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Dedicated to the Protection of Health Freedoms

THE
NATIONAL HEALTH FEDERATION
BULLETIN

Protection of Health Freedoms — *Published Monthly*

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

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Rep. Fountain Urges Review of Laetrile-Treated Cases

Representative L. H. Fountain, Chairman, Intergovernmental Relations Subcommittee, in a letter to Elliot L. Richardson, Secretary of the Department of Health, Education and Welfare, has requested that a thorough investigation be made of the recent clinical experience with Laetrile. Admittedly, this letter was written as a result of the vast amount of mail which he and other members of Congress have received regarding Laetrile. Apparently sensing the possibility of delaying tactics on the part of the FDA in handling the Investigational New Drug (IND) application submitted by the McNaughton Foundation for Laetrile, Rep. Fountain noted the passage of the many months since the application was first submitted. Rep. Fountain stated in the letter and in remarks printed in the **Congressional Record**, ". . . the public has a right to know if any of the therapeutic claims made for this drug are justified. The responsibility is clearly the Department of Health, Education and Welfare's to resolve whether or not Laetrile has any value in the treatment of cancer and to make the facts available to the American people."

NHF wholeheartedly agrees with Rep. Fountain on this latter point but emphasizes that this can only be done through fair trials on human cancer sufferers. NHF has not in the past, and does not now, endorse Laetrile as a clinically effective or useful anti-cancer drug. To determine its usefulness in the treatment of cancer is the whole idea of the ultimate testing in humans for which permission is sought in the IND application. Accordingly, NHF has actively urged a speedy, fair, and unbiased consideration of the IND application submitted by the McNaughton Foundation with the view of speeding the day when Laetrile's value may be properly determined in accordance with the usual FDA-IND precautions as to safety, patient protection, and informed consent of the patients. We further agree with Rep. Fountain in his statement, "In the fight against cancer, we surely cannot afford to ignore any leads, whatever their source."

Rep. Fountain saw fit to insert his letter to Secretary Richardson in the **Congressional Record** along with preliminary remarks regard-

(Continued next page)

"The Food and Drug Administration's handling of this matter has created the impression in some quarters that our Government is party to a conspiracy to suppress an effective and inexpensive anticancer drug."

ing the Laetrile matter. The following is taken from the **Congressional Record** of March 15, 1971:

HEW SHOULD ASCERTAIN IF LAETRILE IS EFFECTIVE FOR TREATMENT OF CANCER

HON. L. H. FOUNTAIN

OF NORTH CAROLINA

IN THE

HOUSE OF REPRESENTATIVES

Thursday, March 25, 1971

Mr. FOUNTAIN. Mr. Speaker, in testimony on June 9, 1970, before the Intergovernmental Relations Subcommittee, of which I am chairman, the Commissionar of Food and Drugs stated that the McNaughton Foundation of California was not given an investigational use exemption—IND—to conduct clinical tests with the drug Laetrile—amygdalin—for the treatment of cancer patients because of serious deficiencies in the sponsor's application. Although there have been numerous meetings between representatives of FDA and the McNaughton Foundation during the past 9 months, the status of this drug remains unchanged: It cannot legally be sold in the United States, and no physician is authorized to investigate in cancer patients whether or not Laetrile is of value.

Mr. Speaker, I have no basis for judging whether or not this drug is safe and effective for the treatment of cancer, nor do I know if the McNaughton Foundation has provided FDA with adequate data to warrant clinical testing with Laetrile.

I do know, however, that a great many Americans believe that they, or members of their families, have been helped by Laetrile treatments obtained in Mexico or elsewhere. I know this from letters sent me from all parts of the country and from the numerous inquiries I have received from Members of both Houses of the Congress.

For the information of my colleagues who are concerned with this matter, I am including with my remarks a letter which I have sent to Health, Education, and Welfare Secretary Elliot L. Richardson. In that letter I have urged Secretary Richardson to arrange for an impartial review and evaluation by cancer experts of the patient records for the approximately 1,000 cases in which the McNaughton Foundation claims Laetrile has already been used successfully in the treatment of cancer. I have also proposed that the National Cancer Institute perform further animal tests with Laetrile, inasmuch as this drug apparently has shown some

"The public has a right to know if any of the therapeutic claims made for this drug are justified."

activity in the tests sponsored by the McNaughton Foundation.

An immediate and objective evaluation of the recent clinical experience with Laetrile, particularly in Mexico and Germany, is imperative in my judgment both to give the American people the facts about this drug and to strengthen public confidence in our Government. Unfortunately, the Food and Drug Administration's handling of this matter, as my letter to Secretary Richardson indicates, has created the impression in some quarters that our Government is party to a conspiracy to suppress an effective and inexpensive anticancer drug.

Mr. Speaker, the responsibility is clearly the Department of Health, Education, and Welfare's to resolve whether or not Laetrile has any value in the treatment of cancer and to make the facts available to the American people.

The material follows:

CONGRESS OF THE UNITED STATES,
HOUSE OF REPRESENTATIVES,

Washington, D.C., March 16, 1971

HON. ELLIOT L. RICHARDSON,
Secretary, Department of Health, Education, and Welfare, Washington, D.C.

DEAR MR. SECRETARY: The President has requested 100 million in special cancer research funds for fiscal year 1972, in addition to a larger regular appropriation for the National Cancer Institute. A study group sponsored by a Senate Committee has proposed spending many times that amount.

Unquestionably, the American people would support expenditures of any magnitude if such expenditures offered promise of a cure or prevention for cancer. The sad truth is that over a period of years the Federal Government has spent vast sums on cancer research and the results of this effort have been rather meager.

It is with this perspective that I strongly urge your Department to make an objective evaluation of the demonstrated efficacy claimed for and the potential of the drug Laetrile (Amygdalin) as an anti-cancer agent. The use of this drug for cancer therapy has been banned in the United States for a number of years.

I and many other Members of Congress have received a large volume of mail from individuals who claim they or members of their families have benefited from Laetrile treatments, and from people who believe the Government is party to a conspiracy to suppress an inexpensive, non-toxic, and effective anti-cancer drug. Whatever the merits of these claims, public confidence in our Government has not been strengthened by the highly unusual actions of the FDA in first advising the sponsor of IND 6734

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"In the fight against cancer, we surely cannot afford to ignore any leads whatever their source."

on April 20, 1970 that clinical studies with Laetrile could be initiated, and then terminating this authorization on April 28, 1970. Copies of these FDA letters are enclosed.

According to the McNaughton Foundation of California, the sponsor of IND 6734, Laetrile (Amygdalin) has already been used successfully in the treatment of cancer by 10 physicians and cancer researchers in approximately 1000 cases. The McNaughton Foundation states that the most recent clinical work with Laetrile has been done by Dr. Ernesto Contreras in Mexico, and Dr. Hans A. Nieper in Hanover, Germany.

In view of this background and the deeply held conviction of a large number of Americans that they are being forced by their Government to leave the country in order to obtain therapy with a drug that is both safe and effective for the control of cancer, I believe it imperative that HEW take immediate steps to review the clinical records of patients by Doctors Contreras and Nieper. This review should be done by cancer experts who have no conflicting interests and who are able to evaluate the evidence objectively. There is precedent for a retrospective study of patient histories in the evaluation of Krebiozen cases some years ago under the auspices of the National Institute of Health. The cost of such a study would be relatively small. Also, the Food and Drug Administration has the organization and the experience in gathering of patient case history records to assist in this undertaking.

In addition, there would appear to be merit in the National Cancer Institute's performing further animal tests with Laetrile. I note that in writing to Congressman Edwin W. Edwards on January 26, 1971, Dr. Carl G. Baker, Director of the National Cancer Institute, stated that the preclinical data provided by the McNaughton Foundation does indicate some activity for Laetrile in animal tumor systems. While I understand that the Cancer Institute at one time did conduct studies with Amygdalin in a small number of tumor-bearing mice, it is alleged by Dr. Dean Burk of the Cancer Institute that these animals were tested at inadequate concentrations of a drug of questionable origin and chemical authenticity. In the light of the tremendous sums of money that have been spent with relatively little productivity in the Cancer Chemotherapy Program, I find it very surprising that the Cancer Institute has not sought on its own initiative to do further animal testing with this drug which ap-

(Please turn to page 27)

California Attorney General Seeks Court Order to Restrain NHF and Others

By CHARLES ORLANDO PRATT
Washington General Counsel

"CANCER IS THE MAJOR CAUSE OF DEATH AMONG CALIFORNIA CITIZENS," SAID THE ATTORNEY GENERAL OF CALIFORNIA ON OR ABOUT MARCH 29, 1971.

A Judge, *Pro Tempore*, of the Superior Court of the State of California for Los Angeles County entered an Order on March 31, 1971, against *The National Health Federation President*, among other defendants, to show cause why their agents, servants, employees, and representatives should not be enjoined and restrained from making any representations that LAETRILE has any value in arresting, alleviating or curing cancer.

The defendants named in this *Court Order* are as follows:

"International Association of Cancer Victims and Friends,
Lorraine Rosenthal, Secretary
Cancer News Journal, Norman Fritz, Editor,
Stuart Goldthwaite, Publisher
National Health Federation, Fred J. Hart, President
Gena Larson, and Does I through XX"

(Note: Charles I. Crecelius is President of The National Health Federation, not Fred J. Hart. This error will be corrected.)

The pertinent part of this Court Order is as follows:

"IT IS HEREBY ORDERED that the defendants, and each of them, shall appear before this court in the courtroom of Department 65 at 111 North Hill Street, City of Los Angeles, California at 9:30 a.m. on May 3, 1971, then and there to show cause, if any they have, why they and each of them, and their agents, servants, employees, and representatives should not be enjoined and restrained during the pendency of this action from engaging in or performing directly or indirectly any and all of the following acts:

(Continued next page)

Violating section 10400.1(d) of Title 17, California Administrative Code, and that defendants be restrained from making any representations that Laetrile has any value in arresting, alleviating or curing cancer."

It is significant that the Attorney General in the first sentence of his brief entitled "Points and Authorities" stated, "Cancer is a major cause of death among California citizens."

In the Attorney General's "Points and Authorities" he stated, among other things, as follows:

"Pursuant to this authority, the California Cancer Advisory Council and the Department of Public Health have found that laetriles are of 'no value' in the treatment of cancer and have prohibited 'any representative that said agents have any value in arresting, alleviating, or curing cancer' when made for the purpose of distributing laterile. California Administrative Code, Title 17, section 10400.1; a copy is attached hereto as Exhibit 'D'. Plaintiff seeks now to enjoin defendants' violation of section 10400.1 pursuant to the authority granted by Health and Safety Code section 1712."

Section 10400.1 of Title 17 provides as follows:

"(b) The Department of Public Health hereby finds that betacyanogenetic glucosides including amygdalin (with or without the addition diisopropyl ammonium iodide), and prunasin, commonly known as "Laetriles," are of no value in the diagnosis, treatment, alleviation or cure of cancer and that the use of one or more of these agents in early cancer to the exclusion of conventional treatment might well be dangerous since treatment with acceptable, modern, curative methods (surgery or radiation) would thereby be delayed potentially until such time as metastases had occurred and the cancer therefore might no longer be curable. In late disease palliative effect is lacking. The Department recommends that the public refrain from using any of the said agents or any agent, drug, medicine, compound or device substantially similar thereto in the diagnosis, alleviation, treatment or cure of cancer."

The complaint For Injunction filed herein against The National Health Federation and its representatives included the following charge:

"Defendant National Health Federation violated section 10400.1 of the California Administrative Code in that defendant, for the purpose of distributing laterile, represented that laetrile is safe and effective in the treatment of cancer. Said defendant caused to be distributed a collection of literature, attached hereto as Exhibit 'C', at a public meeting held on February 16, 1971. Said collection contains statements describing the efficacy of laetrile as a treatment for cancer."

Exhibit C to which reference is made to the foregoing charge is an Affidavit, the pertinent part of which is as follows:

SUPERIOR COURT OF THE STATE OF CALIFORNIA FOR THE COUNTY OF LOS ANGELES NO..... AFFIDAVIT OF ROBERT W. STRINGHAM

I, ROBERT W. STRINGHAM, residing at 11088 Culver Boulevard, Culver City, California, declare under penalty of perjury that the following is true and correct:

I am a Food & Drug Inspector employed by the State of California, Department of Public Health, Bureau of Food and Drug, and was so employed during the month of February, 1971, under the immediate supervision of C. M. Duggie, Food and Drug Inspector IV of the State of California, Department of Public Health, Bureau of Food & Drug.

That during the month of February, 1971, Mr. Duggie instructed me to attend a meeting of the North Hollywood Chapter of The National Health Federation, held at the Howard Colonial Building, 4475 Vineland Avenue, Hollywood, California, on February 16, 1971. That I went to that address and arrived at approximately 7:30 p.m. and went to Room 32, the time scheduled for the meeting to begin. At 7:45 p.m., Mr. Paul Hermann, who introduced himself as president of the North Hollywood Chapter of The National Health Federation, started the meeting off. Shortly thereafter, Mr. Hermann introduced Lorraine Rosenthal. Mr. Hermann told the audience that Mrs. Rosenthal had put together cancer packets which would be sold at the book table. After a lecture by a Mrs. M. Charlotte Holmes, speaker for the evening, I went to the back of the room and purchased one of the cancer packets for $1.57.

That the documents annexed as Exhibits 1 thru 21, respectively, are the true contents of the cancer packet I purchased at this meeting."

The twenty-one (21) items of printed material contained in the "cancer packets" were itemized in the Affidavit of Robert W. Stringham, and have been filed with the court, according to said Affidavit.

If, in fact, cancer is a major cause of death among California citizens, it would appear that treatment of cancer with "acceptable, modern, curative methods (surgery or radiation)", which The Department of Health of California considers conventional treatment, has not been so effective and so successful as to deny the California citizens the right to try or use unproven methods of treatment which have not been found to be dangerous, *PROVIDED* those citizens are clearly informed that such methods

(Continued next page)

are not acceptable, approved or recommended by the official medical establishment.

The legal and moral position which The National Health Federation takes is that it does not know whether Laetrile is safe and/or efficacious. NHF believes that the drug Laetrile should be given a fair and unbiased test for efficacy and/or safety by the Federal Government according to the applicable provisions of the Federal Food, Drug and Cosmetic Act and according to laws and regulations applicable to the National Cancer Institute of the National Institutes of Health.

The National Health Federation believes that no Federal or State Statute or official Regulation, issued pursuant thereto, can, or is intended to, deny NHF or any of its representatives the right of free speech and free press to educate and to advocate an idea which encourages only fair and impartial research, studies and testing by authorized Federal Government Agencies of the drug Laetrile to determine officially whether, in fact, it has value in arresting, alleviating or curing cancer.

NHF believes that everyone in America has the right of freedom of speech, of press, the right of people peaceably to assemble, and to petition the Government for a redress of grievances in health matters.

NHF and each and everyone of its agents, servants, employees and representatives have the inalienable right to advocate and to educate American citizens concerning the availability and the use of a product, such as Laetrile, in a foreign nation where that availability and use are legal, at least until the appropriate United States Health and Medical Authorities do determine in fair and unbiased tests that the product is, or is not, safe and/or effective in the treatment of cancer.

It would be raw censorship for any governmental agency of California to enjoin or restrain anyone from making any representation concerning the use of Laetrile in a foreign country where such use is legal and where licensed doctors of medicine have found it to be safe and effective in some cases.

In truth, and in fact, Section 10400.1(d) of Title 17 of the California Administrative Code does *not* apply to The National Health Federation, is President, agents, servants, employees and representatives or anyone directly or indirectly representing in speech or in press that Laetrile is, or may be, useful in "arresting,, alleviating or curing cancer" when such representation is to urge that the product should be given a fair and unbiased test for efficacy and safety in the United States, including California, to determine for once and for all its value.

Section 10400.1(d) of Title 17, California Administrative Code, which the Judge *Pro Tempore* cited in the said Court Order No. 999731 (Complaint For Injunction) is not applicable to The National Health Federation and its President, because the Federation, its President, agents,

servants, employees, and representatives has not *willfully and falsely* represented the value of Laetrile in speeches, publications, or in the press *for the purpose of prescribing, administering, selling or otherwise distributing* amygdalin, commonly known as Laetrile, or that the product has value in arresting, alleviating or curing cancer.

This Section of the Code applies *only* to those who may make such claims, whether true or not, *for the purpose of prescribing, administering, selling or otherwise distributing Laetrile.* NHF and its representatives have not, do not, and will not prescribe, administer, sell or otherwise distribute Laetrile for the purposes prohibited by this Act.

None of the Sections, including Sections 1701, 1707, 1711 and 1712 of the Health and Safety Code of California is applicable to The National Health Federation, its President, agents, servants, employees, and representatives.

Section 1714 of the Health and Safety Code of California provides as follows:

> "It is a misdemeanor for any person *willfully and falsely* to represent a device, substance, method or treatment as effective to diagnose, arrest, prevent, or cure cancer. *Nothing in this section shall abridge the existent rights of the press.*" (Emphasis Supplied)

The National Health Federation, its President and those associated with it, did not *willfully and falsely* represent Laetrile for any purpose prohibited by Section 10400.1(d) of Title 17, California Administrative Code or prohibited by any sections or provisions of the Health and Safety Code cited in the Complaint For Injunction or the said Court Order.

The rights of press include also the rights of speech under Section 1714 of the Health and Safety Code of California and under the First and Fourteenth Amendments to the Constitution of the United States, since no speech was made, and no press statement or publication mentioned in the Complaint For Injunction was written or distributed by or for the Federation and its said associates which *willfully and falsely* represented the value of Laetrile for the purpose of prescribing, administering, selling or otherwise distributing Laetrile to anyone.

Mr. Hart founded The National Health Federation to serve as a bulwark and forum for all Americans in their struggle for freedom of speech, freedom of press, and for freedom of choice in health care when the exercise of those freedoms harms no one.

Now is the time to stand up against any illegal, unnecessary or unreasonable attempt by the State of California to deny Constitutional Rights on the alleged basis of protecting Californians from the use of a drug, which that State and the Federal Government has thus far refused to test fairly for reasons known only to them. •

WASHINGTON REPORT

By Clinton R. Miller, NHF Legislative Advocate

Senate Moves To Demand Completion of First National Nutrition Survey

The National Health Federation is throwing its support solidly behind Senator Ernest Hollings (D-S.C.) and several other Senators and Representatives in their effort to force completion and publication of the first national survey on nutrition made in the United States.

The attempt to bury the nearly completed survey is one of the blackest pages in the continuing history of an attempt by the Department of Health, Education and Welfare to not only deny that malnutrition is widespread in America, but also to make it a criminal offense for any food supplement manufacturer to represent, suggest, or imply that significant segments of the U.S. population are, or are in danger of, suffering from a dietary deficiency of vitamins or minerals.

U.S. Senator Ernest Hollings (D-S.C.) has charged HEW is covering up the nutritional survey which reportedly shows that 15 million Americans in 10 states are suffering from "hard-core" malnutrition.

The U.S. Public Health Service has financed, conducted, completed and published surveys of population nutrition in 33 countries around the world but until 1968 had never even started to survey our own.

Indeed, on July 11, 1967, the then Surgeon General, William H. Stewart, testified before a Senate Subcommittee on Employment, Manpower and Poverty that:

> "We do not know the extent of malnutrition anywhere in the United States. I cannot say what the extent is because we just don't know.
>
> "It hasn't been anybody's job to find out.
>
> "We can do it all over the world, but not in the United States."

The Senate was appalled. It passed an amendment which said:

> "The Secretary of Health, Education and Welfare, in consultation and cooperation with other officials of the Federal Government and of the States, shall make a comprehensive survey of the incidence and location of serious hunger and malnutrition and health problems incident thereto and shall report his findings and recommendation for dealing with these conditions within six months from the date of enactment of this section."

This mandate was first proposed by Senators Robert Kennedy and Javits. To the credit of HEW, they chose a highly qualified and respected nutrition expert, Dr. Arnold Shaefer, to conduct the survey. He launched his study in 1968.

Ten States were chosen—Texas, Louisiana, New York, Kentucky, Michigan, California, Washington, South Carolina, West Virginia, and Massachusetts. (It is interesting to note that 13 additional states asked to be included in the survey but were turned down.)

Dr. Schaefer brought together health officials from the Federal Government, the states and from medical universities to conduct these studies. Methodology was devised based on surveys in foreign countries which could be adapted to our domestic situations.

By January 21, 1969, the survey was far from complete, but a preliminary report was made to the Senate Select Committee on Nutrition and Human Needs chaired by Senator George S. McGovern. The South Dakota Senator read Dr. Schaefer's report and told him he was shocked by it. NHF members have declared for years that malnutrition was ubiquitous in the United States. Now for the first time we were getting official confirmation of our warnings.

A little over a year later, April 27, 1970, to be exact, Dr. Schaefer again reported to the Senate Subcommittee. His survey was nearly completed. Senator McGovern, recalling the '69 hearings, said:

"Last year, when Dr. Schaefer testified for the first time before the select committee, I told him I had read his statement and was 'shocked' by it. Today, over a year since Dr. Schaefer came before us, I am even more shocked by the final findings he is reporting for the national survey. *There is no longer any question that malnutrition in America is a public health problem of great magnitude.*" (Emphasis supplied)

Dr. Schaefer then gave this testimony:

"Mr. Chairman, I welcome this opportunity to appear again before the committee and to present a second progress report on the National Nutrition Survey . . . I will briefly summarize the current status.

"The data collection has been completed in nine states and New York City and will be finished in the 10th state (Massachusetts) very shortly. The most complete analyses available are from Texas and Louisiana and we are completing the analysis of the data from New York State, Michigan, and Kentucky. Data have been received from New York City, South Carolina, California, West Virginia, and Washington and are being processed for analysis.

(Continued next page)

"Last year, we reported that our preliminary data clearly indicated the presence of malnutrition in an *unexpectedly* large population of the sample population. We found a *high prevalence* of signs associated with inadequate nutrition, including growth retardation. Anemia, unacceptable levels of serum albumin, Vitamin A, Vitamin C, and urinary riboflavin were *very common.*" (Emphasis supplied)

Sen. McGovern expressed his impatience . . . "with how slowly the wheels turn in this field . . . Even the speed with which your survey is moving seems to me to be somewhat less than what the Congress had in mind."

He recalled the language of the Kennedy-Javits Congressional mandate which said, in part . . . "The Secretary of HEW . . . shall report his findings . . . to Congress within six months from the date of enactment of this section."

The impatient South Dakota Senator then added: "Now, as you know, that legislation was passed and signed into law on December 5, 1967, and yet, we are actually only through the survey of two States, Texas and Louisiana. We are well into 1970.

"How long is it going to be before we get the full results of this 10-State survey?"

Dr. Schaefer was never allowed to answer. Instead, he was interrupted by a Dr. David J. Spencer, director of the National Communicable Disease Center (CDC) who had been assigned to accompany Dr. Schaefer.

Dr. Spencer, in answer to the question directed to Dr. Schaefer, said: "Mr. Chairman, if I could answer that question: We are all dissatisfied with the speed with which the survey is going. It is no reflection upon the nutrition program. There have been a variety of problems that have come up. This is one of the reasons that CDC has been asked to join in the nutrition program in trying to bring this to a speedly conclusion. I would like to give you an indication of when this data will be available but at this time we can't."

Senator McGovern pressed the point: "Can you tell us what the problems are? Do you need additional funding? Is there a shortage of equipment and computers or are other things being given higher priority than identifying hunger in the United States?"

Dr. Spencer continued to avoid giving a direct and responsive answer. He replied, evasively, "It is a variety of things. We do not need additional funding at this time. We have the equipment available. We will be making sure that the information gets processed as rapidly as the machine can run it."

Dr. Schaefer Is Forced to Resign His HEW Post

The balance of the survey information was never fed into the computer machines. Instead, Dr. Schaefer was shortly forced to resign his HEW position. He has reluctantly taken an assignment with the Pan American Health Organization. His alternative, according to the January 20, 1971 issue of the *Miami Herald,* was to be banished to the CDC in Atlanta. He refused. He was not allowed to publish the findings of his $5 million survey.

Sen. Hollings Demands the Survey Be Completed and Published

This thinly disguised defiance of the U.S. Congress by HEW is not going unchallenged. Sen. Ernest F. Hollings (D-N.C.) has introduced a sense-of-the-Senate resolution on the National Nutrition Survey. It is Senate Resolution 70. Cosponsors in the Senate are Senators Chiles (D-Fla.), Cranston (D-Calif.), Hart (D-Minn.) and Nelson (D-Wis.). Four of these powerful Senators are members of the Senate Subcommittee on Health of the Committee on Labor and Public Welfare, to which the bill has been referred. They are Senators Kennedy (Chairman of the Health Subcommittee), Nelson, Cranston and Mondale.

Senate Resolution 70 reads as follows:

RESOLUTION: Expressing the sense of the Senate with respect to disclosure of the results of the national nutrition survey.

Whereas the Congress of the United States in 1967 issued a mandate to the Secretary of Health, Education and Welfare to make a comprehensive survey of the incidence and location of serious hunger and malnutrition and health problems incident thereto in the United States; and

Whereas the nutrition program of the United States Public Health Service was designated by the Secretary to plan, develop, and carry out the mandate; and

Whereas Doctor Arnold E. Schaefer, chief of the nutrition program, National Center for Chronic Disease Control, Bureau of Disese Prevention and Environmental Control, Public Health Service, Department of Health, Education and Welfare, was placed in charge of the national nutrition survey; and

Whereas Doctor Schaefer and his team of experts, using methodology devised in thirty-three international surveys since 1956, did conduct the national nutrition survey in the States of Texas, Louisiana, New York, Kentucky, Michigan, Massachusetts, California, Washington, West Virginia, and South Carolina; and

Whereas the national nutrition survey has been completed with the examination of more than seventy thousands persons at a cost in excess of $5,000,000, and has produced data approved as valid by the Food and Nutrition Board of the National Academy of Sciences; and

Whereas official results have been produced in only two States, Texas and Louisiana, in April 1970, but no other results have been forthcoming, despite the fact that the raw data is available to be fed into computers for results: and

Whereas the Department of HEW has announced plans to undertake a continuing probability

(Continued next page)

survey without reporting on or implementing any findings of the national nutrition survey, but has yet to examine the first patient: Therefore be it

Resolved, That it is the sense of the Senate that the Secretary of Health, Education and Welfare should, not later than sixty days after the date on which this resolution is agreed to, submit to the Congress the results of the comprehensive survey, required by section 14 of the Partnership for Health Amendments Act of 19674, of the incidence and location of serious hunger and malnutrition and health problems incident thereto in the United States, together with his findings and recommendations with respect thereto."

What you can do to help this sense-of-the-Senate resolution to pass:

1. Write at once to both of your U.S. Senators. If either of them are alredy one of the 8 sponsors of the bill, congratulate and thank him. If your Senator is not yet a cosponsor, urge him to cosponsor S. Res. 70 and work for its immediate passage.

2. Write your U.S. Representative and ask him to introduce an identical bill in the House and work to get it passed.

3. For your convenience, two letters have been printed on the following two pages. These may be used by carefully removing them. Insert the name of one of your Senators on the designated letter and the name of your Representative on the other. Sign and mail the letters at once. You are urged to make a copy of the letter to the Senator so that you may send a letter to each of your Senators. Additional copies of our form letters on S. Res. 70 are available from NHF. Send a stamped, Self-addressed business-size envelope with your request. Send copies of all replies to me, Clinton R. Miller, 121 2nd Street N.E., Washington, D.C. 20002.

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."

The Honorable
United States Senate,
Washington, D.C. 20510

Dear Senator:

I respectfully and urgently request you to co-sponsor S. Res. 70 with Senators Hollings, Cranston, Chiles, Hart, Kennedy, McGovern, Mondale, and Nelson. I agree with Senator Hollings that it is time for the Senate "... to state in clear and unequivocal language that we demand the production of the results of the National Nutrition Survey." S. Res. 70 does this.

On March 30, 1970, HEW, under prodding, released a preliminary, but incomplete, report. The evidence contained in this partial report makes it even more mandatory that the complete findings be made available. It is unthinkable that HEW should spend $5 million for a survey and not release a complete evaluation of the data collected.

I agree with Senator George McGovern, when he eeclared, as Chairman of the Select Committee on Nutrition, on April 27, 1970:

"There is no longer any question that malnutrition in America is a public health problem of great magnitude."

Please read the Congressional Record of March 10, 1971, pp S 2770-2771 and March 23, 1971, pp S 3526-3531 in which Senator Hollings explains the incredible attempts to suppress the results of the first and only nutrition survey in the United States.

Respectfully yours,

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P.S. No reply is necessary. For additional information, phone Clinton R. Miller, Legislative Advocate of the National Health Federation, at 547-2547.

The Honorable
U. S. House of Representatives,
Washington, D.C. 20515

Dear Congressman:

I respectfully and urgently request you to introduce a bill in the House indentical to S. Res. 70 which has been cosponsored by Senators Hollings, Chiles, Hart, Cranston, Kennedy, McGovern, Mondale, and Nelson. I agree with Senator Hollings that it is time for Congress "... to state in clear and unequivocal language that we demand the production of the results of the National Nutrition Survey." S. Res. 70 makes that demand.

On March 30, 1970, HEW, under prodding, released a preliminary, but incomplete, report. The evidence contained in this partial report makes it even more mandatory that the complete findings be made available. It is unthinkable that HEW should spend $5 million for a survey and not release a complete evaluation of the data collected.

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Respectfully yours,

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P.S. No reply is necessary. For additional information, phone Clinton R. Miller, Legislative Advocate of the National Health Federation, at 547-2547.

Senate Bill 34: The Conquest of Cancer Bill

Science for the People

By RICHARD P. HUEMER, M.D.

A medical researcher states his views on the proposal to establish a National Cancer Authority.

Senate Bill 34, the Conquest of Cancer Bill, represents a bold new approach to medical research in the United States. In place of our existing fragmented approach to disease, S. 34 offers coordinated planning and directed research toward a defined goal. The defined goal of S. 34 is the conquest of cancer at the earliest possible date.

S. 34 is a major innovation in medical science. It would create a new agency, termed the National Cancer Authority, inspired by the successful AEC and NASA programs. The same managerial approach that put Americans on the moon would now be turned toward the conquest of inner-space—probing the nature of the human body, and the mysteries of disease. If it works, similar programs will likely be developed to eliminate heart disease and other major health scourges.

Most cancer research is presently funded or conducted by the National Cancer Institute, which occupies a relatively low position in the hierarchy of the Department of Health, Education and Welfare. Under S. 34, the facilities and personnel of the National Cancer Institute would be transferred to the new National Cancer Authority, in a favored position under an Administrator appointed by the President. Appropriations to run the National Cancer Authority would begin at $200 million per year and increase to the low billions.

The work of the National Cancer Authority would have far-reaching consequences. Its planners envisioned, among other things, a

(Continued next page)

Dr. Huemer is a physician engaged in full-time medical research for the past ten years, in the fields of cancer and gerontology. He is the author of a half-dozen scientific papers on cancer immunology. He is also the volunteer medical news editor for the listener-sponsored station KPFK-FM in Los Angeles.

major thrust in the area of environmental carcinogenesis, with a view toward preventing cancers caused by pollutants and adulterants. Nutritional, occupational, and social factors in cancer would also receive consideration. The planners recommended that the Authority be empowered to cut through existing red tape in order to test experimental anti-cancer agents.* And research in promising fields such as virology and immunology would be greatly expanded and accelerated.

"State of the Art" in Cancer Research

The time is ripe for such a bold approach to cancer. Thirty-three years ago, when Congress established the National Cancer Institute, science did not understand cancer sufficiently to devise a cure. Even ten years ago, our knowledge was scanty by today's standards. But the scientists have done their job well. In 1971, even though there are still considerable gaps in our understanding of cancer, we do possess the basic facts for a successful attack on the cancer problem.

It is time to take the next step. In nuclear physics, the next step was the Manhattan project; in the science of rocketry, it was the Space Program. In the field of cancer research, it must be nothing short of the technological development of cures for a disease that takes 300,000 American lives annually. This can be accomplished through an independent National Cancer Authority that will apply our existing research findings while developing new basic insights into the disease.

The plan for a National Cancer Authority was originally recommended last November to the Senate Committee on Labor and Public Welfare by a prestigious Panel of Consultants on the Conquest of Cancer. The consultants included distinguished scientists and laymen from many fields. The chairman of the panel was Benno C. Schmidt and the cochairman was noted cancer specialist Dr. Sidney Farber. The American Cancer Society and the American Heart Association supports S. 34.

Powerful Opposition to S. 34

However, major criticisms have been directed against S. 34 by the universities, scientific organizations, Department of HEW spokesmen, and the American Medical Association. The critics are politically powerful, and they may turn the tide against S. 34. Many members of the key Senate Labor and Public Welfare Committee are undecided, and other members, such as Sen. Cranston of California, have reportedly been turned against S. 34 in recent weeks.

It is easy to understand why the universities oppose S. 34. Under the existing set-up, a university professor may get a Federal grant for any project he dreams up. His project does not have to bear any relation to a health problem. The fewer restrictions there are for academic research, the happier the universities will be. Then, too, the universities fear the eventual break-up of the National Institute of Health, which has traditionally financed many university projects.

*Editor's Note — See "The Evaluation of Cancer Drugs" by the McNaughton Foundation in our April issue.

It is true that the National Institutes of Health (NIH) will be diminished if S. 34 passes. The bill calls for removing the National Cancer Institute from the NIH and placing its facilities and personnel under the new National Cancer Authority. NIH officials fear that if the National Cancer Authority is successful, the NIH will stand a chance of losing its Heart Institute and certain other institutes.

Bringing Scientists Together

Thus, critics of the National Cancer Authority usually speak of "wreckage" of the medical research enterprise, and "isolation" of researchers. Nothing could be further from the truth. The National Cancer Authority's master plan will arise from the cooperative interaction of the researchers themselves. Communication among scientists will be greatly facilitated by centralized information storage and retrieval—in contrast to today's unwieldy methods of information dispersal.

In fact, the National Cancer Institute has gone about as far as it can under NIH. It has supported most of the excellent basic research by which we have reached our present level of knowledge about cancer. In addition it has supported much academic research in other fields, and some of this academic research has even shed light on the cancer problem. The administrative machinery of NIH is adequately suited to basic or academic research. But it is *not* tailored to the demands of technological development. For this next essential step, the facilities and personnel of the Cancer Institute should be placed under the special management of the National Cancer Authority.

How Tricky Can You Get?

The American Medical Association has apparently opposed the plan for goal-directed cancer research ever since they got wind of it. Last September, an AMA editorial intimated that the "target approach" to cancer might increase the cost of health care and create an excessive demand for physicians' services. The editorial suggested adopting a "target approach" to the physician shortage, instead. Of course, a truly effective cure for cancer would *reduce* the staggering economic cost of cancer (estimated at $3 to $5 billion a year for medical care). It would diminsh the need for prolonged and expensive treatment, creating in effect a *surplus* of certain physicians. And one surmises that the AMA might not view a physician surplus with equanimity.

Earlier this year, President Nixon called for an extra $100 million to launch his own cancer campaign, and he urged "a total national commitment" to the goal of conquering cancer. The extent of that "total" commitment became clear a few weeks later when Presidential Science Advisor Dr. Edward David

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addressed the Association of American Medical Colleges. Dr. David said, "Indeed we do not believe in an AEC or NASA for cancer . . . the instrument for our campaign against cancer must be forged from, and within, the National Institutes of Health to assure the greatest chance of success . . ." Meanwhile, in the House of Representatives, Congressman Smith of Iowa had analyzed the Administration's budget proposal, and he came to the conclusion that certain figures had been been shifted within the budget. The net effect was that cancer research would be supported at the same level that Congress would have appropriated anyway. In other words, the national commtiment was *not* "total," and the $100 million was *not* "extra." Needless to say, the President of the AMA has sent a letter of support to President Nixon.

Science for the People

To summarize: S. 34, which embodies the proposal for a National Cancer Authority, is an imaginative, consumer-oriented approach to the conquest of a major disease. S. 34 is gravely jeopardized by the forces of the medical-scientific establishment and the voices of the status quo. You, the taxpayer, can tell your elected representatives what kind of medical research you want your tax dollars to support. The medical - scientific establishment must yield to the strength of an idea whose time has come. That idea is *science for the people*, through an independent National Cancer Authority. •

Book Reviews

INDIAN HERBOLOGY OF NORTH AMERICA by Alma R. Hutchens (Homeo House Press, Kumbakonam, S. India; available from Merco Herbalist, 620 Wyandotte Street East, Windsor, Ontario, Canada; $10.00; 492 pages, illustrations, glossary, indexes and annotated bibliography)

This indeed is a monumental contribution to the field of herbology. The serious student of herbology will find this volume an invaluable reference book, clearly written, profusely illustrated and exceptionally well indexed. The book describes slightly over 200 herbs and giving for each, the descriptive features of the plant, the bodily influences when used medicinally, the method of use and dosage, and the homoeopathic uses of the herb.

The book was written with the acknowledged invaluable assistance of N. G. Tretchikoff, of Windsor, one of the foremost herbalists of Canada, if not North America. The greater portion of his life has been devoted to the study of herbs and has collected and classified all available material on Herbology. It has been said that the most progressive literature on Herbology and Folk Medicine up to now is in Russia. Much information contained in this volume has been translated from Russian.

In addition to the main section dealing with the description and use of specific herbs, there is fascinating reading to be found in the introduction and historical review.

Mrs. Hutchens labored daily for four years preparing the material for this volume and it shows it. Her work has been meticulous. •

Houston Chronicle

Protein Malnutrition Study Show Brain Cell Damage

Evidence that severe protein malnutrition before and after birth interferes with the ability of nerve cells in the brain to transmit messages to each other was reported Saturday at the Massachusetts Institute of Technology. The conclusion was reached after experiments with rats. While the findings cannot be applied directly to humans, it is believed to constitute some of the first evidence explaining how inadequate nutrition might damage intelligence and learning ability. Experiments in recent years have linked early malnutrition and starvation to learning behavior problems in children and animals. But the chemical events underlying this link have not been well understood.

*

Houston Chronicle

Anti Depressants, Herring Don't Mix

If you are on anti - depressive drugs, stay away from pickled herring; also from aged cheeses, sherry, chocolate and chicken livers. These and other foods contain the organic compound tyramine, which interacts unfavorably with the drugs. The warning comes from the Medical letter, a publication for some 45,000 doctors and health professionals. The current issue warns patients to tell doctors what drugs they are already taking so that any new prescriptions will not result in adverse reactions. Certain tyramine containing foods, when eaten by patients on anti - depressants, can produce a high blood pressure crisis. Other combinations to be avoided are: Aspirin with anticoagulants, which can increase bleeding tendency. Oral contraceptives with anticoagulants, which can reduce the effectiveness of the anti-clotting agents.

New Perpetual and Life Members

Perpetual Member . . .

Dr. and Mrs. John C. Vann

Life Members . . .

Mr. and Mrs. Edward Bain
Arlington Helbing, Jr.
N. J. Willwerscheid
Frank Stockton, D.D.S.
Mrs. Flora S. Coyle
Sunrise Farm Stores, Inc.
Melvin E. Page, D.D.S.
Vance Phillips
Mrs. Frank Awes
Martin L. Orban
Mrs. Fern Stratton
Miss Esther R. Ulrich
Mrs. Sovena V. Foster

Received mid-March to mid-April

THE FAMILY CIRCLE

FRED J. HART
Chairman of the Board of Governors

This is a call to our members who, through a keen sense of justice and fair play, have become sick and tired of the harassment, intimidation, illegal publicity, persecution and unwarranted prosecution which they have seen various agents and departments of the government heap upon loyal Americans who are striving to supply the public with food supplements, organically grown produce, natural approaches to health, or even merely information concerning the natural or other unorthodox approaches to the maintenance or restoration of health. While it is not the purpose of NHF to foster or promote the so-called natural approaches, NHF is vitally concerned with the equal rights of both the consumers who choose these approaches and the providers of such products and/or services, naturally, within the confines of the usual sanitary or licensing laws.

The opponents of the natural approaches to health have thrown the torch and the Federation has taken it up and will carry it to them. Many years ago, it became apparent that these opponents were engaged in an aggressive campaign to use the legislative halls (at local, state and federal levels) to reinforce and insure a perpetuation of their monopolistic position in all matters relating to health, through the passage of laws favorable primarily to themselves. It further became apparent to NHF that if the rights of those holding contrary views were to be protected, a similarly aggressive, counter-legislative program must be inaugurated. Thus, it was then that NHF established its presently-active and strong Legislative Department. Now, for somewhat similar reasons, it has become imperative that NHF expand its legal activities and develop a fully active Legal Department.

Our new headquarters Legal Department will, I am sure, meet the hearty approval of all members. Previously, our able Washington General Counsel, Mr. Charles Orlando Pratt, has handled all the legal matters related to the Federation. Mr. Pratt will continue to render his usual capable services on the Washington front and in other instances where his unique background of experience is required. The need for an attorney in our Monrovia headquarters office has long been felt however and the growth of NHF now makes it imperative. Accordingly, a very able attorney, a member of the California Bar, has been employed to head the NHF headquarters Legal Department. Incidentally, he has long held personal views in harmony with the policies, viewpoints and objectives of the National Health Federation and has been a Life Member for over a year.

The Legal Department will have a three-fold purpose: (1) To provide legal counsel to the Executive Committee and staff as necessary so that competent decisions may be made in connection with the work at headquarters and also to assist the staff in the preparation of briefs and their presentations before legislative committees. (2) To establish a library of legal documents which will be of help to other attorneys who have been called upon to defend members, or others, accused of alleged violation of laws but resulting from acts motivated by a sincere desire to serve humanity through natural approaches to health. (3) To assist attorneys employed by any of our members to defend them in legal cases arising from their advocacy of natural approaches to health.

The cost of properly staffing and carrying on the work of this new Legal Department, for the balance of this year, will not be less than $10,000. This amount was not included in the budget for the current year so we must depend on the generosity of our members and friends to share in this project by contributing the necessary funds for this important undertaking which will increase the effectiveness of the Federation manyfold. No gift can be too small or too large.

Early in April the advocates of medical monopoly, with the cooperation of the California Attorney General's office, prevailed upon the court to serve on the National Health Federation an order to show cause why a permanent injunction should not be issued to prohibit the Federation, and other cited, from even mentioning the words, Laetrille or Amygdalin in connection with cancer. On the face of it, such action is unconstitutional inasmuch as it is a denial of freedom of speech. A court hearing has been set for May 3rd.

Your organization is on the firing line, so we must have the ammunition. The forces which seek to deny you freedom of choice in health matters have been kept off balance by the actions of NHF and we intend to keep them in that position. David slew Goliath with but one stone, because he was right and God was with him. NHF has been likened to David opposing a giant monopoly, Goliath. In the tradition of David, we too shall see victory because we are right and we are confident that God is with us.

Truth forever on the scaffold,
Wrongs forever on the throne,
Yet that scaffold sways the future,
And behind the dim unknown
Standeth God within the shadows,
Keeping watch above His own.
—James Russel Lowel

You have a choice -

YOU CAN BE A PART OF THE PROBLEM

or

YOU CAN BE A PART OF THE SOLUTION

Legislators earnestly want to know the wishes of their constituents to guide them in their voting. Your legislators cannot know what YOU want unless you tell him. The strength of NHF and its effectiveness in influencing legislation has been due to the letters written by members to their legislators. When you write you are part of the solution, but when you don't write, you become part of the problem. Which will it be?

You can double your effectiveness as a member of NHF by getting just one new member who is willing to write. But, better yet, set your goal to get a new member every month.

Become a member of THE 10-PLUS CLUB

When you get at least ten new members during one calendar year, you become a member of the 10-PLUS CLUB. Talk your friends, neighbors and relatives into joining — give memberships as gifts for birthdays, Christmas, etc. Your rewards for becoming a 10-PLUS CLUB member will be better legislation, a good feeling of accomplishment, and a FREE ticket for a luncheon held in conjunction with an NHF convention OR your own NHF membership dues paid for the following year. Keep a record of the memberships you have sent in during the year and, if you qualify as a 10-PLUS CLUB member, send your list to NHF headquarters in December for verification and indicate whether you will want a luncheon ticket or your membership dues paid.

Rep. Fountain Urges Review of Laetrile-Treated Cases...

Continued from page 4

parently has shown some activity in the tests sponsored by the McNaughton Foundation.

It should be clearly understood that I am not endorsing Laetrile (Amygdalin), since I have no basis for judging whether or not it is safe and effective for the treatment of cancer. However, the public has a right to know if any of the therapeutic claims made for this drug are justified. I am sure you are fully aware of the anguish and desperation experienced by those persons who are given no hope for the cure of cancer through conventional means, and the great temptation for them to try unorthodox remedies which are said to be nontoxic. In the fight against cancer we surely cannot afford to ignore any leads, whatever their source.

Your Department can render an important public service by arranging for a thorough investigation of the recent clinical experience with Laetrile. I hope you will agree with me that an appropriate study should be initiated without delay.

Sincerely,

L. H. Fountain, *Chairman, Intergovernmental Relations Subcommittee*

Dr. Dean Burk, Head of the Cytochemistry Section of the National Cancer Institute, has long advocated the reinstatement of the McNaughton IND application to the approved status. Apparently Dr. Burk has recognized a potential peril arising from Rep. Fountain's request that a thorough investigation be made of the recent clinical experience with Laetrile. The FDA could use this request as an excuse to further delay favorable action on the IND application pending completion of the requested study. Accordingly, Dr. Burk immediately wrote Dr. Richardson the following letter:

Dear Mr. Secretary:

Through the courtesy of the Office of Congressman L. H. Fountain I have been privileged to see a copy of his letter to you of date of March 16, 1971. I may say that I am largely in agreement with the views and ultimate objectives set forth in this letter, but believe that the *modus operandi* for attaining such objectives should be further clarified. Before you may take any definitive actions on this letter, beyond formal reply thereto, I should like to present to you the following considerations, some amplified in detail in appended attachments, regarding possible directions of such actions.

First, the FDA-IND-6734 application of the McNaughton Foundation of California, originally submitted on April 6, 1970 re Phase I, II, and III studies of laetrile (Amygdalin-MF), was amended on

(Continued next page)

"When any or all of these parties have declared that laetrile is clinically worthless and ineffective anticancerwise, one can but wonder upon what vicariously acquired medical or scientific evidence they can base their remarks, in the absence of, as yet, any FDA-IND-approved studies."

October 31, 1970 to restriction to initial clinical studies at the Phase I level. Such restriction was not made by the McNaughton Foundation out of scientific or medical considerations, but as a simplifying and possibly speeding-up procedure in view of the evident unreasonable intractability of the FDA, and in view of outside influences acting upon the FDA to effect a rescinding on April 28, 1970 of the FDA-IND-6734 application *approval* granted April 20, 1970 as outlined in the two FDA letters enclosed in Congressman Fountain's letter to you of March 16. Since then, Commissioner C. C. Edwards on June 9, 1970 at Fountain Committee hearings (see Attachment I) and FDA Congressional liaison officer Mr. M. J. Ryan in frequent communications to Congressmen and laymen, have deliberately and falsely given out that the letter of April 20, 1970 consisted of merely formal acknowledgment of receipt of the IND-6734 application, whereas reading of this April 20 letter clearly shows that permission for initiating clinical studies was indeed also granted, regardless of any and all subsequent denials.

The fifth round of FDA-questioning - McNaughton Foundation - answering is now in process, the latest submission of the McNaughton Foundation dated February 26, 1971 having been received by the FDA on March 2, 1971, to which the FDA by its own rules would ordinarily reply within 30 days of the latter date, i.e., by April 1, 1971. Mr. McNaughton, President of the McNaughton Foundation believes that his latest reply has narrowed down any significant area of remaining disagreement with the FDA on IND-6734 to a point of negligible difference, but in view of the indications given in various Attachments to this letter to you, it is not possible to predict at this juncture what the FDA reply will be, regarding approval or disapproval of iniial Phase I studies on Amygdalin-MF (laetrile).

It would appear from Attachment I enclosed that Dr. Jesse Steinfeld, Surgeon-General, USPHS, played a prominent and definite role, whether by instruction or otherwise, and whether in writing or otherwise, in the rescinding of FDA-IND-6734 on April 28, 1971. On the basis of Attachment II (and others which could similarly be prepared concerning still other public pronouncements by Dr.

". . . it behooves the FDA to grant immediate approval for commencement of IND-6734 Phase I studies, the requirements for which by any fair and reasonable FDA standards have been overwhelmingly met."—Dean Burk

Steinfeld) I have no hesitancy in declaring to you that, whatever excellent merits Dr. Steinfeld may possess in the field of medicine generally, nevertheless in the field of laterile he is, in my considered and experienced opinion, one of the most ill-informed and demonstrably incompetent,. in terms of his position, responsibility, and ability to obtain true information should he so desire. Running a close second to him in this is Dr. Carl Baker, Director, NCI (see enclosed Attachment III), followed by Mr. M. J. Ryan, FDA (see enclosed Attachment IV) and other top officials of the FDA, including Dr. Bryant Jones, who stated on December 15, 1970 to Miles Robinson, M.D. (the latter acting for, and at the request of, the Office of Senator William Proxmire): "There just isn't any justification for the trial of Amygdalin in man, because we know - - - - good and well it's ineffective as an antineoplastic agent."

The foregoing declaration on my part is made in no sense *ad hominum* with respect to the parties named, most of whom I have met no more than once of twice at most, if at all, and none of whom to my knowledge have ever personally worked clinically or experimentally with laterile or the Amygdalin-MF form of laetrile involved in FDA-IND-6734. When any or all of these parties have declared that laetrile is clinically worthless or ineffective anticancerwise, one can but wonder upon what vicariously acquired medical or scientific evidence they can base their remarks, in the total absence as yet of any FDA-IND-approved studies on Amygdalin-MF or other forms of laterile, which studies would appear to constitute the necessary legal, medical and scientific evidence required as a *sine qua non*, for such declarations.

In seeking FDA-IND-6734 approval, the McNaughton Foundation is asking for no special FDA consideration, but at the same time it is asking for no special lack of consideration, of the type which has so far been forthcoming in great abundance, as spelled out in detail in enclosed Attachment V among others enclosed.

In making the foregoing declaration, I am mindful of the *Code of Ethics* for federal employees clearly set forth by the Congress, which states, "Any person in government service should not put loyalty to the highest moral principles and to the country above loyalty to person, party, or government department." I am also mindful that as a scientist

(Continued next page)

"In the case of laetrile-Amygdalin-MF, we have a material that is essentially non-toxic, that has already demonstrated efficacy in certain rat tumors, that has already been tried in over 5000 cancer patients (most outside the U.S.), . . ."

I have a duty to not only seek truth at all times but to challenge evident untruths or statements that require evidence. If the above-indicated parties persist in making statements that laterile or Amygdalin-MF is clinically worthless, it is fair to demand that proof be submitted in detail to such effect, of a character on a par with that which the FDA would require in granting an approval of IND-Phase I, II, III studies or an actual NDA; otherwise, to paraphrase Thomas Jefferson, "the man who never hears such statements is better informed than he who makes them; inasmuch as he who knows nothing about them is nearer to the truth than he whose mind is filled with falsehoods or errors."

In the opinion of Mr. McNaughton, myself, and a large number of physicians and laymen, it behooves the FDA to grant immediate approval for commencement of IND-6734 Phase I studies, the requirements for which by any fair and reasonable FDA standards have been overwhelmingly met. Indeed, except for possible minor, readily suppliable technical points, the requirements for Phase II and Phase III have already been met, as they were so judged to have done last April 20, 1970 when their approval was also granted, only to be revoked a week later as a result of interference and pressures discussed earlier in this letter.

Consequently, any additional animal studies or retrospective clinical studies, as suggested in paragraphs 6 and 7 of Congressman Fountain's letter of March 16, 1971, should not interfere with the immediate granting of FDA Phase I approval, but could be carried out independently and supplementarily, looking forward to possible eventual granting of not only IND but NDA status to Amygdalin-MF.

A multiplicity of further animal tests is not needed or required scientifically for Phase I clinical studies, however interesting any additional data along such lines might be. I have spelled out on pp. 4-6 of enclosed Attachment II how extremely variable animal tests of efficacy (as distinguished from pharmacology) can be, and how dubious negative (as distinguished from positive) results can be, and especially so in the case of agents so remarkably nontoxic as latertile (as distinguished from the great run of toxic anticancer agents now employed clinically).

However interesting retrospective clinical studies and case reports might be, I do not believe they could ever replace domestic Phase II and III clinical studies conducted in first class hospitals in this country according to fair and reasonable FDA standards, leading toward possible eventual granting of NDA (as distinguished from) IND status. The McNaughton Foundation has indeed provided certain clinical data (unneedful for Phase I studies) in its IND-6734 application, and most effectively so in the 6th and latest volume of this application with reference to certain "terminal" cases treated finally with laetrile two to four years ago, with 80% survival as of this date.

I need scarcely point out difficulties that would almost certainly be involved in setting up a board of "cancer experts who have no conflicting interests and who are able to evaluate the evidence objectively." I have yet to see a "cancer expert" who cannot be fairly said to be biased, in one direction or another. This, however, I would regard in general as a virtue, because it means that the expert has gathered sufficient evidence — on any given subject — to form a bias with some justification. I doubt if a totally unbiased board could ever come to any effective decision, if decision is what is desired. Therefore, if any board on laetrile were ever to be assembled, I would strongly recommend that it include initially at least one or two individuals already possessed of extremes of bias at each end of the spectrum, and to do this only to insure the preparation of minority reports on both sides as needed. Otherwise, one might well expect some form of one-sided whitewash as has indeed occurred in earlier instances of such boards at NIH, with respect to non-laterile agents.

In any event, any delaying of granting IND-6734 approval by HEW-FDA on a basis of awaiting such board deliberations, or further multiplicity of animal testing, would obviously leave the Department of HEW wide open to the claim that the main purpose of such board and animal testing work was indeed to delay granting IND-6734 approval for one or more years, and this objective I do not believe Congressman Fountain had in mind at all.

As Congressman Fountain has stated, "In the fight against cancer we surely cannot afford to ignore any leads, whatever their source." In the case of latertile-Amygdalin-MF, we have a material that is essentially nontoxic (beyond compare), that already has demonstrated efficacy in certain rat tumors, that has already been tried in over 5000 cancer patients (most outside the United States), for which no contraindications have developed for its use along with virtually any and all anticancer therapies (including surgery and radiation) and for which excellent U.S. hospitals and physicians are awaiting an opportunity to test its efficacy in humans along fair and reasonable FDA - approved lines, and for which there is no adequate scientific or medical demonstration of unworthwhileness (all statements to the contrary notwithstanding), and concerning which many

(Continued next page)

physicians and laymen have asked time and again why should it not then be tested, only to receive answers long out of date by many years, and answers not specifically directed at the study of Amygdalin-MF via IND-6734, and answers only by persons who have never worked personally in the clinic or laboratory with Amygdalin-MF or other laetriles,—answers vicariously based at best. The great majority of the 330,000 annual cancer deaths in the United States represent patients with disseminated metastatic cancers that are inoperable and unresponsive to irradiation and for which all currently conventional chemotherapeutic drugs have failed. To repeat Congressman Fountain again, "we surely cannot afford to ignore any leads." In my judgment, Amygdalin - MF (laetrile) is such a lead, that should be tried.

Recommendations

If, Mr. Secretary, the foregoing paragraph carries the weight and conviction for you that I think it should, then my recommendation to you would be to take steps, by instruction or otherwise, to reinstate FDA-IND-6734 to the approved status it held last April 20, 1970 with respect to an orderly advance of Phase I, II, and III studies, requirements for which I believe have already been set by fair and reasonable standards, as a result of five additional submissions by the McNaughton Foundation since May, 1970 running to hundreds of pages. Even as of last April 20, the FDA was prepared and did grant such approval, only to be then further influenced to the contrary by outside forces of the type indicated in my enclosed Attachments, forces arbitrary and ill-informed and improperly motivated by considerations scarcely medical or scientific.

Sincerely yours,

Dean Burk, *Head,*
Cytochemistry Section,
National Cancer Institute

Dr. Burk added the following disclaimer to his letter:

Disclaimer: (cf. HEW-539 10/69 Standards of Conduct, pp. 6-7, paragraph 73-735-402-d-2): The present letter represents the considered views of the oversigned research scientist who has had some 32 years of civil service experience in the laboratories of the National Cancer Institute; these views may differ materially from those of the administrative Director of the National Cancer Institute, and no such official support or endorsement is intended or should be inferred. Conversely, the over-signed scientist desires that his views herein expressed be dissociated from those of the NCI Director where they may differ.

as we go to press...

LOS ANGELES, May 3, 1971: The Court today refused to issue the Order sought by the California Attorney General to restrain the NHF, the International Association of Cancer Victims and Friends, and others affiliated with IACVF from making any representations that Laetrile has any value in arresting, alleviating or curing cancer. For background on this action, see page 5.

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?

FEDERATION ELECTED OFFICERS AND THEIR RESPONSIBILITIES

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LATE BULLETIN

SENATORS HART AND PROXMIRE DEMAND FDA CEASE BLOCKING LAETRILE TEST

Senators Hart and Proxmire, two of the most respected and influential senators, have sent strongly worded letters to Elliot L. Richardson, Secretary, Department of Health, Education and Welfare, demanding the H.E.W. fairly resolve the Laetrile issue.

HELP SAVE OUR HEALTH FREEDOMS