been invited to participate in the rally including several members of Congress, TV and motion picture stars, radio personalities, health authorities, as well as athletes, musicians, singers and entertainers.

NEW PERPETUAL AND LIFE MEMBERS

Perpetual Members

Mrs. Frank Tease
Mrs. E. J. Larime

Life Members

Paul Borlee
Mr. and Mrs. T. W. Airhart
Frances Whitener
Dr. and Mrs. M. D. Lowry
Irma H. Moon
Variety Health Foods, Mansfield, Ohio
Mrs. Arthur Epstein
Mr. and Mrs. Lewis E. Donnell
Miss N. L. Foote
Roger C. John
Vic Boff
Sunflower Health Foods, Gainesville, Florida
Mrs. Helene B. Mitchell
Mr. and Mrs. Gilbert E. Gooch
Elsie H. Van Noy
Mr. and Mrs. Arthur W. Snyder
Mrs. Jean Munding
Alyne Williamson
John L. Albers
Ira Hatch
Judith Karen Felmlee
Sylvia Glickman
Mrs. Max Joehnke

Received mid-August to mid-September

WASHINGTON REPORT . . .

Continued from page 9

in your label, but the watered down disclaimers are relegated to a side panel.

I can understand the political reasons for your attempting to bring the subject of "Florida orange juice" into every discussion of the dietary supplement regulations. As you know, however, Sec. 80.1(e) (6) of the regulations flatly excludes raw agricultural commodities with levels of naturally-occurring vitamins or minerals that would otherwise fall into the dietary supplement or drug category. Thus, Florida orange juice may continue to be marketed in the same way that it always has been, with the same nutritional claims, as long as any pertinent requirements of Sec. 1.17 for nutrition labeling are met. Neither the standard of identity for dietary supplements nor the drug provisions of the Act are applicable to orange juice or any similar raw agricultural commodity unless specific therapeutic claims are made.

The Food and Drug Administration has no objections whatsoever to a "dual label" that would satisfy both the food and the drug provisions of the Act. If a dietary supplement were to contain 90 mg. of vitamin C, for example, it would not be at all difficult to devise a label which would recommend one tablet per day as a dietary supplement and, for example, three tablets a day as an OTC drug. The labeling would, of course, be required to differentiate between these uses, and to disclose forthrightly their different purposes (i.e., the difference between a dietary supplement use to insure adequate daily nutrition and a therapeutic or medicinal use to treat deficiencies). There is, however, no legal or practical impediment of which we are aware to this type of dual labeling. We would be happy to review prototype labeling if that would be helpful.

The inclusion of a nutrient in a product represented for dietary supplement (food) uses at a therapeutic or medicinal (drug) dosage level raises problems of an entirely different nature. Certainly, the labeling that you propose, whereby the disclaimer is relegated to a relatively insignificant part of the label, cannot withstand legal scrutiny under the Federal Food, Drug, and Cosmetic Act. It is this type of labeling that has so frequently caused deception in the past, and indeed that has required promulgation of new vitamin-mineral regulations by the Food and Drug Administration.

The courts have uniformly held that a disclaimer is insufficient to cure an otherwise misleading label. In *United States* v. *3 Cartons . . . No. 26 Formula GM*, 132 F. Supp. 569 (S.D. Calif. 1952), for example, the court held that use of the term "nutritional" in the sales promotion of an article does not immunize it from the drug provisions of the Act if it is in fact

(Continued next page)

intended for therapeutic purposes. The court went on to state that where the impression is created that an article has value in the treatment of disease, the article is properly classified as a drug regardless of a disclaimer asserting that there is no scientific evidence that the article has therapeutic value. There are a number of similar cases, e.g., *United States* v. *Millpax, Inc.*, 313 F.2d (7th Cir. 1963), *cert. den.*, 373 U.S. 903 (1963); *United States* v. *Nutrition Service, Inc.* 227 F. Supp. 375 (W.D. Pa. 1964), *aff'd per curiom*, 347 F.2d 233 (3d Cir. 1965); and *United States* v. *47 Bottles . . . Jenasol RJ Formula*, 320 F.2d 564 (3d Cir. 1963), *cert. den.*, 375 U.S. 953 (1963).

The pro forma label you submitted is for a product containing 100 mg. of vitamin C and 25 mg. of bioflavonoids. Vitamin C is an essential nutrient, the U.S. RDA for which is 60mg. per day. Under Sec. 80.1, a dietary supplement may contain 90 mg. per day of vitamin C. Any greater quantity results in the product becoming a drug. There is no more credible scientific evidence that the bioflavonoids have nutritional or therapeutic value than there is for hundreds of other food additives.

The only type of statement that might begin to inform consumers about the nature of such a product – even though inadequate to prevent the basic consumer deception caused by the very marketing of the product – would be something like the following. First, it would be nesessary to explain the vitamin C content:

> "The U.S. Recommended Daily Allowance for vitamin C is 60 mg. per day. This amount, from all sources, will provide adequate nutrition for virtually all healthy individuals. An additional 30 mg. of vitamin C is permitted in a dietary supplement in order to make certain that it will cover the nutritional needs of all healthy persons. There is no known nutritional value whatever for more than 90 mg. of vitamin C per day. Thus, the extra 10 mg. of vitamin C contained in this product could be useful, if at all, only for specific therapeutic or medicinal purposes, and 10 mg. of vitamin C is plainly insufficient for any such purposes. Any representation that this product is of therapeutic value would therefore be fraudulent."

Any such explanation would have to be set forth immediately following the designation of "vitamin C" on the principal display panel, without any intervening material, in type size at least one-half the type size used for "vitamin C."

We have not permitted this in the regulations because it has seemed abundantly clear that this type of statement makes the representation of such an article as a food utterly absurd and contrary to the requirements of the Act. Since there is no known food or nutritional use for a daily amount of vitamin C in excess of 150% of the U.S. RDA, it is wholly irrational and misleading to allow it to be marketed even with such an explanation. Similarly, the inclusion of an extra 10 mg. of vitamin C for drug purposes is patently inadequate and misleading. The entire product concept is thus fundamentally deceptive. If you wish to discuss this approach further, however, we would certainly be happy to meet with you about it.

The second question involves the deception inherent in inclusion in the product of a quantity of bioflavonoids, a food ingredient of unproven nutritional value. The same question would be raised whether the product were classified as a food or as a drug.

As you know, there are only two cases in which the legality of mixing essential nutrients with such ingredients of unproven value has been litigated. *United States* v. *Vitasafe*, 226 F. Supp. 266 (D.N.J. 1964), *aff'd*, 345 F.2d 864 (3d Cir. 1965), *cert. den.*, 382 U.S. 918 (1965); and *United States* v. *Nuclomin*, No. 71 C 585 (E.D. Mo. 1972), *aff'd*, No. 72-1626 (8th Cir. 1973). In both cases, the District Court held, and the Court of Appeals unanimously affirmed, that inclusion of such ingredients of unproven nutritional value in a dietary supplement constitutes a representation that the ingredients are of some nutritional value, and thus results in the product being misbranded in violation of the Act. The most recent decision, upholding this concept, was handed down by the U.S. Court of Appeals for the Eighth Circuit on July 9, 1973. Thus, there is no longer any question about the correctness of our legal position on this matter.

The same principles discussed above also apply to prohibit the use of disclaimers to legalize the otherwise clearly unlawful use of these unproven and unnecessary ingredients. Indeed, the labels involved in both the *Vitasafe* and *Nuclomin* decisions included the customary disclaimer that "the need for this ingredient in human nutrition has not been established," and in both instances the courts held that this was insufficient to dispel the otherwise clear misbranding of the product.

Once again, the only type of statement that could arguably be regarded as accurate – even though insufficient to prevent deception – with respect to such ingredients as rutin, other bioflavonoids, inositol, and PABA, would be something like the following:

> "There has been widespread fraudulent promotion that this ingredient has nutritional value, when in fact it is nutritionally worthless and adds nothing to the value of the diet. Any representation that this ingredient is of nutritional or therapeutic usefulness would herefore be fraudulent."

As with the other explanation, any such statement would have to follow the label designation of the ingredient on the principal display panel, in prominent type at least one-half the size of the type in which the ingredient itself was labeled.

As you know, the regulations do not provide for this type of explanation for basically the same reasons already discussed above with respect to vitamin C. Since it is an adequate and reasonable statement of the facts, both we and the manufacturer would look foolish permitting such a product on the market, and indeed its marketing is prohibited by the Act.

It is precisely because of the promotional practices of the health food industry over the years that we have been forced to promulgate the new

(Continued next page)

vitamin-mineral regulations. If the industry had marketed these products without false or misleading nutritional or therapeutic claims, the Food and Drug Administration would never have begun the proceedings leading to the promulgation of these regulations and indeed would not have been required to take any legal action at all. There is no question but that these regulations were the direct result of unnecessary and grossly deceptive industry practices extending back for many, many years. I am enclosing the case summaries for just three years of FDA legal action involving such products and claims, which readily demonstrate the need for our action.

On the other hand, as we have repeatedly said, the Food and Drug Administration is a strong advocate of the right of every consumer to eat the food of his choice. We are in no way precluding or hindering any consumer from continuing his freedom to choose, purchase, and consume whatever food ingredients he wishes, including rutin, other bioflavonoids, inositol, PABA, and others. Their lack of nutritional value is of no concern of our as long as they are safe and are not represented to be of nutritional value by claims made for them either in promotional literature or by their inclusion in products labeled as dietary supplements or as containing valuable nutrients. It therefore simply is not true that we are in any way opposed to the fundamental consumer right to freedom of choice. Our concern resides solely in unwarranted representations in the marketing of commercial products.

We are pleased to note that consumer advocates are coming to the defense of the new Food and Drug Administration regulations. The National Retired Teachers Association and the American Association of Retired Persons have just "strongly endorsed" these new regulations. They have recognized, in this endorsement, that "statements by various groups opposing the regulations that 'the government is trying to take away your viamins' are just not true." The well-known consumer columnist, Sidney Margolius, has noted that your Federation has misinterpreted the regulations, and attributes opposition to "blatant scare selling by some merchandisers" rather than scientific facts.

We are, of course, always prepared to meet with anyone to discuss this and any other matter involving the need for full and informative labeling. The pro forma label enclosed with your letter of July 13, however, obscures the facts and is in no sense accurate and truthful. Should you wish to discuss other possible approaches, in light of the comments made in this letter, we would be happy to arrange a meeting with you.

Sincerely yours,

Peter Barton Hutt
Assistant General Counsel
Food and Drug Division

THE NATIONAL HEALTH FEDERATION
Washington Office
121 2nd Street, N.E.
Washington, D.C. 20002

Honorable Peter Barton Hutt, General Counsel
Food and Drug Administration
Rockville, Maryland 20852

Dear Mr. Hutt:

No doubt you will recall the extended conference which you attended in the offices of Congressman Paul Rogers, on July 12, 1973, together with Dr. Ogden Johnson, also representing FDA, while the undersigned and Kirkpatrick W. Dilling, Esq. represented National Health Federation and its consumer membership; former Congressman David King and Milton Bass. Esq., representing the National Nutritional Foods Association. At that time, Congressman Rogers inquired why labeling could not be evolved, in cooperation with FDA, so that perfectly safe products containing nutritional factors found in common foods could be sold without violating regulations propounded by your agency.

By way of comparison, it was pointed out to the Congressman that one glass of Florida orange juice contains 127 mg. of vitamin C, containing naturally associated citrus bioflavonoids. Why then, under recent regulations published by FDA, does a 100 mg. vitamin C dietary supplement, also containing citrus bioflavonoids, become a "drug"? And why cannot this product be labeled for sale, as it has been for decades?

Solely and only because of Congressman Roger's suggestion, a label for such a product was submitted to you on the following day, with an appropriate accompanying communication. As Mr. Dilling stated to you in advance, there is "no way that FDA would approve such a product regardless of the label."

Your letter of July 27, 1973, and purported response to the submission in question, is a masterpiece of legal phraseology, not to say voluminous, taking multiple pages to say "no." To us, it is a classic example of "overkill" concerning denial of freedom of choice to those who might wish to purchase a safe, nutritious product. Indeed, it is this "freedom of choice" which constitute the basic difference between the consumers represented by the Federation and the agency outlook, whereby it is deemed that FDA should make the "choices," for everyone, not the consumer himself.

If nothing else, your recent communication points up the need for legislation to preserve the freedom of choice of the American consumer to choose his diet, no matter what the bureaucracy of FDA may consider should be eaten by everyone.

Sincerely yours,

Clinton R. Miller

(Continued next page)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
ROCKVILLE, MARYLAND 20852

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

Dear Mr. Miller:

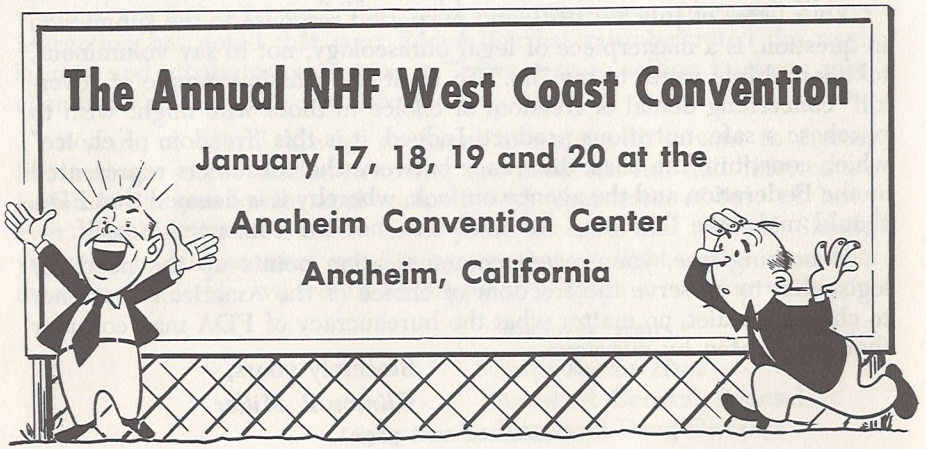
This is in response to your letter of September 7, 1973, relating to the labeling of vitamin-mineral products.

As you know, the new FDA regulations fully preserve the consumer's freedom of choice with respect to vitamins, minerals, and other food ingredients. Not one vitamin, mineral, or food ingredient has been prohibited from the American diet by these regulations. At the same time, consumers will be provided with far more accurate and reliable information about these products, because false and misleading representations are prohibited. Thus, it will be an informed consumer who will make all his own decisions about his consumption of these nutrients and ingredients, and certainly not FDA.

We believe that any legislation designed to overrule the new regulations would promote consumer deception and destroy informed freedom of choice. This entire matter is now in the courts, where it must properly be resolved. We are, of course, willing to abide by whatever decision is reached by the courts on this matter, and we trust that you will also.

Sincerely yours,

Peter Barton Hutt
Assistant General Counsel
Food and Drug Division



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

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

Betty Lee Morales — Secretary

Dorothy B. Hart — Treasurer

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

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

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

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.

ATTENTION

If the last numbers in the code appearing under your name above read 12-73, it means your membership renewal will be due January 1, 1974. Sending in your renewal now, in advance, will save your Federation the time and expense of billing you.

HELP SAVE OUR HEALTH FREEDOMS