PRIVATE PAPERS PERTAINING TO LAETRILE

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FOREWORD

The purpose of this volume is to place into the public record the author's private collection of letters and documents cited or quoted in his book *World without Cancer; the Story of Vitamin B17* (Westlake Village, CA: American Media, 1997). Few if any of these items have been published elsewhere. This volume, therefore, represents the means by which they shall be preserved for public scrutiny and future research.

The papers are arranged alphabetically, first by the last name of the document's author, and secondly by the name of the recipient, if applicable.

In some cases, these documents contain pencil markings along the margins and underneath selected phrases. These markings were added during the initial stage of research as aids for locating key passages during the final stage of writing. It was not practical to remove them.

The image quality of several items is rather poor due to the fact that, in many cases, the author's original was, itself, a second-generation photocopy. Furthermore, they were made during the 1970s when photocopy technology was in its infancy. All items are legible, however, and that is what matters for our purpose.

It is the author's conviction that the substance of these papers will someday be recognized as one of the great scientific scandals and medical turning points of history.

G. Edward Griffin

CANCER CONTROL JOURNAL —MAY/JUNE 1973

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

Room 4E—16, Building 37
National Cancer Institute,
Bethesda, Maryland 20014
May 30, 1972

Honorable Lou Frey, Jr.,
214 Cannon House Office Building
Washington, D.C. 20515

Dear Congressman Frey:

Pursuant to your letter to me of May 4, 1972, I am pleased to submit to you the following comments and attached enclosures regarding the current status of the anticancer agent variously known as Amygdalin (the chemical name given to it upon its discovery in 1830); Laetrile (a contraction of its long chemical formulation); B—17 (vitamin B—17); or, more generally, nitriloside.

Food and/or Drug. Amygdalin occurs natively in over one thousand species of plants, many of which are edible, and in this lay sense it is fundamentally and historically a *food* constituent or supplement. It becomes a *drug* in a legal sense when it is purified in a pharmaceutical preparation for specifically indicated medical purposes; of which anticancer activity is the most prominent of several activities reported in the scientific literature on Amygdalin.

Chemical Compositon and Crystalline Form. Pure Amygdalin is a chemical compound containing one molecule of benzaldehyde, one molecule of cyanide, and two molecules of glucose (blood sugar), all bound together so tightly that at ordinary temperatures it can be decomposed into its indicated components only by the action of a very special enzyme, glucosidase, found in many plants and in some animal tissues. Like many chemical compounds, Amygdalin may exist in several crystalline forms, depending upon the number of molecules of water of crystallization attached (e.g. 0, 1, or 3 H_2O), all of which forms, however, when dissolved in aqueous media, yield one and the same Amygdalin.

New vs. Old Drug. One particular crystalline form of Amygdalin containing one molecule of water of crystallization, known as Amygdalin—MF, is many times more readily soluble than any of the other known forms, and was first prepared by the NcNaughton Foundation about eight years ago, and, with regard to potential anticancer activity, is classed by the U.S. Food and Drug Administration as a *"New Drug"*. Other crystalline forms may perhaps be regarded as *"Old Drugs"* under the so-called Grandfather Clauses (a matter still requiring Court adjudication), since they entered into commerce and medical usage either before passage of the Federal Food, Drug, and Cosmetic Act of 1938 or more particularly before passage of the Kefauver Amendment to this Act, the "Drug Amendment of 1962 (public Law 87-781, 87th Congress, S. 1552, October 10, 1962), — which amendment added the further requirement of demonstration of drug efficacy in addition to drug safety, and an amendment whose constitutionality with respect to safe anticancer drugs remains to be tested (see below). Furthermore, prior to passage of the Kefauver Amendment, Judge W.T. Sweigert of the San Francisco Federal District Court ordered limited distribution of supplies of Amygdalin (laetrile) to the McNaughton Foundation of Canada and to certain American physicians for investigation with, or treatment of patients (cf. Case 38179, Exhibit A, Proviso, May 17, 1962 et seq.) thereby federally recognizing the elements of commerce and pharmaceutical medicine with respect to Laetrile before October 10, 1962.

Interstate Commerce. The various forms of Amygdalin are currently enjoined by the FDA from interstate commerce when they are prepared as pharmaceuticals for *human* medical investigation or use, but not when they enter commerce as chemicals such as now sold by many leading chemical and biochemical firms with published catalog price listings. In this connection, Dr. Earl L. Meyers, Bureau of Drugs, FDA, has written Mr. A.R.L. McNaughton, President of the McNaughton Foundation, on April 7, 1972: *"There is nothing to prevent you from importing Amygdalin MF for* animal *testing if you choose to do so"* **(emphasis added).** Thus, on such a basis, I have recently received 300 grams pure Amygdalin—MF sent from Mexico, and across state lines, to my laboratory here in Bethesda, for continued conduct of animal experimentation with normal and tumor-bearing mice; as have similarly Drs. Saul Schepartz and John Venditti (Drug Research and Evaluation Branches, NCI) for experimentation with various cancer-bearing mice and rats; and likewise 5,000 grams Amygdalin to Mrs. Helen Nauts, Executive Director, New York Cancer Research Institute, for experimentation with cancer-bearing dogs and cats at the New York Animal Medical Center laboratories, under the experimental supervision of Drs. William Hardy and Lloyd Old of the Sloan-Kettering Institute for Cancer Research, all in accord with Dr. Meyers's directive.

Parenthetically, I may add that the patient-care-use of medical drugs, New or Old, is not under the intrastate legal control of the federal FDA, on bases of either IND (Investigational New Drug) exemption or NDA permit therefrom, *if* they are nontoxic as prepared and dispensed under the supervision of a within-the-state M.D. and are no threat to the within-the-state public health. Indeed, there are also exceptional instances where this is also true even interstate (cf. 38 Corpus Juris Secundum, pp. 726, 804; Brennan vs. Titusville, 14 S. Ct. 829, 153 U.S. 289, 38 L Ed 719; 12C Juris, p. 20), as, for instance, when a drug gift for a donee living in another state may be delivered by the donor to a third party who delivers it to the donee for the donee's use. Dr. A.C. Ivy, M.D., Research Director, Ivy Cancer Research Foundation, Chicago, has been

proceeding on this basis in the State of Illinois for a number of years with respect to the potential anticancer agent, "carcalon", without effective challenge or restraint.

Current Human Usage of Laetrile. In spite of the aforementioned FDA prohibition of Laetrile in interstate commerce, there are well over 2000 cancer-afflicted persons in this country using Laetrile for cancer treatment and amelioration, and a goodly number of non-cancer persons using it merely with prevention of development of cancer in view, and these various persons include M.D. physicians as well as laity. I have had considerable personal experience in this regard, for in the past year alone at least 750 persons, including more than 50 physicians, have contacted me for information on the use and availability of Laetrile, and I know of others with approximately the same quantitative extent of similar experience. In over 20 countries of the world, well over 5000 cancer patients have been treated with Laetrile, with, significantly, no demonstrable noteworthy clinical contraindication of its use either along or in conjunction with virtually any other anticancer agents, chemotherapeutic, radiological, or surgical. Laetrile at physician-prescribed dosages is nontoxic by a factor of 100-1000 times when compared to essentially all anticancer drugs now used with FDA approval on an IND or NDA basis. The human use of Laetrile is growing rapidly, in and out of the United States; partly because in the last two or three years five factories have been developed for its production, in Mexico, Monaco, Italy, Germany, Jugoslavia. Court and legislative actions to facilitate American usage are in progress (see below).

Although the foregoing Laetrile utilization in this country is proceeding, as indicated, in spite of FDA prohibition, it is even more so *because of* unwarranted FDA procedures, and lack of FDA scientific and medical justification for its stand, extending to probable unconstitutionality, concerning which many thousands of cancer-afflicted persons and their relatives and physicians are rapidly becoming aware. In this connection, I have hundreds of letters sent to me enclosing FDA information sheets and pronouncements, in which the senders of these letters point out the extensive falsification, duplicity, deviousness, red herrings, and literal lies (the preferred euphemism of the ever-chivalrous Hon. James Symington is "mendacities") promulgated by the FDA with respect to Laetrile, as well as similarly on the part of a limited number of certain high officials (though scarcely ever rank-and-file members) of the American Medical Association, the American Cancer Society, the U.S. Department of Health, Education, and Welfare, and state agencies (most prominently the California Cancer Advisory Council, see below), as I have specified in detail on pp. 706-707 and 714-720 of the herewith enclosed material taken from the Hearings before the Subcommittee on Public Health and Environment of the Committee on Interstate and Foreign Commerce, House of Representatives re H.R. 8343, H.R. 10681, S. 1828, September 15-October 11, 1971, that led eventually to the passage of the "National Cancer Act of 1971", and as I more extensively documented by further submissions requested by the Subcommittee and staff for their files, to the extent of some 400 pages.

In any event, it is becoming evident that the current generation of cancer sufferers is coming to regard the intransigence and palpable lies of the FDA and the above-indicated related organizations with a marked measure of contempt on the basis of prima facie evidence provided by these organizations themselves as to their integrity and credibility and that something of a Boston Tea Party mode of action is being undertaken by an increasing number of cancer-sufferers in this country, who intend to be hoodwinked no longer; in short, an active backlash is developing even at the grass-roots level and along various lines, some of which follow:

Proposed Congressional Action. The enclosed letter from Jay M. Hutchinson, Chairman, *"Test Laetrile Now Committee"*, reports on the first petition of 1000 signatures of Americans who ask for the clinical testing of Laetrile on human cancer sufferers who have given their informed consent, which requests: "We the undersigned citizens petition your committee to recommend to the Congress that special authority be immediately granted for the clinical testing of Amygdalin–MF (Laetrile, an internationally used cancer controlling agent) by recognized medical authorities in accordance with the testing data submitted by the McNaughton Foundation for the Investigational New Drug (IND) No. 6734 of the Food and Drug Administration." Other 1000-signature petitions will follow in large number,* and will be sent to various U.S. Senators and Congressmen, as the first one already has and will proceed from all parts of the country, the first one coming mainly from the San Francisco area. I may add that I have been reliably informed by the staff member in charge of handling IND applications in one of the largest cancer research organizations in the country that the McNaughton Foundation IND applications made by and granted to said cancer research organization, and this in spite of the report of the "kangaroo court and jury" of the FDA described in my testimony on pp. 719-720 of the enclosed Hearings by the Rogers Subcommittee on Public Health and Environment (cf. also letter of Jay M. Hutchinson, paragraph 8).

A Bill, H.R. 12092, has already been introduced (December 7, 1971), herewith enclosed, and along the lines of the aforementioned Petition, that is intended to cover not only Laetrile but a large number of safe and nontoxic drugs, foods, vitamins or other substances for study and use on cancer mitigation in human patients, and that directs the Director of the National Cancer Institute to pursue activities along such lines as part of the expanded, intensified and coordinated cancer research program to which the Institute is now committed to by the National Cancer Act of 1971. A similar Bill is being proposed for introduction into the Senate, with respect to anticancer agents that are safe and nontoxic at dosages far less toxic than the "safe" anticancer drugs or substances now approved and allowed by the FDA, and far below any dosages producing even mild or moderate sublethal effects.

The National Cancer Act of 1971 would appear to raise a question as to conflict of jurisdiction of authority between the National Cancer Institute and the Food and Drug Administration as to which agency shall hereafter set standards

* over 20,000 by Feburary 1973.

of safety and care regarding *cancer* patients being treated with biological materials and other therapeutic substances (cf. Section 407, (b) (5)). The legislative intent as to disposition of IND authority is not clear as yet, apparently.

Proposed Court Actions. An action is scheduled* for initiation in a U.S. District Court by a New York law firm acting on behalf of a Plaintiff Mrs. Joan Andrews and a number of co-plaintiffs who suffer from cancers in various forms, to enjoin the United States Post Office, the U.S. Customs Office Service, and the Secretaries of the Treasury and the Department of Health, Education and Welfare from preventing entry into the United States and into Interstate Commerce, the material known as Amydgalin (Laetrile) for personal use pursuant to a physician's prescription. The scope of the action is a narrow one, i.e., it will not attempt to permit introduction of such material into interstate commerce for *commercial* purposes, but rather permit freedom of individual use. No claim will be made in this litigation as to the anticancer efficacy of laetrile, but rather only that it is safe for humans at applied physician-prescribed dosages. The position taken is that the efficacy standard of the Kefauver Amendment, as applied to a narrow class of persons who are cancer patients and diagnosed as such is unconstitutional, violating, among others, the Ninth Amendment constitutional right to privacy. The action may well proceed through District and Appellate Courts to the Supreme Court.

Parenthetically, I may add that I have been reliably informed by a co-writer of the Kefauver Amendment that the original legislative intent was not concerned with agents, non-toxic or toxic, against what were then regarded as essentially noncurable (or noncured) diseases such as cancer, but was directed against diseases essentially curable on a large scale, such as pneumonia or tuberculosis, for which a number of effective agents were then already and otherwise available.

A Court action with respect to the Grandfather Clause status of Laetrile (hereinbefore referred to) is under consideration, following upon similar Court actions now underway with respect to a number of quite different drugs and substances where it would appear that the FDA has taken inappropriately retroactive measures with respect to the Kefauver Amendment, and such Court action has already reached the Court of Appeals.

Constitutional Free Press Court Action. On March 31, 1971, the Attorney General and Deputy Attorney General of the State of California, as attorneys for the Plaintiff, Louis F. Saylor, M.D., Director of Public Health of the State of California, instituted an action (no. 999731) in the Superior Court of the State of California for the County of Los Angeles to restrain the Defendants: International Association of Cancer Victims and Friends, Cancer News Journal, National Health Federation, certain officials of these organizations, and Does I through XX, from making any *representations* that Laetrile has any value in arresting, alleviating or curing cancer, in violation of section 10400.1(d) of Title 17, California Administrative Code. At the hearing of the case on May 3, 1971, Superior Court Judge Wisot refused to issue the preliminary injuction sought by the state authorities, basing his decision on the finding that the requested prohibition would violate the First Amendment of the U.S. Constitution guaranteeing freedom of the press. Judge Max Z. Wisot said he could not deviate from the principle that individuals have the right to determine their own course of action and to be influenced by or to ignore what they read. Judge Wisot further pointed out that the very statute in question had declared that nothing therein contained shall be deemed to abridge the freedom of the press. Freedom of the press has been construed down through history since the enactment of the First Amendment to the Constitution as applying to every means of communication, including books, pamphlets, films and verbal expressions, as well as newspapers and magazines. The protection aimed at by the writers of the Bill of Rights was not solely for persons in intellectual pursuits unrelated to action. The First Amendment is a charter for government, not for an institution of learning, and "Free trade in ideas" means free trade in the opportunity to persuade to action, not merely to describe facts.

In a closely related, widely cited case, Near vs. Minnesota, the Supreme Court reversed the decision of the trial court that had ordered a certain periodical abated, and had enjoined the defendants from distributing it; the Supreme Court held that the Minnesota authorities' actions were unconstitutional as imposing an unconstitutional *previous restraint* and censorship upon the defendants' right to freedom of the press. Mr. Chief Justice Hughes wrote the opinion that *"it is the chief purpose of the guaranty to prevent previous restraints upon publication."* Earlier, Blackstone had written, *"The liberty of the press is indeed essential to the nature of a free state; but this consists in laying no previous restraints upon publications, and not in freedom from censure for criminal matter when published. Every freeman has an undoubted right to lay what sentiments he pleases before the public."*

In view of the foregoing, rather well-known, elementary considerations, one can but wonder how and why the California officials involved should ever have attempted to institute a suit of prior restraint amounting to total blanket injunction along lines contraindicated since the time of Blackstone. The concluding points and authorities cited by the California officials to the effect that a competing consideration should take precedence, namely that of "The interest of a person who wants her cancer treated with a drug which medical and scientific evidence shows is worthless," is odd, to say the least, even from a legal point of view, but is further demerited by the consideration that in the year 1971 Laetrile is indeed already regarded, medically and scientifically, as far from "worthless" by many authorities, granted that the matter, like most scientific and medical matters, is controversial. For, it is a widely held maxim that *"In science one cannot prove that there are no ghosts."* The California administrative authorities have widely overstepped the bounds of science here, and, similarly, the bounds of medicine also. Their action may be likened to the well-known state legislature that attempted to declare that thereafter in that state the value of π, the nu-

*for hearing in the Federal 4th Circuit court ca. April 2, 1973, in Baltimore.

merical ratio between the circumference and the diameter of a circle, would be an even 3, instead of 3.1416 . . . One cannot help but wonder whether the California officials introduced the suit mainly to tighten up their own pseudo-medical loopholes by a legal but scarcely scientific device.

Judge Wisot denied the requested restraint, but added, "without prejudice to any application for renewal, in the event there can be or is shown to the Court any greater need or any greater grounds than an invasion of constitutional rights of speech". Apart from the aforementioned dubious scientific and medical grounds, the California officials would be well advised to recall first that state laws and regulations can extend and go no further than federal laws and regulations by the legal rule of pre-emption (supersession) an instance of which was very recently confirmed and upheld by a decision of the U.S. Supreme Court dated March 22, 1972 (92 Sup Ct 1029, Supreme Court Reporter).

In the May 3, 1971 Hearing before Judge Wisot, the constitutional issues were ably presented by the Defendants' lawyers, Kirkpatrick Dilling of Chicago and Charles Pratt of Virginia, both of whom have had legal experience on food and drug matters for over 35 years, and both of whom are frequently called upon to protect small businesses against tyrannical and unwarranted acts of the FDA involving, e.g., illegal search and seizure, electronic snooping and entrapment, scare techniques, "book burning", jury softening and intimidation, all extensively described and documented in "The Dictocrats: Our Unelected Rulers" written by Omar Garrison (1970) to which I may invite your careful attention.

Red Herring Ploy: On a more academic level, it is a very commonly employed ploy on the part of administrative and health officials to attempt to pass hypothesis off as fact, as in the following very recent instance so advanced by Ralph W. Weilerstein, M.D., Executive Secretary, California Cancer Advisory Council (Department of Public Health): "The use of Laetrile in early cancer cases 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 occurerd and the cancer, therefore, might no longer be curable." (College of Marin Times, Kentfield, California, April 26, 1972). This line of "reasoning" can be run across hundreds of times, and was indeed a ploy frequently set forth by the recently removed Director of the National Cancer Institute and his letter-writing assistants, and, it is to be hoped, will be discarded by the newly-appointed Director Dr. Frank Rauscher. Of the 350,000 cancer patients dying of cancer in the United States every year, and of the twice this number suffering currently from cancer, I doubt if proponents of this idea could produce as many as ten instances, even five, perhaps even one; certainly to my knowledge, they never have, and may herewith be presented with the challenge to do so. Of the thousands of cancer patients who have contacted me, I have yet to find one who had not been treated with "conventional" methods before seeking Laetrile, and nearly all of those so seeking were in "terminal" or near-terminal cancer status. (As earlier stated, I know of noncancer persons who do take Laetrile, in one form or another, with prevention in view). There is, of course, a growing number of cancer patients who come to take Laetrile along with "Conventional Treatments", in view of its widely recognized nontoxicity, and lack of medical contraindication of such a course of action. The Editor of the College of Marin Times, which had just earlier printed "prolaetrile" material, editorialized, "We are at a loss as to which side (pro-laetrile and anti-laetrile) has the right story. You can be sure that one of the sides is fraudulant." In the opinion of the undersigned, there is little doubt as to which one is.

Conventional Failure: Let us now examine more closely the implications of "conventional treatment" so referred to above by Dr. Weilerstein (as well as by countless others). To set an appropriate stage, let us begin with citing Benjamin Rush, M.D., Surgeon General of the Continental Army of the United States, and Signer of the Declaration of Independence, "To restrict the art of healing to one class of men and deny equal privileges to others will constitute the Bastille of medical science. All such laws are un-American and despotic, . . . and have no place in a republic . . . The Constitution of this Republic should make special provision for Medical Freedom as well as Religious Freedom."

The 350,000 cancer deaths a year in the United States referred to above represent patients almost exclusively with disseminated, metastatic cancer, their deaths occurring on the average many years before otherwise allotted time. They represent the number who failed of the benefit of "acceptable, modern curative methods" cited by Dr. Weilerstein. Estimates of the percentage of disseminated-cancer patients who survive more than a very few years vary most frequently between 5 and 15%.

> Thus, at a White House Press Conference following immediately upon the swearing in of Dr. Frank Rauscher, Jr., as new Director of the National Cancer Institute, Dr. Rauscher reported a figure of about 7.5% as follows: "of the 100 cancers that afflict man, about 15 percent of these can be treated extremely well, to the point of at least 50 percent 5-year survivals" (15% x 50% = 7.5%). A considerable part of the 7.5% is in fact made up of leukemias, and only a much smaller fraction by patients with solid tumors (sarcomas and carcinomas). According to Dr. Albert Sabin, "85% of cancers do not respond to any drugs."

This is also confirmed approximately by citations listed in the enclosed "A Very Grim Picture", which gives direct quotations from a number of prominent physicians reporting in the Sixth National Cancer Conference Proceedings, published July 1970, under the auspices of the National Cancer Institute and American Cancer Society, who selected the reporting physicians. At a very recent, heavily attended Chemotherapy Conference held in the main auditorium of the NIH, Dr. Charles Moertal of the Mayo Clinic stated at the end of his lecture on May 18, 1972, after being introduced by Chairman Dr. Stephen Carter (NCI) as "probably one of the country's foremost, if not the foremost expert in this area (of gastrointestinal cancer)": "Perhaps some small and hesitant progress has been made, but it is evident that in this year of 1972 there is no remarkably

effective specific therapy for any types of gastrointestinal carcinoma that cannot be surgically extirpated. There are none that can be accorded the stature of treatment of preference. Our most effective regimens are fraught with risks and side-effects and practical problems, and after this price is paid by all the patients we have treated, only a small fraction are rewarded with a transient period of usually incomplete tumor regressions." At the beginning of his lecture, in which a large variety of experimental anticancer agents studied by Dr. Moertal were reported in detail, Dr. Moertal said, "Our accepted and traditional curative efforts therefore yield a failure rate of 85%. These patients with advanced gastrointestinal cancer present us with one of the most frequent major disease problems encountered in medical practice today . . . The patient with gastrointestinal cancer is still getting the same old 5-Fu he got 14 years ago. Some patients with gastrointestinal cancer can have very long survival with no treatment whatsoever." Dr. Moertal was followed by Dr. Bernard Fisher of the University of Pittsburgh on the subject of breast cancer, who spoke in equally frankly pessimistic vien on breast cancer, with respect to current, available therapies. The two physicians just referred to, and the some 15 others reporting in "A Very Grim Picture", are unquestionably men of highest integrity, sincerity, and effort, and one may well ask Dr. Weilerstein where are all the modern curative methods to which he, the California Cancer Advisory Council, and indeed so many administrators so glibly refer? One must bear in mind here that "trilingual" English is often met with: (a) M.D.'s speaking frankly among themselves, (b) administrators speaking to Congressional Appropriations Committees, and (c) for patients and their families. No, disseminated cancer, in its various forms and kinds, remains by and large as "incurable" as at the time of the Kefauver Amendment 10 years ago, or the California Cancer Commission 20 years ago, – Dr. Weilerstein or no Dr. Weilerstein, FDA or no FDA, ACS or no ACS, AMA or no AMA, NCI or no NCI. Their practising M.D. spokesmen say so, as I have very briefly indicated, in their plain, unadulterated English, class (a).

And what about Laetrile, by comparison? Leading Laetrile physicians (M.D.'s) claim about the same kind of 5 – 15% objective benefit, though they do not do so on particular bureaucratically required forms of e.g., the FDA or the California Cancer Advisory Council. But, with these added benefits: (a) no such bodily harm of the type produced by virtually all toxic drugs now conventionally employed and recommended; (b) much higher percentages of pain relief than the 5 – 15% objective benefit. That the various administrative agencies claim Laetrile is worthless, may be dismissed (as indicated above) as unscientifically based, together with the fact that few or none of such claimants have ever worked personally with Laetrile and patients, nor have they seriously if at all ever visited hospitals and clinics where Laetrile is used, and their alleged medical basis goes back to the 1953 report of the California Cancer Commission which described no patient ever receiving a *total* dosage of Laetrile as great as is now the current standard *daily* dosage (3 gram/day or more). Fewer and fewer people are being hoodwinked by this last consideration, unless it be the indicated agencies repeating it over and over to themselves

As for the conventional pain-relievers employed, one of the speakers at the May 18-19, 1972 NCI Chemotherapy Conference said: "Our primary responsibility is relief of pain . . . after centuries of experience dating back to Paracelsus and beyond, it is astonishing how little we really know about relief of pain with oral medications. Our prescribing habits are usually guided by such unimpeachable sources as the physicians' desk reference, or the detail man's testimonial, or the throw-away literature that accompanies the free ball-point pen". Many cancer patients on Laetrile have reported heretofore usage of conventional pain-relievers has been reduced greatly, even completely. Pain, of course, is a subjective consideration, but by and large, the patient himself is the highest authority, with respect to himself.

A popular fallacy (rather than intentional ploy) found almost universally among practised employers of the ploy, is the concept that if an agent cannot harm the body it cannot harm cancer. The fatal weakness in this view is that wherever cancers differ from normal body cells (and they in several well-established ways do, e.g. metabolically, catalase content, water content – broadly speaking) then an anticancer agent may have specificity against cancer compared to the normal cell. This specificity may be absolute or relative. It may yield anticancer efficacy as distinguished from pharmacologic harm. Even a simple ordinary body compound, such as glucose (blood sugar), has been shown in the very extensive work of Manfred von Ardenne to have remarkable anticancer activity, and the more so when used in multitherapy involving several simultaneously employed anticancer agents, all used, of course, under predetermined optimizing conditions.

The Carcinogenicity of Conventional Anticancer Drugs.
A recent report from the Southern Research Institute, dated April 13, 1972, several hundred pages in length (see enclosed Summary first 11 pages), conducted for the National Cancer Institute (Contract PH-43-68-998), shows that a majority of the common clinically used "Weilersteinein conventional" anticancer drugs are highly carcinogenic in rats and mice, and in a surprising variety of organs thereot. The suggested indication is that virtually all such conventional toxic anticancer drugs will yield the same result when the studies are fully completed. These are the drugs now approved by the FDA for cancer treatment, on an IND or NDA basis, before or after the enactment of the Kefauver Amendment. As Dr. Saul Schepartz has remarked to me – this is something we will really have to start worrying about when and if some of these drugs get to producing several years – "cures" – for after that time carcinogenicity will rear its ugly head. Ironically, when it comes to *foods* the FDA is required by the Delaney Amendment to preclude usage of any compounds in foods for which the slightest carcinogenic effect has been reported in animals so fed. The gap in thinking here is almost infinite, but currently *sotto voce*. The rationalizing argument made is "efficacy vs. risk" (as in so much of medicine) or, in plainer language, "the lesser of two evils".

New Animal Experimentation with Laetrile. I have referred in column 2 of this letter to Laetrile experimentation with animals about to be taken up anew, in the National Cancer

Institute by two separate groups, and by the New York Institute for Cancer Research, with mice, rats, cats and dogs, and may add that currently similar studies with, in addition also rabbits, is underway in the Paris laboratory of Dr. T. Metianu of the Pasteur Institute. These can certainly be interesting academic and scientific studies, and where positive might particularly aid in studies with humans, though the same cannot so readily be said where negative, because as with all searches for anticancer agents, variability of efficacy, as distinguished from pharmacology, can vary enormously from organ to organ, species to species, cancer type to cancer type, etc, as everyone knows or should know. Pharmacologic results with animals are far, far more readily transferable to humans than are anticancer efficacy studies.

New Food Containing Laetrile. Recently, starting in Europe, efforts are underway to produce food products relatively rich in Laetrile, where (a) it will not be a drug, and (b) can be consumed in sufficiently small food quantities yet provide current daily recommended Laetrile dosages of the order of several grams/per day, at approximately one-tenth the cost per unit of Laetrile now otherwise prevailing. Thus flours may be made from bitter almonds (extensively available in Europe,) or apricot kernels (extensively available in this country), or other kernels of the Prunus family. A variety of foods are under consideration, including bread, pastry products, even milk shakes. The bitter almonds themselves have long been readily available in European grocery stores, just as the apricot nut kernels have been here.

> I have found that adult mice can live indefinitely when their normal chow diet is made up to contain 50% defatted apricot nut flour. This provides them with approximately 125 mg amygdalin per mouse per day, or 4000 mg amygdalin/kg mouse/day, and is in addition excellent food material, rich in protein and minerals.

SICKLE CELL ANEMIA:

Other Laetrile Possibilities. There are about two million persons in the United States with the sickle cell trait, and some 50,000 with actual sickle cell anemia, which very recently has been found to be ameliorated – at first by urea – and now much better by an impurity in urea, namely cyanate. Tablets or capsules of cyanate may be ingested to overcome the anemic hemolytic crisis. Cyanate can also be produced by hydrolysis of Laetrile, and conceivably it might be more sensible to obtain cyanate from ingested Laetrile – a working hypothesis yet to be demonstrated as efficacious, be it clearly noted, but which, if demonstrable, could be demonstrated with far less scientific effort than has been involved with Laetrile and cancer. This approach has been suggested to me by one of the most brilliant biochemists I know of in this country, who writes me further regarding his hypothesis: "A relatively few simple clinical applications of Amygdalin in pure form or Laetrile in food rations should give us the answer. If the answer is confirmatory, I wonder if the FDA will attempt to perpetrate a discriminative genocide against the black population of this country who have sickle cell anemia?" He adds that "Populations in Africa who have diets rich in vitamin B–17 (nitriloside) do not have sickle cell anemia no matter how loaded they are with sickle cells." He further points out that there appears to be a remarkable difference in cancer incidence among Nigerian natives who do and do not have large amounts of vitamin B–17 in their diets, greatly in favor of those who do, with respect to absence of cancer, – according to reports by Dr. O.L. Oke, University of Ife, Ibadan, Nigeria.

Sincerely yours,

Dean Burk

Dean Burk, Head,
Cytochemistry Section, NCI

DISCLAIMER: The above views of the oversigned research scientist may differ materially from those of administrators within HEW, and no such latter official support or endorsement is intended or should be inferred.

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Toward a Nonwatergatean NCI: An Open Letter.

In three parts: Statistical
Biological
Politico-moral.

Dear Sy,

I thank you for your letter of Dec. 19, 1973, with its enclosure (herewith re-attached, as Item A, for the convenience of other readers of this letter) of the "Special Report to Drug Research and Development Division of Cancer Treatment, National Cancer Institute, on Analysis of Life Span Data from Regular Lewis Lung Experiments 34, 47, 54, and 63 on the Evaluation of NSC B900540 and 128056 against Subcutaneous Lewis Lung Tumor," from the Southern Research Institute, Birmingham, Alabama, December 3, 1973, Project 2625-7. I have also received a copy of this report through the courtesy of Dr. Saul Schepartz and Nathaniel Greenberg (NCI-DRD-DCT).

In response to the request in your letter for my possible comments (submitted herewith) on this SRI-NCI report, I have taken occasion to consult on one or more aspects with the following statisticians and/or biologists: Drs. Harris H. Lloyd and J. G. Mayo (SRI); Drs. Lawrence Muenz, John Gart, and James L. Murray (NCI-B), and Dr. John Hearon (A-MR), all of NIH; Dr. Peter Stacpoole (Univ. Tennessee Medical School, Nashville); Dr. Vincent Lisanti (Council for Tobacco Research USA, New York City); and Dr. W. Edwards Deming (Washington, D.C.). Responsibility for any errors, major or minor, in my comments is, of course, solely mine, but, as of this date of writing, no essential exceptions to my statistical proposals and conclusions have been advanced to me and persisted in by any of the aforenamed scientists. In any event, all of the latter will be sent a copy of this letter for their further possible comment and/or exception before material in this letter is published by me.

At the outset, I should make it clear that my analyses and conclusions differ diametrically from those of the SRI-NCI report wherein it is concluded that Amygdalin MF (NSC B900540, a form of Laetrile) "does not possess activity in the Lewis Lung carcinoma system" (letter of Dr. Saul Schepartz, Dec. 19, 1973), or that "NSC B900540, either alone or in combination with NSC 128056 (beta-Glucosidase), was inactive against established subcutaneous Lewis lung tumor when administered on the schedule of QD 7-15 days" (SRI Report Abstract, Dec. 3, 1973).

In my opinion, the statistical analysis employed by the SRI was far from adequate, certain overriding biological considerations were neglected in the SRI-NCI report (though they should not have been), and, on top of this, certain upper NCI administrative spokesmen have been guilty of scientific and immoral falsifications amounting to corruption in the sense of the Congressional Code of Ethics. This Code, which I personally intend to follow to the limit of my ability, calls for "Exposing corruption wherever discovered," and "Putting loyalty to the highest moral principles and to country above loyalty to persons, party, or Government Department."

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In my view, in a scientific institution such as the NCI, scientific truth should never be perverted, as it clearly and demonstrably has been here, on grounds of a politico-medical expediency that is potentially as far-reaching and dangerous as things Watergatean, so far as the pursuit of life, liberty, happiness and health by our citizenry is concerned.

Although the aforeoutlined difference of conclusion refers specifically to the matter of Amygdalin MF activity in Lewis lung tumor, a number of questions are thereby raised as to the general validity of various arbitrary, rigid, or robot-like statistical and biological procedures widely adopted by various contract laboratories as standardized efficacy-testing methods with respect to a large number of quite other anticancer agents that have been or will be tested in animals. These questions will be liberally illustrated by what follows with respect to Amygdalin MF in particular. And here, indeed, the methodology appears to have been aimed at avoiding a seeking out and developing of potentially interesting positive leads, even to the point of ostrich-like denials of the existence of such leads as may have shown up anyway, and notably denials set forth in public information reports sent out all over the United States and abroad (e.g., Items B-G). As Goethe warned, "Error is being preached about us all the time, and basks in having the majority on its side."

STATISTICAL CONSIDERATIONS

The Raw Data. Neither the copy of the SRI-NCI report you sent me, nor any other copies sent outside of NCI by NCI offices that I aware of, have contained the original SRI raw life span data essential for anyone to make independent checks and extended analyis of the statistical median data and conclusions given in the report. Mr. Nathaniel Greenberg kindly and promptly supplied me, upon my request, with this necessary raw data, copies of which I append herewith as Item H (four sheets for the four Experiments 34, 47, 54, and 63), for the convenience of interested readers.

Negative Efficacy. It is evident by simple inspection that Exp. 47 has no significant suggestion of any positive anticancer effect, indeed virtually every calculated %ILS (Percent Increased Life Span), last column) is essentially zero or negative. Since one should be looking for any positive Amygdalin MF efficacy, I shall herewith dismiss Exp. 47 from any further detailed attention, except to discuss later in due context (cf. BIOLOGICAL CONSIDERATIONS) why there probably was no activity in this experiment.

Positive Efficacy. On the contrary, in Exp. 34, 54, and 63, any average grammar school science student could, any SRI-NCI scientist should, and any sufficiently experienced statistician would, be able to see at a glance widespread evidence of Amygdalin MF efficacy, in terms of both absolute and percent positively increased median life spans, most uniformly and notably so in the treatments with Amygdalin MF alone, but also in certain instances when beta-Glucosidase was additionally given. There would remain, however, after such intuitive displays of cognizance, the questions of just how statistically significant the positive displays of efficacy were, in terms of probabilities (e.g., Confidence Levels, as employed in the Report), i.e., a quantitation of the role that chance alone might have played, in part or wholly. Even so, as Dr. Lloyd (SRI), looking at the data in these three experiments under

consideration, has told me (Dec. 28, 1973), "I am inclined to think that a small consistent increase in life span, even if it's not statistically significant, is of course biologically significant if it can be consistently reproduced." However, as will shortly be seen from Tables 1, 2, and 3, this proviso is superfluous here, since very high Confidence Levels are indeed observed in the various median tests reported therein, consistently and in large numbers.

The Median Test. Although there are many possible statistical methods available* for analyzing the raw data of Exp. 34, 54, and 63, I shall, not to go too far afield, continue to use the basic median test set forth in the SRI-NCI Report and their reference to it (C. Mack, Essentials of Statistics, Plenum Press, New York, 1967, pp. 127-8, 156). This is a so-called "non-parametric" (distribution-independent or distribution-free) test where the observations are arranged in order, or in some way ranked, and the median is that variate-value which divides distribution halfway, i.e., half the population have lower and half have higher variate values. The test determines primarily whether the medians of two populations (e.g., controls and treated) from which the samples come are well separated or not, and the test is generally little affected by greater dispersion or spread in one population than the other. The probability Confidence Levels may be calculated, with the aid of Table 1, p. 4 of the Report, from observed values of M, where

$$M = \frac{(|2m' - m| - 1)^2}{m} + \frac{(|2n' - n| - 1)^2}{n} \qquad (1)$$

where m and n are the numbers of mouse life spans in the control and treated groups, respectively, and m' and n' are the corresponding numbers of mouse life spans in the control and treated groups on a chosen side of the median (which side is immaterial) of the "merged" group obtained by merging the life spans of both control and treated groups into one total "merged" group; and where (by definition) $m+n = N$ and $m'+n' = N/2$, and where $|2m' - m|$ and $|2n' - n|$ are "absolute values" (i.e., signs disregarded), and "-1" represents one degree of freedom (when m and n are sufficiently large, " -1" may be disregarded). When $M \geq 3.84$ then the median mouse life spans of the treated and control groups are significantly different statistically at the 95% Confidence Level or greater. I believe this description of Equation (1) will be found by the interested reader to be less ambiguous and more complete than that given in the Report, top of p. 2, or by Mack, both of which accounts neglected certain points essential to adequate understanding. Incidentally, $|2m' - m|$ always equals $|2n' - n|$.

SRI Analysis of Raw Data by the Median Life Span Test. SRI used the median test to attempt to ascertain the degree of statistical significance between the median life spans of concurrent controls groups (ca. 30 mice/group in each of four experiments) and 71 treated groups (usually 10 mice/group), after discarding 16 treated groups grounds of possible or probable toxicity (cf. Report, Table 2, p. 5, footnotes b,d,e). Four of

* e.g., various formulations of "mean" (rather than "median") tests that are parametric - involving normal (bell-shaped, Gaussian) distribution curves leading to Pearson R coefficients, Fisher coefficients, analysis of variance, correlation analyses, etc. But, as is evident from inspection of the raw data (Item H), such normal distributions are seldom obtained in the small experimental treated groups of 10 mice each (or even the control groups of ca. 30 mice each). The median largely avoids such difficulties, even if not entirely. In another direction, Dr. Lawrence Muenz has largely bypassed mean or median analyses, and kindly made an analysis of the data in Item H, pp. 2, 3, 4, on the basis of actuarial survival curves (life tables) using the Mantell-Haenszel test procedure and maximum likelihood estimates (MLE), together with the assumption that, in a given group, the probability of death on a given day, given survival up to that day, does not change from day to day (mouse to mouse), i.e., an assumption of constant probability of death, yielding an exponential decay behavior. The statistical analyses given in Tables 1, 2, 3 involve no explicit assumptions about the underlying natures of the observed survival curves, but "take them as they come;" as Charlie Chan say, "Beware of theory, like dew on eye-glasses, can obscure facts."

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71 treated groups indicated a statistically significant difference ($\geq$ 95% Confidence Level) from that of the respective control groups, of which only two of these four treated groups ("3%") were regarded as also "biologically significant" (Percent Increased Life Span $\geq$ 25%, a highly arbitrary criterion I reject in toto on grounds discussed at length in the section of BIOLOGICAL CONSIDERATIONS). How SRI - and then NCI can logically discard, neglect, or disregard the importance of the two "statistically and biologically" significant positive experiments (let alone the four "statistically" significant positive experiments they themselves report) out of the total of 71 in announcing their categorically negative conclusions cited in the 3rd paragraph of this letter, is beyond my understanding and experience*, even on a basis of what is known in the statistical trade as "simultaneous inference," or what Dr. Schepartz in his covering letter referred to as "total experience."

It is as though one were to examine the heavens every year for the 75 years between the last two arrivals of Halley's Comet in 1835 and 1910, find no such comet in the intervening years 1836-1909, and then conclude from this last set of negative observations that Halley's Comet does not exist#, even though it in fact had appeared twice ("3%" of 75 years). One simply cannot conclude from a large body of negative evidence, that positive evidence, however occasional ("3"%), does not exist or is of no importance or of no interest -either astronomically or mouse-experimentally. Dr. Lloyd (SRI) readily agreed (to quote his exact word, stated twice) with me on this (Dec. 27, 1973), and I have yet to locate a statistician who doesn't so agree. The categorically negative conclusion as to Amygdalin MF efficacy issued by NCI officials would appear to transcend science into the region of medico-politics (q.v. infra, under POLITICO-MORAL CONSIDERATIONS).

However, as you will now see, the above two or four statistically significant experiments (representing 20 or 40 mice) pale into relative insignificance when compared to the large number of statistically and biologically significant positive experiments and mouse numbers found after correcting and expanding the SRI analyses so as to take advantage of additional information contained within the same data (Item H), which information appears to have escaped SRI attention, both here in Item H and, as I have intimated earlier, probably in a great deal of SRI data with entirely different anticancer agents than Amygdalin MF. The immediately following Tables 1, 2, and 3 present my expanded, innovative analyses of hitherto unused raw data in Item H, and, even so, is restricted to those instances where M $\geq$ 3.84, Confidence Level $\geq$ 95%, %ILS (Percent Increased Life Span) and %ILI (Percent Increased Longevity Index) are positive, and mouse toxicity as proposed in the SRI-NCI Report is not clearly involved. The natures of the three major expansions are indicated in detail in the three next marginal sub-headings, each yielding, in the order given, greater and greater demonstration of Amygdalin MF efficacy against Lewis lung tumor.

As indicated by Friedrich von Schiller, "Even the gods are powerless when faced with human stupidity or ignorance."

* I completed my first graduate course in statistics just 50 years ago in 1924; wrote my first published article involving statistical analysis 47 years ago in 1927; and 40 years ago in 1934, with Hans Lineweaver and W. Edwards Deming, coauthored an innovative statistical paper using Pearson's Chi test (Goodness of Fit) on single and combined (aggregate) arrays of data with respect to an assigned 1/y vs 1/x function properly weighted for this "double reciprocal" type expression (The Dissociation Constant of Nitrogen-Nitrogenase in Azotobacter, J. Amer. Chem. Soc., 56, 225-230 (1934)), cf. Item I. Dr. Deming has been my statistical mentor since 1929, and Jerome Cornfield worked hard on me in the early '50's to produce a joint, comprehensive mathematical-biological paper on The Efficient Transformation of Light into Chemical Energy in Photosynthesis Scientific Monthly, 73, 213-223 (1951)).

Table 1. Analysis of various Single Groups (10 mice per group) of Established, Subcutaneously Implanted, Lewis Lung Tumors treated with NSC B900540 (Amygdalin MF), as compared to Untreated Controls (ca. 30 mice), as carried out by the Southern Research Institute (SRI) for the National Cancer Institute (NCI), and as analyzed statistically by (A) the Mack-Lloyd Median Life Span (MLS) test and/or (B) the Burk-Lisanti Median Longevity Index (MLI) test, for those instances where the Confidence Level (CL) is ≥ 95% (M ≥ 3.84), the %ILS (Percent Increased Life Span) and the %ILI (Percent Increased Longevity Index) are positive, and mouse toxicity is not clearly involved.

Set-up														
SRI Exp. No.	34						54					63		
Implant date	7-27-72						5-2-73					8-30-73		
Mouse sex	Male						Male					Female		
SRI Cage No.	8	7	5	4	3	6	16	10	8	6	12	8	7	6
Mg Amygdalin/kg mouse per dose (days 7-15)	25	12.5	100	200	400	50	6.25	50	100	200	25	0.78	1.56	3.13
(A) Life Span Data:														
No. mice: Controls = m	30	30	30	30	30	30	30	30	30	30	30	28*(29)	28*	28*
Treated = n	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Total = N	40	40	40	40	40	40	40	40	40	40	40	38	38	38
N/2 = (m'+ n')	20	20	20	20	20	20	20	20	20	20	20	19	19	19
m'	19(18)	19(18)					20	19(18)	19(18)			18		
n'	1(2)	1(2)					0	1 (2)	1 (2)			1		
Median Life Span, days:														
Controls	19.5	19.5	19.5	19.5	19.5	19.5	19.0	19.0	19.0	19.0	19.0	28.0	28.0	28.0
Treated	27.5	25.5	23.0	23.0	21.5	20.0	27.5	22.0	21.5	23.0	23.0	33.5	33.0	31.0
% Increased Life Span	+41	+30	+17	+17	+10	+2	+45	+16	+13	+21	+21	+19	+18	+11
M	4.93[a]	4.93[a]					10.8	4.93[a]	4.93[b]			6.65		
Confidence Level, %	97	97					>>99	97	97			99		
(B) Longevity Index Data:														
No. mouse-survival days:														
Controls = m	653	653	653	653	653	653	647	647	647	647	647	842	842	842
Treated = n	271	245	241	229	221	220	270	215	238	242	227	336	316	306
Total = N	924	898	894	882	874	873	917	862	885	889	874	1178	1158	1148
N/2 = (m'+n')	462	449	447	441	437	436	458	431	442	444	437	589	578	574
m'	381	376	357	357	357	341	420	457	356	349	367	509	469	439
n'	81	73	90	84	80	95	34	74	86	95	70	80	110	135
Median Longevity Index, days: Controls	20	20	20	20	20	20	20	20	20	20	20	29	29	29
Treated	29	26	29	27	28	21	28	22	22	26	23	34	33	31
% Increased Longevity Index	+45	+30	+45	+35	+40	+5	+40	+10	+10	+30	+15	+17	+14	+6
M	63	56	20	21	22	5.1	77	77	24	14	44	129	101	5.46
Confidence Level (CL), %	>> 99	>>99	>> 99	>>99	>>99	97	>>99	>>99	>> 99	>>99	>> 99	>>99	>>99	98

* Omitting median death, as per Mack, p. 127.

[a] 4.93 = average of 6.53 and 3.33 (only latter value reported in the SRI-NCI Report).

[b] Reported as 6.53 in the SRI-NCI report.

Burk to Perry, March 22, 1974

Table 2. Experiments with Added beta-Glucosidase (NSC 128056). Analysis of various Single Groups (10 mice per group) and/or Combined Groups (20- 70 mice per group) of Established, Subcutaneously Implanted, Lewis Lung Tumors treated intraperitoneally with NSC B900540 (Amygdalin MF) and NSC 128056 (beta-Glucosidase) as compared with Untreated Controls, as carried out by the Southern Research Institute (SRI, Birmingham, Alabama) for the National Cancer Institute (NCI, Bethesda, Maryland), and as analyzed statistically by (A) the Mack- Lloyd Median Life Span (MLS) test and/or (B) the Burk-Lisanti Median Longevity (MLI) test, for those instances where the Confidence Level (CL) is $\geq$ 95% ($M \geq 3.84$), the %ILS (Percent Increased Life Span) and the %ILI (Percent Increased Longevity Index) are positive, and mouse toxicity is not clearly involved.

Set-up	Single Groups (10 mice per group)												Combined Groups (20-70 mice per group			
SRI Exp. No.	34				54					63			34		54	63
Implant Date	7-27-72				5-2-73					8-30-73						
Mouse Sex	Male				Male					Female						
SRI Cage No.	20	15	18	16	34	28	32	44	46	14	17	19	15,20	15,16	28,30,32,34	11-17
Mg 128056/kg QD7-15, i.p.	5	10	5	10	10	10	10	5	5	10	10	5	10,5	10	10	10
Mg B900540/kg QD7-15,i.p.	12.5	12.5	50	6.25	6.25	50	12.5	25	12.5	6.26	0.78	25	12.5	12.5, 6.25	50,25,12.5, 6.5	50,25,12.5, 6.25,3.13 1.57,0.78
(A) Life Span Data:																
No. mice: Controls = m	30	30	30	30	30	30	30	30	30	28#	28#	28#	30	30	30	28#
Treated = n	10	10	10	10	10	10	10	10	10	10	10	10	20	20	40	70
Total = N	40	40	40	40	40	40	40	40	40	38	38	38	50	50	70	98
N/2 = (m'+ n')	20	20	20	20	20	20	20	20	20	19	19	19	25	25	35	49
m'	20				19								20		20(21)	32
n'	0				1								5		15(14)	17
Median Life Span, days:																
Controls	19.5	19.5	19.5	19.5	19.0	19.0	19.0	19.0	19.0	28.0	28.0	28.0	19.5	19.5	19.0	28.0
Treated	25.5	29.5	22.0	21.5	28.0	22.5	23.5	21.0	21.0	33.0	33.0	31.5	26.5	24.0	23.0	31.0
% Increased Life Span	+30	+51	+12	+10	+47	+18	+23	+10	+10	+18	+18	+12	+33	+23	+21	+11
M	10.8				4.32*								6.7		12.6&	
Confidence Level (CL), %	>99				96								>99		>>99	
(B) Longevity Index Data:																
No. mouse-survival days:																
Controls = $\underline{m}$	653	653	653	653	647	647	647	647	647	842	842	842	653	653	647	842
Treated = $\underline{n}$	257	266	210	203	264	221	235	224	207	320	311	318	523	469	959	2044
Total = $\underline{N}$	910	919	863	856	911	868	882	871	854	1162	1153	1160	1176	1122	1606	2886
$\underline{N}/2 = (\underline{m}'+ \underline{n}')$	455	458	431	428	455	434	441	435	427	581	576	580	558	566	803	1443
$\underline{m}'$	381	409	343	347	392	370	356	350	345	497	471	443	381	370	372	452
$\underline{n}'$	74	49	88	81	63	64	85	85	82	84	105	136	207	191	431	991
Median Longevity Index, days: Controls	20	20	20	20	20	20	20	20	20	29	29	29	20	20	20	29
Treated	25	30	21	24	23	23	28	26	21	33	33	32	29	26	23	31
% Increased Longevity Index	+25	+50	+5	+20	+15	+15	+40	+30	+5	+14	+14	+10	+45	+30	+15	+7
M	63	144	15	8.3	99	51	29	16	10.3	318	43	8.4	40	59	24	6.2
Confidence Level (CL), %	>>99	>>99	>>99	>>99	>>99	>>99	>>99	>>99	>>99	>>99	>>99	>99	>>99	>>99	>>99	99

* Average of four solutions: 6.52, 3.33, 5.16, 2.28 (for m-n = 30-10, 30-10, 31-9, 31-9; m'-n' = 19-1, 18-2, 19-1, 18-2, resp.)
& Average of 14.3, 10.8, for m'-n' = 21-14, 20-15, resp.
# Omitting median death, as per Mack, p. 127.

Table 3. Analysis of various Combined Groups (20-60 mice per group) of Established, Subcutaneously Implanted Lewis Lung Cancers treated intraperitoneally with NSC B900540 (Amygdalin MF), as compared with Untreated Cancer Controls (ca. 30 mice per Control Group), as carried out by the Southern Research Institute (SRI, Birmingham, Alabama) for the National Cancer Institute (NCI, Bethesda, Maryland), and as analyzed statistically by (A) the Mack-Lloyd Median Life Span (MLS) test and/or (B) the Burk-Lisanti Median Longevity Index (MLI) test, for those instances where the Confidence Level is ≧ 95% (M ≧ 3.84), the %ILS (Percent Increased Life Span) and the %ILI (Percent Increased Longevity Index) are positive, and mouse toxicity is not clearly involved.

Set-up				
SRI Exp. No.	34	54	63	63
Implant Date	7-27-72	5-2-73	8-30-73	
Mouse Sex	Male	Male	Female	
BDF1 mouse animal farm source	Rawley	Southern	Southern	
SRI Exp. Cage No.	3-8	6,8,10,12,14,16	4,5,6,7,8	7,8
Dosages: Mg P900540/kg mouse, QD7-15 days, i.p.	400,200,100 50,25,12.5	200,100,50,25, 12.5,6.25	12.5,6.25,3.13, 1.57,0.78	1.56,0.78
(A) Life Span Data:				
No. mice: Controls = m	30	30*(31)	28*(29)	28*(29)
Treated = n	60	60	50	20
Total = N	90	90	78	48
N/2 = (m'+ n')	45	45	39	24
m'	20	21 or 20		19 18
n'	25	24 or 25		5 or 6
Median Life Span, days:				
Controls	19.5	19.0	28.0	28.0
Treated	25.0	22.	31.5	33.0
% Increased Life Span	+28	+16	+13	+18
M	4.05	4.48#		7.3&
Confidence Level (CL), %	96	97		>99
(B) Longevity Index Data:				
No. Mouse-survival days:				
Controls = m	653	647	842	842
Treated = n	1439	1403	1514	652
Total = N	2092	2050	2356	1494
N/2 = (m'+ n')	1046	1025	1178	747
m'	381	379	461	533
n'	665	646	717	214
Median Longevity Index, days				
Controls	20	20	29	29
Treated	29	23	32	32
% Increased Longevity Index, %	+45a	+15	+10	+14
M	25b	27	10	135
Confidence Level (CL), %	>>99c	>>99	>99	>>99

* Omitting median death, as per Mack, p. 127

\# Average of 4.92 and 4.05.

& Average of 7.92 and 6.65.

a,b,c: for Cages 2 through 9, %ILI = 30, M = 25, CL = >>99.

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(Life Spans)

Corrected Single Group (10 mice) M and Confidence Level Values. As indicated in Tables 1 and 2, (A) Sections, there are in fact 8, not 4, of the 71 single groups, that display life span M values $\geq$ 3.84 and CL values $\geq$ 95%, and, in my opinion all 8 are also biologically significant (vide infra). The 8 instead of 4 "statistically significant" single group values come about from giving due and proper consideration to cases where the merged group median value occurs on a day when death contributions may come from either the control or the treated group, both of which provide deaths on that day, but which group actually contributes the median death remains unascertained. This leaves two possible solutions (in instances even more) for m' and n' and thence of M, as illustrated Table 1, Exp. 34, Cages 8 and 7; Exp. 54, Cage 10; and Table 2, Exp. 54, Cage 34; so that a duly weighted average value of M must be calculated from the possible solutions. For the three first-cited cages, the SRI M value of 3.33 (C.L. = 93 %) thence becomes 4.93 (C.L. = 97%) by my calculation (not objected to by Dr. Lloyd), and last-cited case 4.32 (instead of the SRI value of 3.33). Actually, these are not really momentous numerical changes, but, if by the rules of the game set down, one is going to insist upon values of M $\geq$ 3.84 (C.L. $\geq$ 95%) then the matter becomes at least as important as in tennis where a ball landing within the line is "quite different" from one landing just outside the line. It is perhaps a little puzzling as to how and why the SRI Report chose the one solution for M = 3.33, where an average of more than one solution was called for, in the 4 new cases just given, but in one instance (Table 1, Exp. 54, Cage 8, they chose the solution M = 6.53, which was higher, not lower, than the averaged solution of M = 4.93 (average, again, of 6.53 and 3.33). Among the four new cases just given, %ILS was greater than 25% in three of the cases (30, 41, and 47%), so that among the total of 8 cases out of 71 there are now 5 cases where %ILS > 25% (the standard of biological significance proposed by SRI, c.f. Report, bottom of p. 3 and top of p. 3); as I have already indicated, I regard all 8 cases as biologically significant (vide infra). In any event, with 8 "statistically significant" single groups out of 71 (by the current rules of the game), of which 5 or 8 are also "biologically significant", only a person fitting Schiller's Law (footnote, last page) could now scientifically contend that "Amygdalin MF does not possess activity in the Lewis Lung carcinoma system." As we shall soon see, however, far more than the 80 mice in these 8 single groups bespeak Amygdalin MF activity against Lewis lung tumor.

(Life Spans)

Combined Groups (20-70 mice per combined group). In my experience with the data of Item H, it appears to me that groups containing only 10 Lewis lung tumor mice are definitely on the small side for wholly satisfactory calculations. Uncertainties can be largely overcome by appropriately combining several such groups into "combined" groups, as illustrated by Table 3 and the right side of Table 2, (A) sections. Although a goodly number of combinations can be made, I have proceeded to combine the longest runs, in any given experiment, where all %ILS values are positive: Table 3, Exp. 34, 60 mice, Exp. 54, 60 mice, and Exp. 63, 60 mice; Table 2, Exp. 34, 20 mice, Exp. 54, 40 mice, - a total of 180 mice - with each combined group to be compared to its respective control groups of ca. 30 mice each. Such a combined procedure is not only quite legitimate since all the component 10-mice groups have received Amygdalin MF (with or without beta-glucosidase), but it is not very material that the Amygdalin MF dosages varied in any combined group since were any variable dosages producing variable magnitudes of effect one would then be measuring some kind of average effect within any given combined group. In all of these comparisons Confidence Levels of 96% to >99% were found, with %ILS values of 28, 16, 18, 33 and 21 respectively, all of them being regarded by me (vide infra) as also biologically significant. In all columns of Tables 1-3, (A) sections, where no M values are given, M is less than 3.84 (C.L. <95%). The use of combined (aggregate) as well as single groups (arrays) is well illustrated in Item I, published 40 years ago (cf. footnote *, p. 4).

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Statistical Analysis by Median Longevity Index (Mouse-survival Days). I come now to what I regard as the most interesting and innovative way of looking at the "Death Pattern Data" reported in Item H, as well as very likely also, as indicated earlier, a great deal of similar type data obtained with many anticancer agents quite other than Amygdalin MF. Whereas in median life span analysis each mouse is given equal weight, whether at the bottom, top, or median or anywhere else in the ranking set up, nevertheless, the data in Item H tells us morethan that - much more than that! - and such added information should be utilized, and not discarded (as in the SRI-NCI Report). Obviously a mouse that dies at 30 days is factually and demonstrably different from a mouse that dies at 20 days, and the latter similarly from a mouse that dies at 10 days. Mathematically this situation can be described and utilized exactly by making a ranking according to mouse-survival days, respectively 30, 20, and 10 for the examples cited, and similarly for any and all other death-days, and then proceding with M calculations based on mouse-survival days (Longevity Index) in the same manner as has been done in terms of Life Span ((B) sections in the tables compared to (A) sections) but now with greatly increased values of $\underline{m}$, $\underline{n}$, $\underline{N}$, $\underline{m}'$, $\underline{n}'$ and $\underline{M}$ (underlined to distinguish them from m, n, N, m', n', and M). This Median Longevity Index analysis, as I term it, does not lose its nonparametric character, even though it adds in a certain aspect of distribution, because the distribution aspect added is given by the data itself and varies from array to array (or group to group), and so does not represent any imposed concept of normal (Gaussian) distribution such as ordinarily involved in the usual parametric analyses. Although Median Longevity Index analysis provides a weighting set by survival time, this weighting is absolute (given by the data itself), and not merely relative as would be case were the survival times multiplied by some coefficient such as 1/10, 1/2, 2, 10, etc., in which case the end results for M would turn out to be quite different; the relative weighting coincides with the absolute weighting only when the coefficient is unity. The concepts and working of the Median Longevity Index analysis have been developed in collaboration with Dr. Vincent Lisanti mentioned on p. 1 of this letter.

As seen in Tables 1, 2, and 3, an overwhelmingly large fraction of the "Amygdalin alone" data now show Confidence Levels above 99% with respect to efficacy against Lewis lung tumor, as does also a considerable fraction of the "Amygdalin plus beta-Glucosidase" data, whether single or combined groups are concerned. There is no particular kind of "magic" involved in attaining this result, but merely a making full use of the raw data itself by adequate, appropriate, statistical methodology, such as was not employed in the SRI-NCI Report, whose "rules of the game" were too restricted and indeed robot-like, notably so with respect to underlying biological consideration about to be discussed. It is evident that Median Longevity Index analysis has brought to light aspects of a larger differential positive efficacy of Amygdalin MF that remained hidden in the simpler Median Life Span Analyses, so fmras the experimental data of Item H, Exp. 34, 54, and 63 are concerned, in terms of Confidence Levels. As seen in Tables, 1, 2, and 3, the Percent Increased Longevity Indexes (%ILI) vary above and below the respective Percent Increased Life Spans, and calculation shows that they are on the average a little larger.

As adumbrated in the last paragraph of p. 2 of this letter, it would appear that what "any average grammar school science student could, any SRI-NCI scientist should, and any sufficiently experienced statistician would, be able to see at a glancellas to the widespread evidence of Arygdalin efficacy, is more than amply confirmed by the statistical analysis given in Tables 1, 2, and 3, or, to put it the other way around, here is a feather in the cap of statistical analysis.

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It is instructive to note in passing that the development in Tables 1,2,3 of the Longevity Index (mouse survival days) concept as distinguished from the simpler concept of Life Span (days) may be compared with the very recent, innovative development by J. L. Murray and L. M. Axtell (J. National Cancer Institute, 52, 3-7 (1974)) of the concept in human cancer statistics of person-years lost and/or work-years lost as distinguished from the simpler conventional measures of cancer incidence and/or prevalence. In both innovations, the values of duration of time for each individual(or group) measured (mouse or man, day or year) is combined with the conventional statistic to yield a more sensitive and more comprehensive utilization of data already at hand. Thus, in the Murray-Axtell concept, person-years lost were calculated by combining U.S. mortality data with life expectancy data for the same given group; and the work-years lost were calculated by multiplying cancer deaths per group by its corresponding number of years of life remaining (cf. Item J, Table 1).

In concluding this section on "Statistical Considerations" I may say that the foregoing text and pertinent attachments were sent at the request of Dr. Bernard Kenton (Division of Clinical Neurology, City of Hope National Medical Center, Duarte, California) for study by him and by Dr. Michael Fox (Chairman, Biomathematics Department, CHNMC, and also of the Biomathematics Department, UCLA, Los Angeles). They have authorized me to state that they regard the "Rank-sum" test (see, e.g., W.J.Dixon and F.J.Massey, Jr., Introduction to Statistical Analysis, McGraw-Hill, 1957, 2nd Ed., pp. 289-290 and Table A-20) as markedly superior, for the type of data involved in Items A and H, to the simpler median test as employed in the SRI Report, for various reasons that they detailed at length to me, but which need not be gone into here. They reported that the Rank-sum test (as I have also found and reported by my procedures) yields more of the experimental groups of 10 mice each with values corresponding to M $\geq$ 3.84 than the few reported by the SRI. Furthermore, the trend of their Rank-sum tests, so far as calculated, were in essential agreement with my results by the Longevity Index test, against which, however, they even so still preferred the Rank-sum test. Obviously, the SRI would be well-advised to make a careful evaluation of the Rank-sum test with reference to statistical situations heretofore and/or to come, where the simpler median test has been employed, with respect to a large number of anticancer results that SRI treats statistically year after year.

BIOLOGICAL CONSIDERATIONS

For reasons yet to be clarified, but scarcely inadvertent, Dr. Lloyd, in writing the SRI report, was never given a set of my biological critiques, set forth in Items K and L, which were written March 25 and 30, and June 19, 1973, and dispatched to various NCI and SRI offices, in response to the interim report of Dr. Saul Schepartz, March 19, 1973, regarding the by-then-completed Experiments 34 and 47. In my judgment, this important omission placed an unnecessary and undesirable burden on Dr. Lloyd's best-intended efforts, since the more a statistician can know about the underlying nature of his subject matter biologically, the better will ordinarily be his statistical deliberations and conclusions, as Dr. Lloyd has agreed.

Items K and L attached, written upwards of a year ago with respect to Exp. 34 and 47, went essentially unheeded in the conduct of subsequent Exp. 54 and 63, but apply with equal force to the latter, and need only be briefly recapitulated here, except where further new criticism must also be brought out.

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First, for a non-toxic, slow-acting agent like Amygdalin MF, the common or conventional treatment on days 7-15 post-inoculation only, employed with respect to cytotoxic, relatively rapidly-acting agents, is highly restrictive when one is looking for large percentage increases in life span with Amygdalin MF. Of course, if and when one is not so looking, then it is quite in order to have overlooked my earlier, clearly expressed suggestions that treatments be begun both near day zero and even say ten days pre-inoculation, and also be continued far past day 15 even until death, all especially in view of the nontoxicity of Amygdalin MF. Even so, as indicated in Tables 1, 2, 3 of this letter, widespread, statistically highly significant increases in life span (and Longevity Index) were in any event extensively observed in three of the four #34, 47, 54 and 63 Experiments with Amygdalin MF treatments alone, and to a lesser extent when the enzyme glucosidase was also added. The enzyme introduced, of course, as was to be expected from much previous experience, clear-cut toxicity aspects of a well-understood nature and a less controllable nature. I have performed many such added-enzyme experiments myself and am very familiar with the aspects of reduced reproducibility almost invariably observed. In fact, I am still not yet clear as to why any such one Amygdalin MF-glucosidase enzyme experiments were performed by SRI-NCI, since, for/thing, no such experimentation was proposed in the McNaughton Foundation FDA-IND application with respect to clinical studies. Indeed, the SRI-NCI studies involved more studies with glucosidase than without, so the obfuscation appears to be still further compounded. I would also point out that in the Dresden experiments carried out by P.G.Reitnauer Arch. Geschwulstforsch. 42, 135 (1973) with amygdalin supplied as bitter almonds fed ad libitum along with the chow diet, significant prolongation of survival time and inhibition of tumor growth of Ehrlich ascites carcinoma was observed, and the treatments were begun 15 days prior to tumor cell inoculation, and continued indefinitely until the end of the experiment, all along lines I proposed nearly a year ago with respect to SRI-NCI experimentation but there unheeded.

The SRI-NCI report very casually assumed that "biological significance" was definable as at least 25% increased life span, but this was based on earlier rule-of-thumb experience with cytotoxic, relatively rapidly-acting anticancer agents acting in a variety of animal species and tumor types. Even so, this rule-of-thumb scarcely applied, with predictive value, in such studies with the Lewis lung tumor. In a report by J.G.Mayo (SRI) dated April 10, 1973, he said, "The Lewis lung tumor is relatively insensitive to all the antimetabolites and most of the alkylating agents tested in our laboratories," cytoxan and nitroureas being the major exceptions(cf. also Item L, p. 2, last paragraph). The fact is, the assumed value of 25 ILS for biological significance is virtually without any basis of merit with respect to Lewis lung tumor, whether one is considering either the usual toxic agents or nontoxic Amygdalin MF. Indeed, with even 5 - 10% ILS (or ILI) given by Amygdalin MF in short-term mouse experiments (but with high statistical significance at the 95-99% level), this might well integrate out to notable efficacy effects when given to human beings over the long periods of time, as made possible by the nontoxicity of Amygdalin MF. In any event, as indicated in Tables 1, 2, 3 of this letter, a goodly number of ILS (and ILI) values above 25% (up to 50%) were indeed observed, at Confidence Levels of 95-99%. And, had the experiments been better designed, along lines I have indicated in Items K and L, to seek out and maximize conditions of efficacy, I can readily conceive of ILS and ILI values well above 100% being obtained, even in mice.

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Technically, the animal testing carried on by the SRI appears to have been brought, from long experience, to a state of near-perfection, and so it is ironic that in design it is not well oriented in the direction of attempting to maximize efficacy. This probably comes about from its rigidly applied overstandardization into "programmed testing" as distinguished from "unprogrammed research," all leading inexorably to "robot unthinking", and inbred satisfaction therewith, under complacent administrative direction and control, if not at SRI then at NCI, - it comes to the same.

It is often stated that a difficulty with the Lewis lung tumor (as distinguished from say L1210) is that the median life spans in untreated control groups vary so greatly as to make anticancer agent testing itself also unduly variable. To my way of thinking, already partly expressed in Item K, such variability has its advantages, by permitting one to work at different regions of length of median life span, e.g., short, medium, long. Thus, it will be noted in Tables 1, 2, 3 of this letter that in general the greatest Amygdalin MF efficacy was observed in Exp. 34 and 54 with short median life spans of 19.5 - 19.0 days, with notable reduction in efficacy in Exp. 63 (median life span, 28 days), and no efficacy in Exp. 47 (median life span, 30 days). Now, such variability in control (untreated) median life spans is by no means purely fortuitous, but can readily be controlled to a marked degree by e.g., size of tumor cell inoculum - the shorter spans being obtained with increasingly large cell cell number inocula, as beautifully demonstrated by J.G. Mayo (SRI) in a report he sent me on July 6, 1973. For an agent like Amygdalin MF, it may be important for high efficacy (high %ILS) not to employ controls with long median life spans (as in Exp. 47), but instead to use controls with median life spans as short as possible, even less than 19 days, but this was a potential lead not intentionally followed up in the SRI-NCI experimentation. Another difference between Exp. 34 and 54 compared to Exp. 63 and 47, in addition to difference in median life span, was that the animals in the former pair were males and in the latter pair females, and conceivably this may have also contributed to the corresponding observed greater efficacy in the former pair.

A blatant biological error still persisting unabated in the SRI-NCI Report - in spite of my admonitions and warnings to the contrary in Items K and L and elsewhere - is the peculiar belief or attitude adopted in the Report that positive experiments can be negated, or can be made to appear to be negated, by negative experiments. Thus, Dr. Schepartz (Item A, p. ii)categorically dismissed to oblivion, on the enigmatic ground of "total experience", even the two to four experiments (out of "71") clearly identified as positive by the very writer of the SRI Report. The scientific basis for this remarkably gratuitous conclusion, apparently drawn from thin air, totally escapes me, and at best remains hidden within this enigmatic concept of "total experience", which in this instance might more accurately be called "untotal experience." I have provided several simple analogies to illustrate the absurdity of this ethereal concept, as e.g., on p. 4 of this letter, paragraph 2 (the Halley's Comet analogy), Item K, p. 3, paragraph 2 (the Drake-Magellan analogy), and Item L, p. 3, paragraph 3 (the fishing schoolboy analogy), all readily comprehensible at grade school level and above.

And, as I see it, although "no further experiments are contemplated at this time," (Schepartz, Item A, p. ii), in fact, innovative original research on maximizing Amygdalin MF efficacy is in a sense only now ready for commencement, using as a basis

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the rigid, standardized SRI testing already accomplished, a host of general Lewis lung tumor background data reported in the past year by J. G. Mayo (SRI), and various suggestions that I have made here and in Items K and L. The conduct of such research is, of course, administratively quite out of my hands, and is conceivably beyond the research capabilities of DR&D, DCT, NCI, to judge from their past performance. Perhaps indeed, there is already a reasonable adequacy of undeniably positive animal experimentation with amygdalin in now at least five, widely distributed, recognized laboratories: (1) Scind (San Francisco), (2) Sloan-Kettering (New York), (3) Pasteur Institute (Paris), (4) Forschungsinstitut Manfred von Ardenne (Dresden), and, of course (5) SRI Birmingham), - adequacy at least in terms of e.g., FDA-IND requirements.

Obviously space does not permit detailing all such positive results here, but Item M presents a brief summary taken from the now widely-publicized Sloan-Kettering results, which are of especial interest because they were carried out with spontaneous mouse mammary adenocarcinomas, and involved metastasizing as well as primary cancers. A second series of such experiments, carried out with a widely different source of amygdalin (from Germany, not Mexico) was essentially negative, and a third repeat series with both amygdalin source materials being run simultaneously is now underway. Amygdalin sources vary as to content of pyrogenic endotoxin content, extent of optical racemization, etc., any of which factors might be partly involved in differential results observed, but it is to be hoped that the scientifically absurd, conceivably malicious principle of "total experience" will not be allowed to becloud the issues and conclusions to below-grade-school levels of analysis.

Thus, some two months ago, "inspired" daily press reports over the country reported that there was no evidence at Sloan Kettering that Laetrile (amygdalin) had any beneficial effect against cancer (Item M notwithstanding!). This statement has since been denied by top Sloan Kettering officials, including President Lewis Thomas, who in the February 1974 issue of the American Druggist Magazine, Section on Telepharmedics, is reported there as saying, "Preliminary studies at Memorial Sloan Kettering Cancer Center, NYC, show it may indeed have anticancer properties." On February 5, Mr. Mike Wallace told me that on February 1 Director Robert Good used to h words to the same effect, as did similarly another top Sloan Kettering official to me on March 4, so the principle of "total experience" does not yet seem to have infected such informational sources as it clearly has within the NCI.

POLITICO-MORAL CONSIDERATIONS

I have already testified at some length in Congressional Hearings as to the unrestrained propensity of certain top officials or spokesmen of HEW, NCI, FDA, AMA, and ACS to tell lies (deceptions, red herrings, obfuscations...) about Amygdalin MF-Laetrile. The following page reports some of my testimony as it appeared on pp. 705-7 of the Hearings before the Subcommittee on Public Health and Environment of the Committee on Insterstate and Foreign Commerce, House of Representatives, 92nd Congress 1st Session, Serial No. 92-41, on H.R. 8343, H.R. 10681, S. 1828, leading on to the National Cancer Attack Act of 1971 - my testimony having been given on October 7, 1971 I would now add here that I regard the above-referred to unrestrained propensity as highly Watergatean, and that something ought to be done about it! More recent detailing of NCI Watergatean activities with respect to amygdalin is reported in Item L.

Mr. SYMINGTON. This interests me for a number of reasons.

One, it illuminates an area we haven't much covered and that is the relationship between the NIH and FDA and specifically NCI and FDA.

For example, after this rebuff from FDA, what prevented you from going higher in your own organization and saying, "Now look, this might be effective against cancer. These fellows have rejected an experiment and conclusion which proves that Laetrile is less damaging than sugar and that we cannot allow this conclusion to stand, we must proceed with further testing," and why could you not then pit the mighty against the FDA and get done what you as a scientist want to see done and have a duty to see that it is done?

Dr. BURK. The answer I think is fairly plain. They are all of the same bureaucracy, where the first rule is all stick together. They are like cogs and wheels, and wheels within wheels in a clock, the winding up of which is done by outside medical bureaucracies, who give orders.

Mr. SYMINGTON. Your superiors?

Dr. BURK. Yes, administrative—though not scientific—superiors, acting along with part of the AMA, American Cancer Society, and FDA. I will name them if you like; Dr. Carl Baker, Dr. Kenneth Endicott, formerly in Dr. Baker's position, Surgeon General Dr. Jesse Steinfeld, Director of NIH Robert Marston, and now Secretary of Health, Education, and Welfare Elliot Richardson. It is easier for them to stick together, than to be upright and forthright as individuals.

Mr. SYMINGTON. Would you give the title?

Dr. BURK. Yes, Dr. Baker is now the Director of the National Cancer Institute.

Mr. SYMINGTON. Was he then?

Dr. BURK. Part of the time, yes. And before him was Dr. Kenneth Endicott, and then, of course, Dr. Jesse Steinfeld has been Surgeon General for 2 or 3 years. I regard the latter as the ring-leader of the anti-Laetriliters in the United States although one of the least scientifically informed on the matter, any protestations to the contrary notwithstanding, as I have specifically delineated in my letter of March 23, 1971, to Secretary Richardson; copy of which letter will be provided you.[1]

All of these gentlemen have written letters essentially at the untruth level of the FDA. All of them have told literal lies along with innumerable red herrings. I mean documentable lies, such as I will submit to you in exampled documented detail in due course.[1]

Mr. SYMINGTON. All of the gentlemen you just mentioned?

Dr. BURK. Yes, all of them without exception.

Mr. SYMINGTON. Wittingly have told a lie?

Dr. BURK. Yes, a lie is deliberate.

Mr. SYMINGTON. Why would they do such a thing, do you suppose?

Dr. BURK. I have been asked that by many lay persons and physicians. The above named persons don't want Laetrile or any similar nontoxic drug to even be tested, officially or unofficially, at the clinical level. As documentable facts show, they have been willing to stop such testing at virtually any and all costs, including prevarication and a variety of subtle inequities.

Mr. SYMINGTON. Why would they want to stop something? When they are looking forward to a half billion dollars to search for an unknown thing, why would they refuse to take something that is there that would work, if indeed it would?

Dr. BURK. For a number of reasons, the most innocuous of which is their previous training.

Mr. SYMINGTON. Taught them to reject a cure?

Dr. BURK. Let us not put it quite that way. Let us say that it has restricted their outlook in that particular direction.

Mr. SYMINGTON. To the point of mendacity?

Dr. BURK. Yes, if you mean by that financial——

Mr. SYMINGTON. No, that is "mendicancy." I mean to the point of lying about it.

Dr. BURK. Yes, I have declared so in print and it has been printed many times that Commissioner Edwards deliberately so lied before the Fountain Committee on June 9, 1970, and a vast number of people have read of this, and the FDA congressional liaison officer, M. J. Ryan, and others have continued unabated to promulgate such untruth.

I am now writing a letter to Secretary Richardson in which I make the same charge to and about him regarding his letter of August 26, 1971, to Chairman Fountain. I will submit a copy of my letter to Secretary Richardson along with my corrected verbal testimony, which would be included here or as a concluding formal statement.

(See letter dated October 19, 1971, p. 714, this hearing.)

Mr. SYMINGTON. That would include Secretary Richardson as well?

Dr. BURK. It does now because he repeated many of the same lies—prevarications, mendacities, call them what you will—and red herrings.

Mr. SYMINGTON. It is a good thing the President has not mentioned it.

Dr. BURK. I would hope that the President has more important things to do than lie about Laetrile. Now, at FDA-Richardson level, they are not worried too much about what Congress would do about such lies. On the other hand, people that are down below FDA-Richardson level would probably innocently assume, as even you have scarcely raised your eyebrows about, that this administrative level would not lie, so it would seem a usually pretty safe thing for powers that have power to lie from time to time.

The only trouble with it is that is that if some other power takes enough exception, then trouble can develop. I do not think I am telling you anything that you could not have told me 40 years ago.

Mr. SYMINGTON. In my case, about 20 years ago.

Dr. BURK. Well, then, your father.

[1] The material referred to was transmitted to the committee by letter dated Oct. 20, 1971, and may be found in the committee files.

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Dr. Seymour Perry - 12

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When Mr. Mike Wallace, with a staff of six, interviewed me on Feb. 5, 1974, with TV cameras and tape recorders, for material of possible use in his proposed CBS program "60 Minutes" about Laetrile, scheduled for perhaps sometime this March or April, it became clear in a some two-hour struggle between us that although Mr. Wallace is almost universally regarded as a Toughey, he does appear to have a soft underbelly (I do not say Achilles Heel) in the form of a passionately expressed regard for the media Sacred Cows of not only Love, Motherhood and Country but also of the Medical Establishment with respect to its honesty, morals, truthfulness, and nobility of motivation, - what he called their "essential goodness." Mr. Wallace said, "Look, Dr. Burk, you're a scientist, your Bona Fides are immaculate everyone agrees, no one questions your motives, surely you will agree that AMA, FDA, NCI, ACS officials are public-spirited, decently motivated human beings, -they would like a control for cancer every bit as much as Dean Burk?" My answer: "I would hope so..... but after noting for years their actions re Laetrile, I don't think so. I cannot adequately explain this to you in a few minutes, but I could show you plenty of documentation, which I shall do when I have finished replying to the very document you hold in your hand - the SRI-NCI Report. I do not class lying as coming under the heading of decent motivation."

Mr. Wallace went on, "I can't believe that a man attracted to scientific pursuits - even as a spokesman for scientific pursuits - can be manipulated to keep something life-giving off the market in the interest of fear, money, establishment...Besides money, what else might persuade these spokesmen, if not acting in a conspiracy, to act in concert to lie about Laetrile?" My answer: None of these spokesmen have worked with Laetrile, personally, with their own hands;even without planned conspiracy, but as members of a tightly interlocked bureaucracy, all feel that they must support each other, quite as the whole world has now seen among top White House staff, with and/or without conspiracy."

Mr. Wallace then ventured upon another alternative: "Pride, ambition, jealousy" - all those things that are part of human nature. But the explanation goes beyond Homo sapiens, right up to canine levels. I asked, "Why should Aesop's dog in the manger worry about other dogs sleeping in the same hay, or other cows eating it? .....If you you will tell me what that dog is thinking, I will tell you why certain Medical Establishment spokesmenoften do as they do about Laetrile. You are looking for logical reasoning, but I would stress the unreasoningness of the dog, giving rise to a blind fear of the unknown." - Not unlike the unreasoned blind fear of a non-toxic compound like Laetrile, leading on to the standard Spokesman* red herring that "maybe not toxic per se, but by preventing a cancer patient from first seeking out proven remedies" (the last two words with citation marks innocently omitted). I am still attempting to find such a patient in real life, but no Spokesman* has ever presented me with one, or, better, five or ten, even though, by way of encouragement and as a sporting proposition, offered real wampum to do so.

*Such Spokesmen can reach way down into their Bureaucracies in Lock-Step. Thus, on September 21, 1972, an otherwise highly experienced worker in the NCI Public Information and News Branch echoed the Spokesmen line to perfection, telling me, "All of this publicity on behalf of Laetrile is causing a lot of cancer patients not to have operations and the kind of treatment that might be of some help to them... one out of 20 or one out of 10 go to Mexico. We get about 20,000 public inquiries here a year in

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in this office. I would say about a fifth or a sixth of them might concern Laetrile. There are four ladies who work here full time answering written and telephonic inquiries, and they probably could document many, many if we wanted to." My answer: "I doubt it, I doubt one, let alone five or ten even."So far I have not had one authentic single case reported to me, with or without wampum. On checking the one and only one alleged case ventured to me by the aforementioned otherwise highly experienced worker, I found that the patient had indeed had a breast operation here in Washington before going to Mexico for Laetrile treatment, and since then has been having regular check-ups at George Washington Medical Center with no overt sign of cancer disease.

Mr. Wallace's Experiment Toward the end of our interview I said, "O.K., Mr. Unsophisticate Wallace" (an appellation he took with infinitely good-natured grace -without so much as a tremor on the part of his Adam's apple),"I propose to let you see with your own eyes a representative instance of Establishment Bureaucracy pursuing its chicanery. Let one such instance be as convincing to you as any number of vicarious documentations. The experiment is this: tomorrow, when you go to interview NCI Director Rauscher make it quite plain to him that you are well aware of the fact one of his long-time scientific staff has found many gross errors of omission and commission of fact and conclusion in this SRI-NCI that now lies between us on this table and which you brought here; also that I so informed Dr. Seymour Perry on January 7 and again on February 4, and suggested that he take steps to so inform his "uppers," promptly. The experimental test will consist in what the NCI does about the situation: Will they immediately investigate, or let matters slowly take their course while NCI continues to hand out copies of the Report all over the country, fallacious though it may be. Still sceptical, but ever so slightly shaken, Mr. Unsophisticate agreed to carry out the experiment. Now let us look at the result:

As is clearly evident from Item B, pp. 1,2, Dr. Robert M. Hadsell, Office of Cancer Communications, NCI, continued to send out copies of the SRI-NCI Report, on Feb. 12, 1974 to the Editor of the Berkeley Daily Gazette, and on Feb. 22 to the President of the York Foundation for Scientific Research in Ontario, Canada, in both instances restating with respect to Laetrile that "all testing by NCI has found no evidence of activity against cancer" (underlining added). On Feb. 15 I asked Dr. Hadsell if he were still handing out copies of the Report (Answer:"Yes"), and "Had he received any word from either Dr. Rauscher's office or Dr. Seymour Perry to the contrary?" (Answer:"No,is there some sort of problem?"). My answer: "Well, it will be for the NCI, not for me. My analysis of the data is that it is overwhelmingly positive. So you have got a moral problem on your hands." Dr. Hadsell wanted written documentation, so on Feb. 19 I sent him copies of my Tables 1,2,3 in essentially final form. On Feb. 22 Dr. Hadsell told President Spivak of the York Foundation for Scientific Research, "There isn't anything that to our scientists (italics added) makes it look likethere is any basis for any kind of indication of (Laetrile) activity." Evidently, Dr. Hadsell has an awfully short memory or attention span, or he really does have a moral problem on his hands. In any event, it would appear that he has no intention of changing his course, short of earthquakean developments. One may perhaps be pardoned for wondering whether Dr. Hadsell has ever heard of Watergate, or watched it on television, and, if so, with what degree of equanimity?

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Dr. Seymour Perry - 14

I have presented in this letter essentially all data needed for any independently thinking observer to make a choice between my conclusions and those of SRI-NCI as to observed efficacy of Amygdalin MF against Lewis lung tumors, for such data as have now been reported. Assuming that I am essentially correct, the question arises as to how SRI-NCI may have arrived at their incorrect conclusions and sent them unrestrainedly over the country and elsewhere. I believe there are two aspects: (1) irresponsible, buck-passing bureaucratic methods with far too many cooks but no master cook, and (2) deliberate, upper NCI administrative attempts to mislead a variety of outside forces, some of which virtually wallowed in being mislead and misleading still others (e.g., Items F, G, D).

As for (1), it is clear that at the SRI level, no complaints can be levelled at the excellent test and scientific work of J. G. Mayo; nor at the sincere even if incomplete efforts of statistician Harris Lloyd, who told me on Dec. 27, 1973, "I was primarily concerned with the analysis of the data. I did not get involved in the design of these experiments or their biology and their politics." It is still not clear why Dr. Lloyd was, administratively, not given copies of Items K and L before he began his analyses; nor why, among planners and designers of the second half of the test work (Exp. 54, 63) no attention was paid to Items K and L; nor why, in sending out the SRI-NCI Report the essential data of Item H was not also presented, without which adequat independent analysis and checking of the data was impossible, and, therefore, conclusions likewise. Although Dr. Schepartz and Mr. Greenberg promptly provided me with such information upon my request, alas, when I asked elementary questions about the statistical procedures of Dr. Lloyd I was informed that that was beyond their ken and scope. So we see, that at this level, began a breaking in the chain of truth: who administratively above Dr. Schepartz could step in and fill needed understanding - where was the master cook? And how often is this master cook missing likewise in a host of other agents tested besides Amygdalin MF?

As for (2), Items B-G are illustrative of moral problems still not solved by Dr. Hadsell, upper NCI administrators, FDA, Mayo Clinic and some of the press, etc. I believe that such solutions can only be achieved when each and every individual involved in a chain, bureaucratic or otherwise, morally puts the truth above all other considerations, and personally sees to it that it is not shattered, as in Items B-G, in short; to follow some of the precepts set forth by Senator Mark Hatfield on the next and concluding page. And I trust that Mr. Mike Unsophisticate Wallace will soon shed his new middle nam

Sincerely,

Dean

Dean Burk, PhD, Head Cytochemistry Section, NCI

Copies to:
Consultants listed on p. 1, paragraph 2, and p. 7, paragraph 2, of this letter; various staff members of the NCI, SRI, SKI, Mayo Clinic; various public cancer agencies; various interested members of the fourth estate, national electorate, legal profession, laity, et

Disclaimer: The above views of the oversigned research scientist may differ materially from those of certain administrators within the HEW and NCI, and no such latter official support or endorsement is intended or should be inferred.

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Room 4E-16, Building 37,
National Cancer Institute,
Bethesda, Maryland 20014.
October 19, 1971.

Honorable Elliot L. Richardson,
Secretary, Department of Health,
Education, and Welfare,
330 Independence Avenue, S.W.,
Washington, D.C. 20201.

Dear Mr. Secretary:

I have found upon my return from a trip to Europe a letter dated August 27, 1971, from Special Assistant to the Secretary, Mr. Donald T. Bliss, Jr., with the courtesy of enclosures: (1) a copy of your letter of August 26, 1971 to Chairman Fountain on Laetrile, (2) a copy of the report of the FDA Ad Hoc Committee of Oncology Consultants, and (3) an advance copy of the FDA news release on the Committee's findings, - all sent to me in reply to my earlier letter to you of March 23, 1971 herewith attached for ready reference.

I feel it my duty to submit to you a reply for the record, with at this time a partial analysis of the three aforementioned enclosures received from Mr. Bliss. This duty derives from the Congressional Code of Ethics as set forth in Appendix H, HEW Standards of Conduct, Form 539, September, 1970, which states that "Any Person in Government Service should:"

"Put loyalty to the highest moral principles and to country above loyalty to persons, party, or Government Department."
"Expose corruption wherever discovered."

I discharge this duty on the basis of over 42 years of scientific research as a civil servant in the Federal Service, and as one who knows more about Laetrile than anyone in the Department or in the Federal Service generally.

Re: <u>Your letter to Chairman Fountain</u>

Mr. Secretary, in my opinion, your letter to Chairman Fountain contains deliberate, objectively demonstrable lies, deliberate and highly misleading less-than-half-truths, and deliberate avoidance of whole truths essential to adequate understanding, - all amounting to "corruption" in the sense of the foregoing Code of Ethics. I use the word "deliberate" in view of your claim of "careful and thorough review" and Mr. Bliss's claim of "complete and thorough examination," and in view of the statement of Dr. Merlin K. Duval, Assistant Secretary

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for Health and Scientific Affairs on October 1, 1971 that "Both the Secretary and I personally reviewed the findings and recommendations.."

Further in my opinion, your letter to Chairman Fountain fails to answer adequately in good moral faith, and with due scientific and medical attention, the numerous deeply concerned letters written to you and the FDA by more than a score of US Senators and Congressmen, and by thousands of American laity and physicians, copies of a good many of which letters I have in my own files.

In what follows I shall only briefly resketch the basis of the immediately foregoing charges, for such basis is already largely documented in my attached letter to you of March 23, together with the over 100 pages of attachments submitted to you along with this letter.

Your letter of August 26 to Chairman Fountain ignores or fails to answer virtually all of the material submitted to you by me. Such failure and ignoring is remarkable in view of your statement, "I also know the dedication, sincerity, and integrity of those within this Department concerned with cancer research and the evaluation of anti-cancer agents. These officials possess extensive experience in these areas, and <u>have my complete confidence</u>" (italics added).

Clearly, there is one important exception to the last (underlined) phrase of yours: you have chosen to ignore the views and recommendations of the longest-in-civil-service scientist currently on the staff of the National Cancer Institute - a scientist possessed of over 40 years of experience in cancer research and study of anti-cancer agents, with extensive national and international recognition and honors, including the Gerhard Domagk Award for Cancer Research, the Hillebrand Award of the American Chemical Society, and Commander Knighthood in the Medical Order of Bethlehem (Rome). Out of over 200,000,000 Americans, he is one of the only 6000 Americans listed in the current issue of the Marquis "Who's Who in the World"(1971-1972), which cannot be said of any of the members of the FDA Ad Hoc Committee of Oncology Consultants, nor indeed of any of the 34 NIH Institute, Board and Division Directors, with the single exception of the overall NIH Director, Dr. Robert O. Marston. I recapitulate some of the Curriculum Vitae data on the undersigned,-even though it has already been detailed to you, -not for any immediately personal reasons, but for the reassurance of thousands of persons who will also have an opportunity to read this letter to you, including members of the Rogers Subcommittee on H.R. 10601, before whom I gave some 34 recorded pages of verbal testimony, Oct. 7

The 4th paragraph of your letter to Chairman Fountain perpetuates the series of lies and red herrings first promulgated by FDA Commissioner Charles C. Edwards before the Fountain Committee on June 9, 1970, and since repeated hundreds of times by FDA Congressional Liaison Officer M. J. Ryan, concerning the early history of the submission of FDA-IND-6734 by the McNaughton Foundation of California on April 6, 1970, FDA replies on April 20, 27,28, 1971, and FDA termination letter of May 12, 1971. Statements have been made or implied by you and the FDA that the FDA

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notification letter of April 20 to the McNaughton Foundation, signed by FDA Dr. Earl L. Meyers, Director, Division of Oncology and Radiopharmaceuticals, Office of New Drugs, Bureau of Drugs, and assigning the FDA-IND No. 6734, was for routine acknowledgement purposes only, and not for permission to the Foundation to proceed with clinical studies. Yet Dr. Meyers's letter (herewith attached) clearly states in unmistakable language: "As sponsor of the clinical study proposed in this exemption, you are now free to obtain supplies of the investigational drug and to initiate clinical studies" (italics added).

Further in your 4th paragraph you state the following less-than-half truth, "The Foundation was invited to submit additional data within ten days (italics added) and, when it failed to do so, the IND exemption was terminated by FDA on May 12, 1970." The fact is, in his letter of April 28, Dr. Henry E. Simmons, Director, Bureau of Drugs, stated in his last paragraph as follows: "You are invited to provide the data necessary to correct the above inadequacies within 10 days of the receipt of this letter. Otherwise the exemption may be terminated." You omitted the all-important "of the receipt of this letter." (All italics added).

The letter of Dr. Simmons was received by the McNaughton Foundation in Sausalito, California on the morning of May 6, 1970, a not unreasonable period for mail delivery, since the FDA's own mail register system indicates similar periods for the receipt of communications sent by the McNaughton Foundation from Sausalito, California to Rockville, Maryland. On May 9, 1970, three days after receipt of the letter from Dr. Simmons, the McNaughton Foundation mailed an initial response to the a leged deficiencies in which was stated,"...with the possible exception of the material from Dr. Burk mentioned above, we expect to have all of the requested material in the mail to you prior to the expiration of the 10 day period indicated in the final paragraph of your letter." On May 15, nine days after receipt of the Simmons letter, the McNaughton Foundation sent the FDA a completed response to the deficiencies outlined in the Simmons letter. This was within the 10 day period allowed and included the information supplied by"Dr. Burk"of the National Cancer Institute. The records of the FDA indicate that the McNaughton letter of May 9 was received by the FDA on May 13. Nevertheless, the FDA, over signature of Commissioner Edwards, terminated the exemption of IND-6734 on May 12, just 6 days after receipt of the Simmons letter by the McNaughton Foundation.

As I indicated in a letter to Commissioner Edwards, July 7, 1970, the granting of but 10 days, even after receipt of request, to prepare data requiring some 50 pages for description would appear to call for some explanatior I have consulted a former high official of the FDA who recently retired after some 30 years of service in the FDA, and he informs me that he cannot recall an instance of any such proposed short 10 days for reply. On October 1, 1970 Dr. Meyers was unable to find in his FDA manual devoted to termination notices any specification of but 10 days. As a former director of public

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education in the national office of the American Cancer Society, has stated," on the basis of my reading of a considerable collection of documents concerning the status of Laetrile, I am concerned by the curious devices bordering on quackery being used to dodge and discredit the effort to induce FDA to proceed with its IND-6734 and facilitate the testing of of Laetrile. A reading of the text of FDA's letter of April 20, 1970 certainly indicates permission to proceed with clinical studies, and its strange follow-up raises legitimate suspicions. ...At a time when the President, members of Congress, and the American Cancer Society are projecting a billion dollar research drive, why run the risk of a credibility gap by opposing a test of Laetrile by recourse to confusing and careless communications to the public?"

Mr. Secretary, the foregoing exampled iniquities of FDA re Laetrile have increased enormously since April-May 1970 as cited. The "offence is rank, it smells to heaven," and now continues so in your hands, those of a Cabinet member. A case built on lies and red herrings, whatever else, is a weak case indeed. The 7th paragraph of your letter to Chairman Fountain is an excellent example of deviousness, misdirected information, and ignoring of the essential truth involved, which I have already pointed out to you clearly and in great detail on pp. 3-7 of my letter of Feb. 23, 1971 to Congressman Edwin E. Edwards, to which I may again refer you. I will content myself here with a few quotations from this letter, for the benefit of readers other than yourself who will not have seen my letter to Congressman Edwards:

"As to the <u>efficacy</u> of laetrile against animal cancers, I know of no repitition by the NCI-CCNSC of the McNaughton Foundation-FDA-IND-6734-Scind Laboratory data reporting a clear-cut anticancer efficacy of laetrile in <u>rats</u> bearing Walker 256 carcinoma, and therefore of no conflict with this data by any NCI data. ...This Scind Laboratory report was first submitted to the FDA in November 1968, and then again, at FDA request, in connection with the amended 6734 application (pp. 00063-00113) submitted October 31, 1970."

"Concerning NCI-CCNSC studies on laetrile, Dr. Saul Schepartz, Chief, NCI-CCNSC, stated over the telephone on Dec. 15, 1970 that the CCNSC studies involved no work with laetrile on <u>rats</u>, but were limited to L1210 <u>mouse</u> leukemia (apart from the miniscule work with two other mouse tumors of 11 years ago, Attachment XIV)."

"Dr. Schepartz kindly gave me a table (Attachment XV) showing the relative rankings of clinically active drugs in humans with respect to their activities in various rat and mouse tumors. ...although BCNU ranked first against L1210 mouse leukemia, it ranked but 20th with mouse CA-755;...ARA C ranked 5th against L1210 mouse leukemia but ranked 28th with rat Walker tumor; ... and chlorambucil ranked 27th against L1210 mouse leukemia, but it ranked 5th with mouse CA-755 (etc.)."

"In spite of the wide variations in tumor response, for any one clinically active drug against a variety of rat and mouse tumors, or for any one tumor against the 28 listed clinically active drugs, it will be seen that the majority of responses range between 60 and 100%, with a grand average of

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perhaps about 80%. This value would appear to be a quite acceptable value of drug effect in animals, from the NCI-CCNSC data in Attachment XV. This is about the same value as shown by laetrile (McNaughton-MF) in the optimized concentrations reported in the Scind Laboratory data!"

"The variations indicated in Attachment XV as between mice and mice, rats and rats, and mice and rats, raise considerable question as to the absolute merits of animal efficacy experimentation as guides for drug behavior in humans, about which there will of course be wide variation of human opinions. How much must we demand and expect from drug testing for efficacy (as distinguished from drug safety) in animal tumor models, before agents may be tested in man? This is not an academic question posed only by researchers far removed from the scene of human suffering caused by cancer; the question is being asked by more and more laymen and physicians, in and out of chemotherapy circles. The public, and their representatives in Congress, must also be made aware of this problem which affects us all so vitally. As Dr. Michael B. Shimkin has stated (USPHS Pub. # 1162, revised 1969, p. 136), "It would be too much to ask that any one, or a few, types of cancers in animals would have the same responses as the hundred-odd different types of cancer in man." And, as Drs. James Holland and Charles Heidelberger say (Cancer Research, 20, 975, 1960), "the convenience of these (animal) tumors as research tools tends to obscure the need for cancer research in man." This is particularly pertinent with respect to those drugs for which substantial human data already happen to exist as to both safety and anticancer efficacy."

Mr. Secretary, I repeat, in light of the above, that the essential, pertinent data with respect to the McNaughton IND-6734 concerns the positive efficacy data obtained with Walker 256 carcinoma in rats, to which you do not specifically refer but rather obviously avoid consideration of. The negative data obtained with L1210 leukemia and laetrile, to which you do refer, are here irrelevant and immaterial, and were long since reported to the FDA by the McNaughton Foundation and were carried out before, not after, the related work of the NCI-CCNSC; in short, the latter "duplicated" the former, not vice versa as one would would infer from your description. There is, in fact,"confirmation" not"dispute" regarding the particular negative L1210 mouse leukemia studies with laetrile; despite that "NCI-CCNSC did not actually repeat the Scind (McNaughton) experiments verbatim, nor so far as was within their possibility to do so. They used a different form of laetrile (Aldrich Chemical Company amygdalin) instead of obtaining the chemically different form of McNaughton-MF amygdalin " which they could have done. Quite obviously they avoided repitition of the Scind rat experiments, which, incidentally,were performed by a "recognized independent laboratory" in the University of San Francisco. I charge you with having avoided the real issue, here in your paragraph 7.

In paragraph 7 you also state "The Institute does stand ready, however, to entertain an application for grant support from any qualified independent investigator or institution proposing additional animal studies with laetrile." (italic added). Without wishing to sound ungracious, I personally find this gesture rather hollow, since the same would be true of

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almost any compound or material that was clearly not absurd, to the extent of merely entertaining as distinguished from actuating a definite grant: in short, not much of an offer.

Mr. Secretary, unless you are hiding behind some subtle form of semantics, your statement in paragraph 6 of your letter, "Despite claims advanced of the successful use of Laetrile in treating human cancer, repeated requests to the McNaughton Foundation to provide patient case histories or other clinical records in support of these claims have been nonproductive," is untrue. Pages 268-371 and 00007-00130 - a total of 226 pages! - in the IND-6734 application submitted cannot be dismissed so glibly out-of-hand as "nonproductive," or indeed as nonindicative or totally valueless, as numbers of physicians (M.D.'s) have informed me, regardless of what your consultants may have felt called upon to say. Patient case histories and other clinical records vary enormously in extent, quality, and detail in the hands of various physicians, and are seldom if ever perfect or near perfect.

As you should well know, the granting of FDA permission for Phase I studies of and IND has no absolute or invariable requirement for any clinical studies at all, although the sponsor is requested to supply any type of such indication that he may possess, which the McNaughton Foundation has complied with to the limit of current feasibility. Dr. Contreras and Dr. Nieper have been primarily preoccupied, quite justifiably, with treating cancer patients with laetrile and related adjunctive therapies, and not with carrying out a clinical evaluation of laetrile in the precise and complete schedule of FDA protocols. For you to indicate that their records are inadequate for such a purpose is clearly a red herring, since there is no such IND Phase I requirement involved, nor corresponding claim made. Your statement therefore appears to be not only untrue, but potentially highly misleading to nonspecialists, including nonmedical members of Congress and lay persons.

Re: Report of the Ad Hoc Committee of Oncology Consultants and FDA News Release

This Committe was selected and guided throughout its executive sessions by the FDA, without laetrile proponents being present. In the 5th paragraph of your letter to Chairman Fountain you state that Mr. McNaughton and I were present at the May 21 meeting of the Committee, but this is grossly misleading since we were present by courtesy and for the record only before and not during any executive sessions, from which we were indeed excluded even though we had made ourselves available for the executive sessions of May 21-22. We were never consulted by the Committee during the further months of executive consideration, nor by you before your finalizing letter was sent to Chairman Fountain, even though a request for us to see and comment on the Committee report was conspicuously made to you earlier.

The foregoing facts should make it clear to any independent observer that the Committee report and your letter can be properly described as representing a kangaroo report and kangaroo court - completely one-sided, with end-result predictable, and grossly unfair.

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Secretary Elliot L. Richardson - 7.

Had Mr. McNaughton and myself been consulted by you before you wrote your letter to Chairman Fountain, a large number of errors, confusion, and lack of understanding obtaining in the Committee report could have been eliminated, with much alteration in final conclusion. But you chose to do otherwise, and for this the responsibility is yours. A detailed consideration of the errors and confusion would, on grounds of length alone, be out of place here, and would best be postponed until such time as Mr. McNaughton may wish to take advantage of your offer, "We stand ready to consult further with the McNaughton Foundation at any time.."

I do not wish to imply that the work of the Committee was valueless, indeed it would be the proper basis for "further consultation", but most of the points made by it, under close guidance by the FDA, represent, in my opinion, the proverbial grasping at minor straws and making mountains out of molehills. The Committee made some interesting points, but few at best really critical.

I trust that if the McNaughton Foundation takes advantage of your offer, that you will make a clearly genuine effort, with the aid of appropriate staff, to iron out any remaining differences over IND 6734, and do so in fully concrete and adequate detail, such as the FDA has never provided, has almost invariably avoided within their ability, and continues in its latest news release of Sept. 1, 1971, with grossest exaggeration and mendacity, to state to the public, "FDA in fact, has been unable to find any evidence of basic data necessary to assess Laetrile's potential for use in the treatment of cancer."(italic added). To repeat the words of Claudius, the "offence is rank, it smells to heaven."

Mr. Secretary, there is only one way to determine how many of the continuing 330,000 cancer deaths a year in the United States, and still greater number of cancer sufferers, may be ascribable to the laetrile actions of the FDA, Surgeon-General Steinfeld, and now yourself, and that is to permit the initiation of clinical testing of the gentle, virtually nontoxic laetrile, which in my opinion, already many times expressed, is now justifiable, or essentially so. The Congress has placed the legal final responsibility for granting of such permission in your hands; it is your ultimate responsibility - the buck stops there.

It would be no more difficult -much less so in fact - for you to reach a reversal of your recent action, than it was for our President to reach his reversal of judment concerning the China question and other similar ones he has bravely executed in recent months.

Sincerely yours,
Dean Burk
Dean Burk, Head,
Cytochemistry Section, National Cancer Institute.

Disclaimer: The views of the oversigned research scientist may differ materially from administrators within HEW, and no such latter official support or endorsement is intended or should be inferred.

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NATIONAL CANCER INSTITUTE,
Room 4E-16, Bldg. 37,
Bethesda, Md. 20014.
April 20, 1973.

Dr. Frank J. Rauscher, Jr., Director,
National Cancer Institute,
Bethesda, Md. 20014.

Re: The Achilles Heel of the National Cancer Act of 1971 (Public Law 92-218): An Open Letter.

Dear Dr. Rauscher:

This letter is a follow-up promised to you at the end of the meeting and discussion you called with the entire staff of the NCI on March 19, 1973 in the N.I.H. Clinical Center Auditorium, during which you expressed the desire that we all share our various views on the problems, program, and progress of the National Cancer Institute, which, as you pointed out, is now the spearhead of the total national attack on cancer as envisaged by President Nixon and the Congress. During my 34 years on the staff of the NCI I have never attended a more profitable and enlightening staff meeting, and your 50-minute opening presentation was truly a masterpiece of leadership and timely exposition. This is not to say, of course, that I agreed with everything you said

In the discussion period, I took the liberty of bringing up what I believe can remain a fatal flaw in the NCI program until such time as it might be duly corrected, namely a tragic preoccupation with relatively ineffective yet exceedingly harmful chemotherapeutic anticancer agents, coupled with a surrender of responsibility for escape from this paradoxical dilemma. Details of the nature of this Achilles Heel follow below:

(A) Ironically, virtually all of the chemotherapeutic anticancer agents now approved by the Food and Drug Administration for use or testing in human cancer patients are (1) highly or variously toxic at applied dosages; (2) markedly immunosuppressive, that is, destructive of the patient's native resistance to a variety of diseases, including cancer; and (3) usually highly carcinogenic in rats and mice, producing cancers in a wide variety of body organs. These now well-established facts have been reported in numerous publications from the National Cancer Institute itself, as well as from throughout the United States and indeed the world. Furthermore, what has just been said of the FDA-approved anticancer chemotherapeutic drugs is true, though perhaps less conspicuously, of radiological and surgical treatments of human can

(B) At the same time, it can fairly be said that no more than 5 - 10% of all cancers of systemic or metastatic nature can be treated by foregoing FDA-approved drugs to yield five-year survivals. In my opinion, this statistic is, upon detailed analysis, probably unduly optimistic, whether one regards systemic cancers in terms of types (of which there are formally considered to be at least 100) or in terms of individual human cases (of which there are upwards of a million in the United States at any one time). For example, you

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stated in the White House on May 5, 1972, at a press conference on the occasion of your swearing-in induction as NCI Director, "of the 100 cancers that afflict man, about 15 percent of these can be treated extremely well, to the point of at least 50 percent 5-year survivals" (i.e., of the order of 7½ percent 5-year survivals). Even from this, of course, must be subtracted any estimated survival rates of untreated patients, which in instances could amount to a considerable fraction of the observed 5-year survivals. In similar vein, our Scientific Director for Chemotherapy, Dr. Gordon Zubrod, wrote in the April 1972 issue of Proc. Nat. Acad. Sci. (Vol. 69, p. 1043), "Why is it that only 10% of clinical tumors are drug susceptible?" And, of course, effective control is far less in practice, than is susceptibility, as Dr. Zubrod pointed ou

Statements quantitatively or qualitatively similer to the two foregoing statements from top NCI officials could be cited here almost without limit from large numbers of equally qualified cancer specialists throughout the United States and the world, as in the attached "A Very Grim Picture," that cites statements in the Sixth National Cancer Conference Proceedings (1970) whose speakers were selected and sponsored by the National Cancer Institute and the American Cancer Society. A particularly poignant and telling statement was made by Dr. Charles Moertal of the Mayo Clinic on May 18, 1972 in our Clinical Center Auditorium after he was introduced by Chairman Dr. Stephen Carter (NCI) as "probably one of the country's foremost if not the foremost expert" in the area of gastrointestinal cancer:

"Perhaps some small and hesitant progress has been made, but it is evident that in this year of 1972 there is no remarkably effective specific therapy for any types of gastrointestinal carcinoma that cannot be surgically extirpated. There are none that can be accorded the stature of treatment of preference. Our most effective regimens are fraught with risks and side-effects and practical problems, and after this price is paid by all the patients we have treated, only a small fraction are rewarded with a transient period of usually incomplete tumor regressions." ...."Our accepted and traditional curative efforts therefore yield a failure rate of 85%. These patients with advanced gastrointestinal cancer present us with one of the most frequent major disease problems encountered in medical practice today.... The patient with gastrointestinal cancer is still getting the same old 5-Fu he got 14 years ago. Some patients with gastrointestinal cancer can have very long survival with no treatment whatsoever."

A good general summary is given by Dr. Irwin H. Krakoff, Sloan-Kettering Institute for Cancer Research, in an address before the American Society of Clinical Oncology (1968), "Cancer drugs are given at maximum tolerated doses with the possibility of observing a significant therapeutic response in a small proportion of patients. Many of the compounds available are highly toxic but have a weak or negligible therapeutic action against most forms of cancer. We are concerned with a disease for which there is no really satisfactory treatment."

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In spite of the foregoing evidence in Item B, officials of the American Cancer Society and even of the National Cancer Institute have continued to set forth to the public that about one in every four cancer cases is now "cured" or "controlled", but seldom if ever backed up with the requisite statistical or epidemiological support for such a statement to be scientifically meaningful, however effective for fund gathering. Such a statement is highly misleading, since it hides the fact that with systemic or metastatic cancers the actual rate of control in terms of the conventional five-year survival is scarcely more than one in twenty, and that the current annual cancer mortality in the United States of some 350,000 deaths is made up almost exclusively of cases of systemic cancer.

In your answer to my discussion on March 19, you readily acknowledged that the FDA-approved anticancer drugs were indeed toxic, immunosuppressive, and carcinogenic as indicated in Item A above. But then, even in the face of the evidence of Item B above, including your own White House statement of May 5, 1972, all pointing to the pitifully small effectiveness of such drugs, you went on to say, quite paradoxically it seems to me, "I think the Cancer Chemotherapy Program is one of the best program components that the NCI has ever had. I think it, as much if not more than any other program areas, has provided meaningful hope and actual effective treatment for cancer patients all over this country and the world." One may ask, parenthetically, surely this does not speak well of the "other program areas?" Concerning the FDA-approved anticancer drugs, you went on to say, "I don't agree that this is a poor modality of treatment, or that there has been a poor choice of compounds....I think the program is an excellent one."

Frankly, I fail to follow you here. I submit that a program and series of the FDA-approved compounds that yield only 5 - 10% "effectiveness" can scarcely be described, convincingly and in all common sense, as "excellent," the more so since it represents the total production of a good 30-year effort on the part of all of us in the cancer therapy field. My conclusion is that our current approach simply is not working, and that future effort will in no way be helped by overlooking, forgetting, or shutting one's eyes to the 5 - 10% level of achievement. I am well aware that spokesmen confronted with this stark fact rise to point out current progress with choriocarcinoma (a very rare cancer), Hodgkins disease, certain leukemias, Burkitt's lymphoma, Wilms' tumor and a few others well-summarized by Dr. Zubrod in his aforementioned publication, but in my experience this usually leads to more overlooking, forgetting, and shutting one's eyes to the 5 - 10% total level of achievement. A second line of defense often brought up is that "The FDA-approved drugs, bad as they are, are the best we've got, but we are always on the lookout for better ones." I hope to indicate below, albeit briefly, that this last point of view is far, far from the truth, however sincerely but often quite naively uttered. It is this very sincerity, naivety, and limited outlook on the part of the field generally, as well as yourself in particular (as the very head of the spearhead of the total national attack on cancer) that constitutes the Achilles Heel of the National Cancer Act of 1971, in my judgment.

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The NCI has taken very little interest in the discovery of chemical compounds truly nontoxic at actively efficacious dosages. For many investigators within and without the NCI this has been a concept beyond their experience and grasp- perhaps not excluding yourself, but certainly including your immediate predecessor, ex-NCI Director Baker. In the NCI screening program virtually no compounds have been tested at above 500 mg compound/kg body weight. Yet, in my opinion, it is particularly at and above such dosage that one should be looking - i.e. for compounds whose $L.D._{50}$ lies between say 500 and 20,000 mg/kg, depending in part upon the mode of administration.

A host of investigators have said, written and/or taken for granted that "If a compound cannot harm the host, it cannot harm the tumor growing on the host." In my opinion, this is popular fallacy and professional fallacy. For, obviously, where there are biochemical or other differences between a cancer and its host - and such differences do exist, as a generality if not universality (e.g. catalase content, fermentation capacity, oxidation capacity, water content)-there can be a differential action, quantitative or qualitative, on cancer vs host. Such a popular fallacy as indicated has silently but effectively prevented a search for compounds far more ideal than any of the FDA-approved anticancer drugs. Such a popular fallacy is indeed but another expression of the above-assigned Achilles Heel. The fact is, there exists, within and without the NCI, a widespread but scientifically unjustified scorn of searches for truly nontoxic efficacious anticancer compounds, as distinguished from merely less toxic more efficacious anticancer compounds.

An excellent and well-known example of this open scorn is to be found in the booklet issued from time to time by the American Cancer Society under the title of "Unproven Methods of Cancer Treatment," but unsupported by little evidence beyond the oft-repeated refrain, "After careful study of the literature and other information available to it, the American Cancer Society has found no evid that treatment with _____ results in any objective benefit in the treatment of human cancer," a statement with close to zero scientific worth, however much sheer propaganda value. The fact is, to judge from Item B above, there are few "Proven" methods operating on a large scale anywhere, so that the word "Unproven" as used by the ACS is a highly and unjustifiedly weighted word with reference to, in any event, some of the "Methods" the booklet describes. I would submit that no less than six, at the very least, of the ACS's "Unproven Methods" would be worthy of immediate scientific investigation by the NCI on a basis of nontoxic but potential efficacy, but in addition, I am aware of many more methods and compounds already being investigated by individual investigators or small institutes whose efforts are literally dying on the vine for lack of due support that now goes to greatly more expensive but far less immediately promising priorities adopted under the present national NCI program. In this awareness I am of course joined by many others, and what I have just said is in no sense "news" or offered as such, so far as the mere aspect of financial support is concerned. What is generally lacking, however, is an appreciation of truly nontoxic but efficacious compounds and the need for search therefor, as indicated in the two foregoing paragraphs.

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Dr. Frank J. Rauscher, Jr., 5, April 20, 1973. NATIONAL CANCER INSTITUTE

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I have referred in the second paragraph of this letter to the aspect of NCI surrender of responsibility for escape from the tragic and paradoxical dilemma presented by Items A vs B, namely that the FDA-approved anticancer drugs are toxic, immunosuppressive and carcinogenic, and yet, after 30 years of effort we still wind up with only 5 - 10% five-year survivals of patients with systemic cancer, with, in fact, no marked improvement in sight in any near future. Time and again I have seen administrators within and without the NCI shift responsibility for this upon the shoulders of the FDA and the purported "will of Congress" as expressed in the variously amended FDA legislative acts, notably the 1962 Kefauver amendment. I believe this surrender of jurisdiction is unnecessary, unwarranted, and highly undesirable, and that steps should be taken to reverse this surrender, with ends in view perhaps paralleling the current struggle between the legislative and executive branches of the government, where likewise there is widespread feeling that Congress should recover some of the constitutional authority it has over the years surrendered to the executive branch.

To begin with, study of the legislative history of the enactment of the 1962 Kefauver Amendment to the FDA act indicates that "what was contemplated was protection of the public from misleading advertizing of drugs in situations where the drugs would do more damage than the disease" and where drugs already existed capable of effectively treating <u>curable</u> diseases (such as tuberculosis, pneumonia). I am reliably informed that "it never occured to the writers of this Amendment that any part of their proposals would be used to slow down or hamper cancer research or to interfere with the testing of potential anticancer drugs," by such an agency as the FDA, which was generally regarded as having by then "fallen down badly on its status and assigned mission," and "too thoroughly incompetent to understand anything about research," though the Amendment writers "didn't want to say so out loud." Cancer was regarded then, as it should be now, as still largely "<u>uncured</u>" and therefore not to be subjected to regulation by agencies medically incompetent. The Kefauver testimony was concerned "with people trying to make profits at the expense of sick patients or giving out misleading information about drugs. It had nothing to do with giving the FDA control over any kind of research, including interstate research" on cancer amelioration.

In the view of one of my legislative history informants, who aided in the writing of both the Kefauver Amendment and the National Cancer Act of 1971, Sec. 407, Section(b)(5)("In carrying out the National Cancer Program, the Director of the National Cancer Institute shall: Establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for research and <u>set standards of safety and cure for persons using such materials.</u>") provides authority and directions for NCI to take over many functions regarding cancer study and treatment hitherto assumed by the FDA. Obviously, whether this view would be subscribed to by the Secretary of HEW would be another matter, but I believe more than well worthy of his consideration, not to mention your consideration. And, further obviously, the intention of the words is none too clear or delineated in detail.

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Dr. Frank J. Rauscher, Jr., 6, April 20, 1973.

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In any event, so far as might concern nontoxic but efficacious anticancer agents, and Congressional action thereon, the following approximate bill might (and may well be) be introduced into both Houses of Congress:

A BILL

To authorize testing and research on the use of nontoxic substances in the diagnosis, treatment, and prevention of cancer.

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

That (a) the Director of the National Cancer Institute, as part of the expanded, intensified, and coordinated cancer research program to which the Institute is now committed, shall include in such program a program for the testing of, and clinical research on, any drug, food, vitamin or other substance that is essentially safe and nontoxic (e.g. at dosages far less toxic than the anticancer drugs or substances now approved and allowed by the Food and Drug Administration, and far below any producing even moderate sublethal effects, and e.g. with an L.D.$_{50}$ of about 500-10,000 milligram/kilogram body weight), and which, in the judgment of three or more medical researchers, in this country or in other countries, has been demonstrated to be useful or effective to diagnose, prevent, mitigate, treat, or cure cancer, or, in their opinion, may be useful or effective to diagnose, prevent, mitigate, treat, or cure cancer.

(b) No Federal agency may ban or restrict the use of any such essentially safe and nontoxic drug, food, vitamin, or other substance in clinical research or clinical testing carried out to determine its effectiveness in diagnosing, preventing, mitigating, treating, or curing cancer if:

(1) the research or testing is conducted by investigators, scientists, or medical researchers qualified by education or experience.

(2) the drug, food, vitamin, or other substance is administered in the course of such research or testing only to persons, or legally authorized representatives of such persons, who have given an informed written consent to such administration of such drug, food, vitamin, or other substance.

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To summarize the foregoing generic response to your expressed desire to share with NCI staff their views on the problems and progress of the National Cancer Institute national program against cancer:

Since (A). virtually all of the chemotherapeutic anticancer agents now approved by the Food and Drug Administration for use and testing in human cancer patients are (1) highly toxic at applied dosages that yield anticancer efficacy, (2) at the same time immunosuppressive and (3) carcinogenic, and

(B) yield on the grand average only 5 - 10% five-year survivals among patients with systemic, metastatic cancer, even after 30 years of effort, and with no great promise of marked improvement in this percentage for at least some years to come,

it would appear obvious that our current approaches are really not working on the right track, and that future effort will not be helped by overlooking, forgetting, or shutting one's eyes to this tragic situation as is all too commonly done.

It is proposed in this generalized report to you that the NCI program be broadened to include effective consideration of essentially nontoxic but efficacious anticancer agents of the type that the NCIhas hitherto bypassed and even condemned on less than due scientific basis. Further, it is proposed that the NCI make efforts to largely take over responsibility for such efforts from the Food and Drug Administration, which is in great measure responsible for the dilemma and impasse set forth above in (A) and (B) and has done so upon a basis of questionable Congressional authority to do so.

Sincerely,

Dean Burk

Dean Burk, Head Cytochemistry Section, NCI.

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BETHESDA, MARYLAND 20014
Room 4E-16, Bldg. 37,
National Cancer Institute,
Bethesda, Md. 20014.
Dec. 13, 1972.

Mr. Michael Standard, Atty-at-Law,
Rabinowitz, Boudin & Standard,
30 E. 42nd St., New York, N.Y. 10017.

Dear Mike:

Some time ago you asked me to look up the much publicized "Angeleno case" as then reported in various California newspapers and the New York Times, about an alleged couple allegedly made ill by ingestion of an overnight brew of apricot nuts, apricot fruit, and distilled water. After continued enquiries among California friends who I hoped might know or find more about the matter, I at last heard from my friend George Gray (126 Ridge Road, Fairfax, California 94930; 415-453-8131) on December 11, who told me to phone a Mrs. Audrey Calder in the state health offices in Sacramento (744 P St, 916-445-6067) as the authority, and she referred me to one Mr. Vandree (sp.?) down the hall from her, who referred me to Dr. James Chinn in the Berkeley Public Health Offices (415-843-7900) as the authority, who referred me to Mr. Robert Murray of the Los Angeles County Health Department (213-625-3213, Ext. 111) as the ultimate authority since it was Mr. Murray who made the original investigation of the couple and the Emergency Hospital where they were treated, on the basis of whose report the Sacramento office prepared their Sept. 1 "Morbidity Report" which was then used by the newspapers.

In any event, I conclude : this couple, from Los Angeles (but not named Angelenos, which is a term used to describe anyone from Los Angeles) really exists, they really got sick and were treated in an Emergency Hospital, following ingestation by mouth of an overnight brew made from apricot nuts, apricot fruit and distilled water,- a concoction that probably fermented somewhat overnight, and of course contained innumerable compounds, and was undoubtedly very bitter, and which brought on the illness (nausea, vomiting, etc.) after "about an hour", which is rather long for cyanide, which usually acts within minutes of being swallowed. Mr. Murray was not willing to commit himself that cyanide was the chief cause of the illness, from which it would appear they promptly recovered - he said "that under the circumstances it would be very difficult to take samples from them and be able to prove that..... scientifically speaking, you don't want to leap to conclusions and say that their illness was definitely due to the ingestion of amygdalin or amygdalin-containing material, but their illness was certainly epidemiologically related to this; also their illness was compatible with what might be called mild cyanide poisoning." ..... "I think it is important to get this type of information into the mill for people who have to worry about the possible public health significance or hazards to this type of thing, but I don't think I could personally say that I proved that their illness was due to apricot kernels." Dr. Chinn had just earlier told me that "We got that (report from Mr. Murray) as a possible food poisoning incident from the Los Angeles County Health Department. They've worked it up and supplied us with most of the information and then we put it into the California Morbidity Report, and from there it was picked up by the New York Times." I enclose my handwritten verbatim account of my complete conversations with Mr. Murray and Dr. Chinn, which have not bothered to type up, but could do so if needed; it contains my comments and interpretation as well, en passant, but gutteral uh-huhs,

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ahs, ohs, etc. are omitted from the verbatim account. It is interesting, of course, that somehow, out of the I presume thousands of items in the California Monthly Morbidity Reports, the Murray-Chinn material on amygdalin made the press throughout the country -presumably with the help and guidance of the state health authorities. Mr. Gray has written, in an incipient article, "The health department's approach has been to discredit Laetrile without ever mentioning it directly. They have gotten the co-operation of the press when reporters have not gone beyond the offices of the health department in writing their stories. One American Cancer Society official told me, "the less we say about it the better." Their fear is that by merely mentioning Laetrile, cancer patients will without question abandon conventional therapies and use Laetrile exclusively." Mr. Gray has written a number of articles and/or letters to editors on the subject of laetrile.

I enclose a fairly recent article (but over a year old) by Hans Nieper, and a list of a number of chemical firms that make,sell, or distribute laetrile in the United States currently. Undoubtedly many firms in the past have done so for well over a hundred years (as detailed research could show); Ernst Krebs has a Merck catalog for 1907 in particular that I believe is illustrative, and many firms undoubtedly keep thier old catalogs on reference. I have recently acquired a 453-paged Chinese-Korean Herbal Pharmacopeia (1961) by Sun Chu Lea and Yong Chu Lee (Pub. Dong Myung Ltd. Korea) that contains considerable description of herbal sources of amygdalin with reported uses for asthma, cough, shortness of breath, edema, inflamation, cathartic, menstrual cycle, and cancer dissolution.

Sincerely,

Dean

Dean (Sherlock Holmes-Perry Mason) Burk.

cc: George Gray
Stephen Wise
Joan Andrews
Ernst Krebs
Gregory Stout
John Matonis
Kirkpatrick Dilling
Clinton Miller
Andrew McNaughton
Wynn Westover
Betty Lee Morales
Stephen Tornay
Emory Thurston
Ray Siderius

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Room 4E-16, Bldg. 37,
National Cancer Institute,
Bethesda, Md. 20014.
December 20, 1972.

301-4963339.

Mr. Bill Stenjem, President,
Waikiki Chapter, National Health Federation,
Nohona Nutrition Clinic, P.O. Box 4267,
Honolulu, Hawaii 96813.

Dear Mr. Stenjem:

I am writing you herewith in response to a request to do so as received in a letter of date of December 15, 1972 from Ann Yalian, Executive Secretary, International Association of Cancer Victims and Friends, 155-D South Highway 101, Solana Beach, California 92075, to whom you had sent the attached two articles from the Honolulu Star Bulletin and Advertiser, one article of date of December 10, 1972, the other article written by Tomi Knaefler. Both articles were on the subject of apricot kernels purchased in a Honolulu health food store by a young woman who "ate almost a half-pound of the apricot kernels and became violently sick," but "got to the Queen's Medical Center's emergency unit and was released." ."Two similar incidents recently were reported in California, State epidemiologist Ned Wiebenga said, yesterday."

About a week ago I had occasion to look into the history of the "California incident," which had been reported in many newspapers in California and throughout the nation, including the New York Times, in September, following issuance on September 1 of the California "Monthly Morbidity Report" by the state health office in Sacramento. This report described the case of a Los Angeles couple that in July had orally ingested an unboiled,overnight,distilled water brew of thirty ground-up apricot nuts and apricot fruit, and had become ill, though apparently less violently so than the aforementioned Honolulu gastronome.

To start looking into the California incident, a newspaper friend in this state of my birth recommended that I telephone a Mrs. Audrey Calder (916-4456067) in the state health offices in Sacramento (744 P St.) - a fair city in which my father attended grammar school just 100 years ago. Recommended to me as an authority, Mrs. Calder referred me to a Mr. Vandree (sp.?),down the hall from her,as the authority, who referred me to Dr. James Chinn in the Berkeley Public Health Offices Building (415-8437900) as the authority, who referred me to Mr. Robert Murray of the Los Angeles County Health Department (213-6253213, Ext. 111) as the ultimate authority, since it was Mr. Murray who had made the original investigation of the couple in July, after they had recovered, and on the basis of whose report the Berkeley office had worked up the material for the September Monthly Morbidity Report.

One can but admire the aforeoutlined efficiency and dispatch shown by the various channels in the California Health bureaucracy, and, indeed,

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perhaps even more their prompt and highly selective deliverance of their labors to the national press, with elimination of presumably thousands of other less choice items in the Monthly Morbidity Reports. As my California newspaper friend wrote me, "The health department has gotten the co-operation of the press when reporters have not gone beyond the offices of the health department in writing their stories ..... its approach has been to discredit Laetrile (an important component of apricot nuts) without ever mentioning it directly. One American Cancer Society official told me, 'the less we say about it the better,' the fear being that by merely mentioning Laetrile cancer patients will without question abandon conventional therapies and use Laetrile exclusively." True to form, neither of the Honolulu articles used the word Laetrile, nor its biologically equivalent synonym Vitamin B-17. With friends and protectors such as the health departments of the sovereign states of California and Hawaii, no enemies are needed by the inhabitants of these two states.

Apricot nuts are widely sold in food stores throughout the United States, as are likewise their close relatives, bitter almonds, throughout Europe. Such nuts do indeed represent some of Nature's finest food, containing 30% protein, a high content of important minerals, and oils with a high fraction of the unsaturated types. Such nuts are eaten not only for their food and flavor values, but by a considerable number of persons for aid in the prevention or treatment of cancer, attested to by a large body of evidence bypassed knowingly or unknowingly by Wiebenga who "said a false myth has connected the apricot kernels with cancer prevention, and reports indicate consumers have eaten three or four kernels daily without poisoning."

The facts are that a very considerable number of people eat 10-20 apricot kernels throughout a day, and after a while even 50-100 kernels, safely, though hardly all at once as the Honolulu gastronome apparently did, nor as an unheated overnight brew as the Angeleno gastronomes actually did. The same general situation holds with respect to a large number of ordinary foods that can be poisonous or allergic, etc., such as strawberries, onions, shrimps, and so on, that are never removed, en masse or in toto, from food store shelves, by health agencies imbued with the spirit of 1984 as displayed by Dr. Wiebenga where, as reported, "apricot kernels have since been removed from store shelves here, and a search is underway to remove them from Neighbor Island shelves." It is one thing for a health agency to warn people against foolish and rare actions with respect to any aspect of health, and quite another to totally deprive people of excellent food quite safe if ingested in a normal common sense way observed by 99.999% of the population. Thus, a few spoonfuls of water or other liquid taken into the lungs through the windpipe can actually and readily be lethal, but this occasions no need for the Honolulu health agency to cut off the drinking water supply to all citizens in Hawaii, for fear that an occasional citizen might accidentally or otherwise take water into his lungs instead of his stomach. In the same way, millions of automobile gasoline tanks are filled at filling stations every day, yet no government agency has attempted to eliminate all automobiles on the off chance that some consumer might hold a match nearby with lethal results. The fact is, all things in this world can be harmful or lethal, if misused. The solution is not to eliminate "all things in this world" but quite otherwise, namely, as many government agencies do, warn against misuse, and let it go mostly at that, beautifully exampled by warnings on cigarette packs, not removing them totally.

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Mr. Bill Stenjem - 3, Dec. 20, 1972.

It is, of course, not at all clear from the newspaper accounts that the Honolulu gastronome became sick from any cyanide-containing component in the apricot kernels as distinguished from just plain overeating, since the "almost half a pound" of nuts eaten could well sicken some persons on the basis of excessive intake of rich food alone, causing nausea and vomiting. "Almost half a pound" of apricot kernels would amount to some 400 nuts (1 pound = ca. 900 nuts), which not many people ever eat all at once anyway, as distinguished from "throughout the day." As with any food (or drink) there is some upper limit of quantity ingested before adverse effects become evident; in medieval days, convicts were often tortured or killed merely by enforced drinking of plain water, and mice can be killed promptly by putting upwards of on two cubic centimeters of water into their stomachs forcefully with a syringe.

As for the possible role of amygdalin-containing-cyanide in the apricot kernels, Mr. Robert Murray of the Los Angeles County Health Department said with respect to the Angeleno gastronomes, "it would be very difficult to say that their illness was definitely due to the ingestion of amygdalin or amygdalin-containing material, even though their illness was compatible with what might be called mild cyanide poisoning," to which might be added "let alone some other type of poisoning." Although the Angelenos ingested far fewer nuts than did the Honoluluan, the Angeleno brew had stood overnight apparently without heating, thereby presenting the possibility of fermentation processes producing toxic compounds of a non-cyanide nature, just as many a food unconfiscated on food store shelves might similarly do if similarly brewed.

In any event, both the Angeleno and Honoluluan experiences represent but remarkably rare instances among the many thousands of apricot kernel consumers enjoying without adverse effect the excellent food value of such kernels. Taking the kernels "off the shelf" by 1984 (or 1972) methods is no real solution, and philosophically has no place in an intelligent democracy operating under the Bill of Rights. Although one might have a misplaced admiration for the Hawaiian State Department of Health's display of zeal in this instance, there would seem to be no call to admire a display of scientific intelligence here.

One can but feel compassion for the citizens of Hawaii deprived of a maj supply of natural Vitamin B-17 (amygdalin) contained in apricot kernels, possibly leading to an increased incidence of cancer and other human ailments on some as yet undetermined scale, and especially if the deprivation is extended to other amygdalin-containing foods by zealous but uninformed officials. Oh, for the happie days enjoyed in Honolulu by my mother (who was born there 101 years ago), her brother (Walter F. Frear, Governor of Hawaii under three Presidents) and their father who preached there for many years, all of whom died of cancer-free deaths between the ages of 83 and 93.

Sincerely yours,

Dean Burk

Dean Burk, Head, Cytochemistry Section, NCI.

CC: Ann Yalian
Dr. Ned Wiebenga
Honolulu Star Bulletin & Advertiser
And others.

SUBMITTED DEC 17

(preliminary?)
Burk to ~~Wise and Stout~~, December 17, 1972

Provisional report in reply to letters of Stephen Wise (Nov. 8, 1972) and Gregory Stout (Nov. 7, 1972) to Dean Burk, for interim use in the preparation of affidavits, and subject to further expansion and details upon request:

With 45 years of study and research on the cancer problem, the last 33 years in the U.S. National Cancer Institute, and with files of virtually all published literature on the use of amygdalin ("laetrile") with reference to cancer, and with innumerable files of unpublished documents and letters, I have found no statements of demonstrated pharmacological harmfulness to human beings of amygdalin to human beings at any dosages recommended or employed by medical doctors in the United States and abroad, up to the high level of 100 milligrams amygdalin/kilogram body weight/day (either orally or parenterally); and, more specifically, no such statements by opponents of the human use of amygdalin ("laetrile"), in their major publications:

a) Report by the Cancer Commission of the California Medical Association on the "Treatment of Cancer with 'laetrile'" (California Medicine, vol. 78, 320-326, 1953, the basic document most commonly referred to by opponents of "laetrile."

b) Report by the Cancer Advisory Council, State of California Department of Health, on "Treatment of Cancer with Beta-Cyanogenetic Glucosides ("Laetriles"), 1963, 152 pages, containing reports on 130 cases of human cancer patients treated with amygdalin.

c) Report by the American Cancer Society, Inc., 1971, 7 pages, and earlier versions thereof dating back to 1961, including its currently and widely distributed booklet, "Unproven Methods of Cancer Treatment."

d) Reports by the State of California Department of Health to the California Legislature, 1972 and various years, on "Regulation and Control of Diagnosis and Treatment of Cancer Patients," Section 1719, Health and Safety Code.

e) Report on "The Cancer Law, 1959-1964" issued to the Governor of California on the "Activities and Actions of the State of California Department of Public Health and Cancer Advisory Council, January 1965, pp. 32-41.

f) Numerous statements and letters issued by U.S. National Cancer Institute, U.S. Food and Drug Administration, and American Medical Society, including the FDA Ad Hoc Committee of Oncology Consultants report of August 1971, as published in the "National Cancer Attack Act of 1971 (Hearings before the Subcommittee on Public Health and Environment, Committee on Interstate and Foreign Commerce, House of Representatives, 92nd Congress, 1st Session, 1971, pp. 728-751.)

(2) Within my personal experience and observation, various normal and cancerous human adults (lay and M.D.) have taken up to 200-300 mg amygdalin/kilogram body weight/day, orally or intravenously, for varying periods of days-weeks without evidence of toxicity. Common oral dosages of 10-20 mg amygdalin/kilogram body weight/day have been taken routinely for years by many human adults without evident toxicity of any sort. The first (to my knowledge) recorded and published cancer patients to be treated with amygdalin were reported by Dr. T. Inosemtzeff (Gazette Medicale de Paris, vol. 13, pp. 577-582, 1845; Journ. Chirurgie und Augenheilkunde, vol. 25, pp. 7-28, 1846), some 130 years ago. A young man of 20 received 46,000 mg. amygdalin over a period of several months and was living three years later at the time of the report. A woman of 48, with extensive metastasis from a primary right ovarian tumor, received varying amounts of amygdalin over a period of years and was surviving 11 years later at the time of the published report. No sustained pharmacologic harm was observed with these patients.

(3) Obviously, all substances, without exception, can be toxic and even lethal at some sufficiently high dosage and suitable conditions, conversely, they can be neither toxic nor lethal at dosages that can be predetermined. A few spoonfuls of plain water taken into human lungs through the windpipe can be lethal within minutes; a thimblefull of plain air taken into the human blood stream can be lethal within minutes; as may similarly a lighted match applied by a person to an automobile gas tank filled with gasoline. The problem is always to ascertain a substance dosage that is well below a dosage yielding sustained pharmacologic harm (toxicity). This was first done with humans as outlined above in the early 1840's! With dogs, which commonly behave quite similarly to humans, the first pharmacologic experiments were reported by F. Woehler and Frerichs (Arch. der Chemie und Pharmacologie, vol.65, pp. 335-348, 1848) who showed that a totally nontoxic dosage would lie just below about 1000 milligrams amygdalin/kilogram body weight, since this dosage yielded temporary toxic symptoms from which prompt and permanent recovery was made (cf. attached Item A , paragraph 7). From this time on (125 years ago) large numbers of such determinations have been made on man, dog, rabbit, rats and mice (etc.), and reported in articles, reviews and reports, indicating determined dosages that yield no sustained pharmacologic harm (toxicity) as referenced in Items A and B attached, with the most recent reports described in the McNaughton IND-FDA application of April 6, 1970 et seq comprising some 1000 pages of submitted material. The dosages of amygdalin that are nontoxic are far higher, in terms of milligrams amygdalin/kilogram body weight, than virtually all anti-cancer agents now approved by the FDA for usage on an IND or NDA basis by doctors and hospitals throughout the United States. Thousands of humans have taken amygdalin dosages of 1000 - 3000 milligrams (ca. 1 - 3 gms/person) and more daily without any evidence of pharmacologic harm, during the past ten years and more, by both oral and parenteral routes. Any statements to the contrary (none yet known to me), see (1) above, as in a court of law, by opponents of human usage of amygdalin that might be presented would have to be examined in due course on their merits if any. To date, general consensus everywhere, including amygdalin opponents, current has not implicated any serious aspects of toxicity at humanly applied dosages, so that, in a court of law, it could well be important not to overemphasize such aspects until they arise! (Nota bene!)

Burk to Wise and Stout, December 17, 1972

1. Pertinent summary statements on nontoxicity of laetrile (amygdalin) made in IND 6734 submissions made to the FDA by the McNaughton Foundation (details of data omitted but available): See attached sheets. Data of Burk on top, 12 pp., all taken from submissions to FDA re amygdalin; a great deal more similar high-dosages studies with amygdalin have been made with various other tumor-bearing animals (and their controls with and without tumors), all of confirmatory nature, in our laboratory.

2. Prof. D.M.Greenberg (Prof. Emeritus of Biochemistry, Univ. Calif. at Berkeley-San Francisco) and consultant to the Cancer Advisory Council of the California Department of Public Health wrote on October 13, 1969 to Mr. Larry Rucker, "There is no question that pure amygdalin (Laetrile) is a nontoxic (compound)". This is not questioned by anyone who has studied the reports submitted to the Cancer Advisory Council of the State of California."

3. Dr. Carl Baker, Director, National Cancer Institute, wrote on July 9, 1970 to Mr. Andrew R. L. McNaughton, President of the McNaughton Foundation of California,"You will note that attachment 3 presents the results of (NCI-CCNSC) experiment in which 400, 200, and 100 mg/kg of amygdalin were given alone (to mice) and found non-toxic." Higher dosages were not tested, though they could and should have been

4. Dr. Bryant Jones, Deputy Director of Division of Oncology and Radio Pharmaceuticals, FDA, stated on October 1, 1970 that so far as toxicity is concerned Amygdalin is probably innocuous. He said, "We do not have a great deal of concern over the toxicity of Amygdalin, " and intimated that the animal safety-toxicity data supplied in the IND was satisfactory (see enclosed report by Dr. Miles Robinson, M.D. on "Conference on FDA's Termination of IND 6734 for Laetrile-Amygdalin" submitted to U.S. Senator William Proxmire at latter's request; see pages 17-21 thereof.

5. For over 100 years standard pharmacology books have stated that amygdalin is non-toxic, by standards regarded as nontoxic. A"recent" review is given in the classic article by the American pharamcologist Reid Hunt in his article in Handbuch der experimentelle Pharmacologie (Editor, A. Heffter) Berlin 1923, pp. 702-832; see also J. Houben's Fortschr. der Heilstoffchem. 2 Abt. Leipzig 1932.

5a. (added Nov. 29, 1972): Two quite recent reviews of laetrile - amygdalin literature are:

P. G. Reitnauer, "Mandelsäurenitril-Glykoside in Krebsforschung und Krebstherapie," Arzneimittel-Forschung, vol. 22 1347-1361, 1972 (Mandelonitriloglycosides in Cancer Research and Cancer Therapie). (English translation privately available).

H. M. Summa, "Amygdalin, ein physiologisch wirksames Therapeutikum bei malignen Geschehen," ("Amygdalin, a physiologically active therapeutic for malignant tumors"), 33 pages MS, Jossa-Arznei, Steinau, Germany, April 1972 (English translation shortly to be available).

Continued Summary Statements, additional to those submitted to you Dec. 17, 1971.
..and comments..

6. From IND 6734, 5th Volume, 31 October 70, p. 00114 : "Otto Jacobsen in his "Die Glycoside" (v. Eduard Trewendt, Breslau, 1887, 174 pp) wrote - "Das Amygdalin ist nicht giftig (transl.:"Amygdalin is not toxic") and provided references then over 20 years old in his bibliography on amygdalin of 99 papers. F.R.Davidson in his "Synopsis of Materia Medica, Toxicology and Pharmacology", 3rd ed., C V Mosby, 1944 wrote - "The glucoside amygdalin when given by injection produces no harmful effect". (N.B. - our NIH Library does not have either of these particular volumes, but I enclose a 1949 publication extract from F.R.Davidson containing some interesting definitions re Materia Medica - D.B.)

7. From enclosed article of Wöhler & Frerichs, 1848: " 3. Amygdalin (p.337) This compound acts, as shown earlier in the experiments of Buchner, nontoxically." A healthy young dog was given 3 grams and an adult dog was given 5 grams amygdalin with temporary symptoms described from which complete recovery was made, all in harmony with the similar oral results described in IND 6734 pp. 00121-2 122 years later in 1970. The 1848 dosages given to the dogs were, of course, 10-30 times as great as current human dosages where not even "temporary symptoms" are to be observed. Furthermore, the 1848 experiments were almost certainly conducted with less pure amygdalin that possibly contained the enzyme glucoside to some extent. In any event, the reference is not without historical interest as showing pharmacologic studies back in 1848 or earlier.

From American Cancer Society's "Unproven Methods of Cancer Treatment (1966)" enclosed, p. 67: "the United States District Court, San Francisco...permitted a very limited distribution of Laetrile to.. a few other physicians who have claimed that they had experimental patients on the drug."

9. Reid Hunt article with many early references, also found in the Real-Enzyklopädie article. Also in the Fortschritte der Heilstoffchemie article
1838, 1845, 1847, 1851, 1858
10. Samples of U.S.Dispensatory, 1843, 1854, 1924, and 1918

e.g., 1854, p. 92 "Amygdalin appears not to be poisonous when taken pure into the stomach".

LL. Other general references:

Real-Enzyklopaedia der Gesamten Pharmazie, by J. Müller and L. Thoms (Urban and Schwarzenberg, Berlin), 1904, pp. 570-573.

Dispensatory of the United States of America, by J.P.Remington and H.C.Wood, (J.B.Lippincott, Philadelphia and London), 20th Edition, pp. 137-139.

Attachment II

(Presented at U.S. Senate Staffers' Seminar, Judiciary Hearing Room 2226, New Senate Office Building, March 11, 1971, 5:45-7:30 p.m.)

On Some Scientific and Moral Issues re Laetrile

On the Washington, D.C., NBC-TV Channel 4, Feb. 14, 1971 (Deena Clark's "A Moment With ..."), Dr. Jesse Steinfeld, Surgeon-General of the U.S. Public Health Service stated:

"Our bases for putting a cancer drug into test in man are: (1) evidence that the drug has an effect in animals, (2) evidence of pharmacologic tests showing acute and chronic toxicity in a wide variety of animals so that we know what the appropriate dose is, and (3) some reasonable proposal for clinical trials so that it just won't be used randomly. Laetrile has met none of these test ... I have looked at their IND (Called Investigational New Drug application)," (((1), (2), and (3) added in for identification purposes)).

On all three of the foregoing bases Dr. Steinfeld has failed, intentionally or otherwise, to acknowledge very extensively documented information supplied in the McNaughton Foundation FDA-IND-6734 application that contraindicates the above statement that laetrile has met none of these three tests, e.g.:

(1) FDA-IND-6734 application (pp. 247-248, 00000-00003) reports efficacy data showing that laetrile had beneficial efficacy in the treatment of Walker 256 carcinosarcoma in rats, the studies having involved 100 rats (200 as controls). The magnitude of efficacy of laetrile in these rats approached [illegible] average of efficacy in animal tumors shown by some 30 anticancer drugs currently employed [illegible], according to data provided by Dr. Saul Schepartz, Chief, National Cancer Institute-Cancer Chemotherapy National Service Center (NCI-CCNSC). Dr. Carl Baker, Director of the National Cancer Institute, wrote to Congressman Edwin W. Edwards on Jan. 23, 1971: "The data provided by the McNaughton Foundation certainly indicates some activity in animal tumor systems" (emphasis added); evidently Surgeon-General Steinfeld and Director Baker have their signals crossed. Furthermore, there exist no data in conflict with the McNaughton Foundation efficacy data obtained with Walker 256 Carcinoma in rats, as delineated in detail by Dean Burk in a letter to Congressman Edwards of date of Feb. 23, 1971.

(2) Pharmacologic tests on laetrile safety (nontoxicity) have been extensively reported all over the world for over 100 years, and the FDA-IND-6734 application of the McNaughton Foundation of California, submitted to the FDA within the past year (April 3, 1971, as further amended October 31, 1971), and which Dr. Steinfeld indicated that he had looked at, reports 196 pages (pp. 46-226, 00001-00007, 00114-00196) of animal tests on acute, subacute, and chronic toxicity studies in mice, rats, guinea pigs, rabbits and dogs treated intraperitoneally, intramuscularly, or orally with laetrile over a wide range of dosages, all indicating virtual nontoxicity (LD50 of the order of magnitude of grams/kilogram!). Such high safety values virtually never obtain with conventionally employed, clinical, anticancer drugs. The McNaughton Foundation safety (nontoxicity) data were obtained largely by the Ivy Research Laboratories LTD of Canada, and to a smaller element with mice by Dean Burk in his National Cancer Institute laboratory, during the past few years.

(3) Reasonable proposals (protocols) for initial clinical trials, based on and modelled after recent recommendations of the National Cancer Institute, were submitted in 56 pages of the McNaughton Foundation FDA-IND-6734 application on pp. 449-484, 00007a-00007i, and 00008-00062.

Further on Feb. 14, 1971 TV, Dr. Steinfeld stated that "I have reviewed a number of charts of patients who had laetrile and I must say that the only records I have seen are the dates that the patient was seen and the charge for the drug - no evidence that the patient was examined, that any tumor was found, measured, changed, or anything else."

(4) Even a casual reading of the FDA-IND-6734 application (pp. 268-371, etc.) will show, in fact, not "no" but "much" evidence that in patients treated with laetrile, patients were examined, and tumors were found, measured, or changed, and "much" else - regardless of whether such evidence would be completely adequate to establish bases for FDA-NDA approval or even Phase II and Phase III studies, since the current relevant issue of FDA-IND-6734 application is at present restricted to Phase I studies, as Dr. Steinfeld should know or have been informed about.

Dean Burk
Feb. 23, 1971.

P.S. According to the Oxford Universal Dictionary, a quack is "one who professes knowledge concerning subjects of which he is ignorant (1638 A.D. to date)." An alternative to ignorance is deliberate falsification.

To Mr. G. Edward Griffin

Burnett (or Bunnette) to Griffin, December 18, 1972

ACS

Thank you for your note - there are proven cures IF detected in time - Surgery and/or Radiation and more + more, Chemotherapy is playing its part. On page 12 of the booklet will give you more information.

Too much research money goes to improved techniques of surgery, radiation and chemotherapy. Even more time and money goes to try to discover the cause no one yet has come up with WHY the cells go into the wild growth of cancer.

Next time you are at the library ask for Unproven Methods of Cancer Management - and you will understand why the book mark.

Merry Christmas

Mabel Bunnette E.D.

Adelle Davis, 3625 Palos Verdes Drive North, Palos Verdes Estates, California 90274

August 1, 1973

Dear Mr. Griffin:

Since carcinogens surround us by the hundreds in food preservatives, additives, poison sprays, chemical fertilizers, pollutants and contaminants of air and water, the statement that cancer is a deficiency disease is certainly inaccurate and oversimplified. I still believe that nutrition is a factor, but there is a great deal we will have to learn.

Thank you very much for the royalty check.

Sincerely,

Adelle

Adelle Davis

*World Review of Nutrition and Dietetics, Vol. 11, pp. 170-198
Chemistry Department, University of life, Ibadan, Nigeria
(The Role of Hydrocyanic Acid in Nutrition)

MEMO

Krebs to Burk, March 14, 1972

JOHN BEARD MEMORIAL FOUNDATION

TO: Dr Dean Burk

FROM: ETK,JR

SUBJECT: Reprints of Two Monographs by O L Oke and my comments

DATE: 14 March 1972

"The Role of Hydrocyanic Acid in Nutrition" *

P. 172 - " Cyanogenetic glycosides have been found in the following common vegetables: maize, sorghum, millet, field corn, field bean, kidney bean (haricot), sweet potato, cassava, lettuce, linseed, almond and seeds of lemons, limes, cherries, apples, apricots, prunes, plums and pears"

Please note presence in seeds of lemons, limes, lettuce, maize, and sweet potatoes. Nitrilosides appear to be absent from these vegetables as hybridized and grown in Europe and North America.

P. 186 - " Sodium thiosulphate has been isolated .. from the normal urine of cats and dogs by Schmiedeberg (1867) and Fromageot and Boyer (1945) have shown it to be a normal metabolite in higher animals although the mechanism of its formation is obscure. Vassel et al (1944) have found that dogs excreted 2-15 mg thiosulphate in 24 hours.. Gast et al (1950) reckoned that human beings excrete about 20 mg thiosulphate sulfur per 24 hours".

I am impressed by the fact that thiosulphate is a part of the normal biological experience of the organism; therefore, I feel much more relaxed about clinicians who give sodium thiosulphate orally with B-17. At the same time I agree with you that such supplementary thiosulphate is probably not needed. It will be interesting to equate the clinical dose of thiosulphate with the average human excretion of "20 mg thiosulfate sulphur per 24 hours. (We need a score card to keep track of the-fur's and the-fur's)

P. 186 - " The highest figures so far obtained (for thiocyanate) are those of Williams (1967) for cassava and its products. He obtained 600 mg % for gari (made by fermentation of cassava), 700-800mg for cassava flour and 500-600% for yam flour"

Elsewhere in the literature there are numerous data for the concentration of rhodanese in cassava (manioc) and other nitrilosidic plants. In view of this we must not be surprised to find high levels of thiocyanate in such plant amterials after injury - frosting, wilting, harvesting, storage, grinding , etc. etc.

We have basically a common "detoxifying" mechanism in both plants and animals. The nitriloside after being hydrolyzed by beta-glycosidase presents free HCN in plant as well as animal tissues.

P. 179 - "Hydrocyanic acid is therefore a violent protoplasmic poison for all forms of life, be it bacteria, infusoria, yeast or germinating seeds".

The major point that Oke makes here is that ALL plant and animal cells - from bacteria to spermatophytes and from protozoans to primates - are highly sensitive to cyanide poisoning. He emphasizes elsewhere that intact nitrilosides are uniformly non-toxic to both plants and animals. Let's quote the attached paper from Montgomery (p 106):

> " The toxicity of the intact glucoside, however, has never been established by experiment. Auld[34] fed isolated phaseolunatin and amygdalin to guinea pigs in amounts equivalent to a yield of 12 lethal doses of HCN per day (for an unstated period) without ill effects "

Note on p. 103 that Montgomery also lists maize as nitrilosidic. The "sugar cane" to which he refers is, I assume, sorghum cane, which is nitrilosidic even in North America (the blind rationale for sorghum molasses and sulphur as a "Spring Tonic" in generations past)

On p. 105 please note 300 mg HCN per 100 gm of Puerto Rico, black beans or 210 for Burma lima beans. The nitriloside here has a m.w. 247.17. The HCN has a m.w.27. This gives us a factor, roughly, of 9. Nine X 300 mg equals 2,700 mg of nitriloside in a 100 Gm ration of Puerto Rico beans and about 1,800 mg in 100 Gm of Burma beans. This is typical of a great range of nitrilosidic food plants that millions and millions of people have eaten without even very much flatulence* (*This is another story: the flatulence produced through highly domesticated beans is largely the result of the removal or the genetic deletion of nitriloside that normally acts to destroy the bacteria responsible for such flatulence produced by bean protein).

Now let's swtich to Oke's "Cassava s Food in Nigeria". P. 227 - Note that Cassava came from Brazil. On p 228note Table I on " The value of the major food crops of Nigeria during 1956-57" - Yams, cassava (gari), Guinea corn, millet, maize, rice, cocoyams, beans and cowpeas. EVERYONE OF THESE LISTED VEGETABLES WITH THE POSSIBLE EXCEPTION OF RICE IS NITRILOSIDIC - IS A SOURCE OF VITAMIN B-17

I use the qualification "possible exception" advisedly. On p.104 of Montgomery you will note - ".. Clark[8] referred to cyanogenesis in rice, cane, millet and other grasses".. Incidentally, on p 235 of Oke ("Cassava as Food in Nigeria") you will note that the "ascorbic acid (vitamin C)content of fresh cassava root is reported as 42.8 mg/100 Gm." This would be in contrast with about 190 mg of vitamin B-17/100 Gm of fresh cassava root (Oke p 243). .. All of this is certainly in striking confirmation of your experimental studies demonstrating the relevance of vitamin C in the control and possible prevention of cancer. Vitamin C and vitamin B-17 occur very frequently together in common food plants. While we have stumbled upon the fulminating deficiency of our modern diet in vitamin C, we have, of course, so far overlooked the concomitant deficiency or absence of vitamin B-17 (nitriloside). Linus Pauling has in no way over-stated the vitamin C requirements - in my opinion.

Anthropologists and others tell us that Africa was the cradle of the human species. Be this as it may, it is certainly clear that the native dietary pattern in Africa frequently carried upwards of 1,000 mg of vitamin B-17 daily.

How about the incidence of cancer among these populations? I have an abundance of raw data showing the virtual absence of cancer among these population existing on highly nitrilosidic foods.. Rather than to attempt to hash this stuff here,

let me quote Dr Albert Schweitzer's opening sentence in his preface to Alexander Berglas' " Nature, Cause and Cure", Pasteur Institute, Paris, 1957:

> " On my arrival in Gabon, in 1913, I was astonished to encounter no cases of cancer. I saw none among the natives two hundred miles from the coast. .. I can not, of course, say positively that there was no cancer at all, but, like other frontier doctors, I can only say that if any cases existed they must have been quite rare. This absence of cancer seemed to me due to the difference in nutrition of the natives compared to the Europeans.\ The most significant difference being that the natives two hundred miles from the coast consumed no salt.
>
> In the course of years,we have seen cases of cancer in growing numbers in our region".

The greater incidence of cancer along the coast was not due to salt, but to the Europeanized food with which the salt was used. We see this in the native Indians of North America where salt became a trade commodity to them more precious than gold. I have analyzed from historical and anthropological records the nitrilosidic content of the diets of these various North American tribes. The evidence should put to rest forever the notion of toxicity in nitrilosidic foods. Some of these tribes would ingest over 8,000 mg of vitamin B-17 (nitriloside) a day. My data on the Modoc Indians are particularly complete.

At one time the American Medical Association suggested that federal officials find out why there are so few cases of cancer among the Hopi-Navajo Indians. An U P despatch in February 1949 summarized a 5-author paper in the Journal of the American Medical Association of February 5, 1949, in part, as follows:

> " The Indians' diet seems to be low in quality and quantity and wanting in variety and the doctors wondered if this had anything to do with the fact that only 36 cases of malignant cancer were found out of 30,000 admissions to Ganado, Arizona Mission Hospital.
>
> " In the same population of white persons, the doctors said there would have been about 1800 "

In the Navajos there were 36 cases of cancer where there should have been 1800, or only 2 per cent of the expected number.\At the time of this study, the incidence of cancer in rural white populations as compared to urban ones was 70 per cent. The rural white population had a "better" or larger and more calorific dietary. It differed from the Indian population in lacking the vitamin B-17 or nitriloside found in the diet of the Indian population..

The Indian populations (of North America), as I've indicated, were very heavy consumers of salt. They would even use cattle salt-licks to flavor their foods. ... Folklore on the noble savage to the contrary, these American Indians not only used large quantities of salt but they were, to say the least, highly permissive sexually toward the white population. Were there anything basically real to the imbecilic notions of vertical and/or horizontal transmission of "oncogenic viruses" (sic) these Indians with a 98% lower incidence of cancer than the white population of the same age would have reflected this - especially the females. They did not.

Elsewhere I have analysed very carefully the association between the high nitrilosidic content of the diet of the aboriginal Eskimaux, Australian Aborigine, and the Hunzakuts and the absence of cancer. We have shown this also for cats and dogs.

The attempted attribution of carcinogenesis to an excess of salt in the diet reflects a classical psychological phenomenon historically found in speculations on the etiology of chronic diseases. The mind finds no difficulty in comprehending how something can cause something, but it is almost incapable of spontaneously comprehending how nothing can cause something - how an absence of vitamin C can cause scurvy rather than having it caused by a bacterium or toxin as Sir Almoth Wright insisted it was caused . Sir William Osler was sure that pellagra was caused by a microorganism in the diet. Livingstone and others see pleomorphic organisms in neoplastic lesions. The organisms are real enough and there is a good reason for the pleomorphism.

As Warburg-Burk proved, neoplastic lesions have an unique metabolism. This fermentative metabolism is such as to induce regressive pleomorphic changes in organisms that infect these lesions. This retrogression accounts for even the so-called viral forms of such organisms.

Incidentally, Montgomery reminds us - " Hydrocyanic acid as such is not found in healthy growing plants, but develops when normal growth has been retarded or stopped by drought or other adverse conditions". This is true for animals, too. This is why parenteral doses of vitamin B-17 (nitriloside) in rodents have an LD_{50} in excess of 20,000 mg/kg.. Hydrocyanic acid "as such" is found in truly abnormal or neoplastic growths.

These facts emphasize for us the urgency for converting so-called HCN values for plants into their gravimetric equivalents of vitamin B-17 (nitriloside)

It would be somewhat tedious but not difficult to produce a book on the ethnobotany of cancer in terms of vitamin B-17 content.. But this is not too important in view of the fact that we do not rely upon a statistical correlation between the presence of vitamin B-17 in the diet and the absence of cancer in a population (in proportion to its consumption of nitrilosidic foods). Simple horse sense tells us that if by the ingestion of merely a portion of the vitamin B-17 (nitriloside) found in highly nitrilosidic diets - for example 100 mg of B-17 a day as Nieper has used with therapeutic effect - we are able to palliate advanced clinical cancer, inhibit and sometimes destroy the definitively neoplastic cells, then those consuming 17 to 20 times this quantity of nitriloside (vitamin B-17) in their foods will not develop the neoplasm that the 100 mg ameliorates even in its late stages.

II

The antineoplastic reality of vitamin B-17 certainly appears ultimately irrational if it remains uncorrelated with the basic facts on the nature of cancer. How can natural selection provide a specific antineoplastic factor against a phenomenon that is allegedly without its counterpart in the normal life-cycle? Moreover, if cancer is not basically a single disease but rather a multiplicity of perhaps 200 different diseases how can we expect one vitamin to be relevant to all 200 different diseases none of which has a normal counterpart in the life-cycle.

Cancer comprises a constant malignant component - trophoblast. It is a single disease basically; it is not a multiplicity of diseases. The malignant component is not spontaneously generated, is a normal counterpart of a segment of the life-cycle, and is malignant only because it is at the wrong place and/or time. (It is impossible for trophoblast to persist and grow at the wrong place and/or time, except as cancer)

Why should trophoblast occur at the wrong place and/or time? This occurrence is the expression of the differentiation of totally undifferentiated cells (through meiosis) in spatial and/or temporal anomaly. Why should this occur? The cells of origin are a part of the resevoir of cellular regeneration, and the capacity for meiosis at the wrong time and/or place is an evolutionary vestige of the capacity of more primitive organisms for total regeneration, which regeneration includes the transmission of diploid totipotent cells (capable of meiosis) in the regenerated organism. (Not quite!)

Why hasn't natural selection eliminated clinical cancer as an accident in cellular differentiation? For all practical purposes it has eliminated this capacity through the antineoplastic surveillant action of vitamin B-17 (nitriloside) This vitamin is specifically effective against trophoblast differentiated at the wrong time and/or place - the surveillant antineoplastic effect. The vitamin is <u>not</u> abortifacient, but to the contrary it is progestational toward normally canalized trophoblast since it facilitates the hemopoietic needs of the oncoming definitive embryo partially through nitrilizing hydrocobalamin to cyanocobalamin or active vitamin B-12, and thereby providing the necessary support for increased hemopoiesis.

But if cancer has in trophoblast its normal counterpart in the life-cycle, how is this normal counterpart controlled and then ablated from the life-cycle? This is largely accomplished through the selective digestive capacity of blood-borne pancreatic enzymes against the pericellular coat of the trophoblast or neoplast, and also through the immunological machinery of the host. The latter is dependent upon lymphocytes that infiltrate and destroy the trophoblast in hostal somatic tissue. But this infiltration and destruction can not occur <u>until</u> the pericellular sialomucin electron-dense coat has been broken or destroyed by enzymatic digestion. Then the hostal lymphocytes are now no longer repelled by trophoblast or neoplast (probably through the loss of electrons on their surface), and the lymphocytes are now able to proceed with the destruction of the living trophoblast (denuded of its repellent coat).

Why don't the endogenous factors (totality of pancreatic enzymes, lymphocytes) and the exogenous factor (vitamin B-17) completely prevent the differentiation of cancer? Were they capable of doing this they would be capable of preventing gestation itself. They do not prevent the differentiation of tissue nor even the differentiation of trophoblast at the wrong time and/or place. The extrinsic factor or antineoplastic vitamin, however, prevents the metastases of the neoplasm (trophoblast at the wrong time and/or place) though it does not completely prevent the full morphogenesis of the lesion in the presence of sufficient organizer stimulus acting over a sufficient period of time.. Thus vitamin B-17 probably would not prevent the differentiation of papillomata in familial papillomatosis nor even the development of adenomatous tissue in a breast excessively challenged with a continuing supply of estrogen (in the absence of countervailing androgen). What vitamin B-17 (as well as the intrinsic factors) would do is to exert its surveillant antineoplastic activity against the emergent trophoblast and thus either ablated it totally or keep its vestiges non-metastatic.

If we evade the rational biological corollaries of the implicit claim of vitamin B-17 as an antineoplastic vitamin - implicit from our application of it for this purpose - we probably invite irrational or magical expectations from the physician and/or his patient. We leave them to look upon Laetrile as possibly a quasi-magical potion designed to resolve almost magically clinical cancer with all its somatic "lumps and bumps" included.

We have one rational escape from the problems that antineoplasticity presents for vitamin B-17, and this is to consider vitamin B-17 apart from its anti-neoplastic activity. We know that the thiocyanate which it produces is a physiological hypotensive agent applicable to hypertension. We know that the p-hydroxybenzoic acid or benzoic acid produced as a byproduct or a metabolic product is an effective antiseptic and antirheumatic. We know that the HCN yielded is critically associated with vitamin B-12 production and metabolism.

Vitamin B-17 in the non-neoplastic universe presents no special theoretical problems because this universe is relatively well explored - known. The universe of cancer is for all practical purposes totally unexplored - unknown. The unitarian or trophoblastic thesis alone not only identifies this unknown universe of cancer but maps it as well. If we choose to follow this map when bringing vitamin B-17 to this universe we can not fail to apply B-17 effectively and rationally within the parameters of reality that nature, rather than our preconceptions, have in the course of natural selection defined.

..

Back to Oke, P 182 - " If detoxication is equal to absorption no death occurs no matter the amount" of cyanide. This tells us that the organism is obviously metabolically prepared to handle almost any dietary quantity of vitamin B-17. Consider the table on p 182 that labels arrow grass carrying 25-50 mg derivable HCN/100 g dry grass as "relative degree of toxicity Low (safe to pasture)". This amounts to about 500.0mgg for a 100 g ration - worth probably 300 calories. This would be about 5,000 mg of vitamin B-17/kg of dry arrow grass.. Then note that arrow grass with the equivalent of 9,000 mg vitamin B-17/kg is considered dangerous. Compare these figures with 1,?00 mg vitamin B-17 in 100 gm of Burma beans or 18,000 mg vitamin B-17/kg. This is a safe ration for man.

The cyano group is as tightly if not much more tightly bound in the coordination complex of vitamin B-17 as it is bound in that of vitamin B-12 (cyanocobalamin). Intravenous doses of vitamin B-12 up to 1600 mg/kg are non-toxic to mice (Winter, C A and Mushett, C W , J.Am. Pharm. Assoc., 39:360, 1950). A dose of 1600 mg/kg of vitamin B-12 contains the equivalent of about 32 mg/kg of cyanide or about 8 times the LD_{100} dose. (Mushett, C.W., Kelley, M.L. Boxer, G.E., and Rickards, J.C., Proc. Soc exp Biol Med., 81:234, 1952). The LD_{50} of vitamin B-17 (nitriloside) in mice , intravenously, contains the equivalent of about 385 times the LD_{100} dose of cyanide.

P 193 - Oke - " When hydrocyanic acid is converted to thiocyanic acid there is a 200-fold reduction in toxicity"

P 190 - Oke points out that only about 25 mg of cyanide can be detoxified by the hydroxocobalamin. In other words, the cyanide supplied by about 400 mg of Laetrile (vitamin B-17) is sufficient to convert all the hydroxocobalamin in the liver and elsewhere to cyanocobalamin (vitamin B-12).. We see the results of this in the not infrequent and very definite improvement in the hemogram following Laetrile or vitamin B-17

P 175 - Oke - We are reminded that thiocyanate oxidase occurring only in the erythrocytes of man brings about a conversion of thiocyanate to cyanide. We can appreciate that the very low serum thiocyanate levels generally found in vitamin B-17 deficient subjects will often not produce enough cyanide to nitrilize all the hydroxocobalamin in such subjects. This deficiency could obviously play a

role in the etiology of anemia. We have seen the very high levels of thiocyanate that accumulate in such injured nitrilosidic food plants as cassava. It is clear that even when the vitamin B-17 in such plants has been metabolized to thiocyanate the ingestion of the plants contributes to "the metabolic cyanide pool of the organism".

Where there is a basic vitamin B-17 deficiency in the diet there is obviously no plant-contributed thiocyanate in the B-17 - deficient plant material. Thus there is not even the thiocyanate oxidase-derived cyanide available to the organism. The food chain in vitamin B-17 is further fractured in the modern commercial feeding of cattle and poultry that have been raised on non-nitrilosidic plants. Cows so raised show practically no thiocyanate in their milk - as contrasted to high thiocyanate levels in the milk of cows that graze upon nitrilosidic plants. The same is true, of course, of the thiocyanate levels in beef, lamb, and pork.

We have a <u>direct</u> fulminating dietary deficiency in vitamin B-17 (nitriloside) as well as an <u>indirect</u> but equally fulminating dietary deficiency through the meat, poultry and egg levels of thiocyanate.

This deficiency spells a concomitant deficiency in dietary salicylic acid isomers and benzoates with their antiseptic, antirheumatic and anti-inflammatory effects. Since thiocyanate is an established hypotensive agent at serum levels of upwards of 4 mg/%, it would seem to follow that profound and continuing low serum thiocyanate levels could be associated with some hypertensive states - at least those responsive to serum levels of thiocyanate in excess of 4 mg/% induced by administering thiocyanate medically.

The action of thiocyanate in "increasing the efficiency of enzyme action" may be mentioned in passing, since it is not improbable that proteolytic enzymes involved in, among other things, the lysis of living trophoblast may show an increased efficiency in the presence of proper serum levels of thiocyanate.

**

In looking at the dietary concentration of vitamin B-17 (nitriloside), which may run as high as 3,000 mg or more in the diet of certain aboriginal populations, the question as to the metabolic capacity of the organism for B-17 comes to mind. In the descending order of the magnitude of their capacities, we have the following "reservoirs" for vitamin B-17 and/or its metabolic cyanide:

(1) A 70 kg subject may receive in excess of 50,000 mg of vitamin B-17 (nitriloside) intravenously during the course of 2½ hours without toxic effect.

(2) Dietary nitrates and /or nitrites can convert over 50% of the hemoglobin to methemoglobin without permanent toxic effect. The cyanide from about 7,000 mg of vitamin B-17 will combine with the non-toxic methemoglobin in a 70 kg subject to produce non-toxic cyanohemoglobin. (Recall that hemoglobin or oxyhemoglobin as such will not combine with cyanide)

(3) The next reservoir is that of serum thiocyanate (as well as the thiocyanate level in other body fluids). Without

reaching an excessively hypotensive serum level of thiocyanate (i.e., above 8 mg/%) the thiocyanate serum concentration in a 70 kg subject can carry the cyanide from about 5,000 mg of vitamin B-17 (nitriloside)

(4) The precursor to active vitamin B-12, hydroxocobalamin in a 70 kg subject can carry the cyanide from the equivalent of about 400 mg of vitamin B-17

(5) Thiazolidine as a metabolite of vitamin B-17 cyanide will account for the cyanide from about 1,250 mg of vitamin B-17 (nitriloside) in a 70 kg subject

(6) Probably the cyanide from about 250 mg of vitamin B-17 goes to supply 1-carbon fragments for the synthesis of mono- and di-methyl glycines as well as choline for a 70 kg subject Part of the cyanide carbon goes off as CO_2 and some as exhaled HCN in the breath

My simple calculations are derived from the elementary quantitative data of human physiology; these calculations are very easy to check. For this reason I've not bothered with the details of calculation.

In summary, we could generalize that a 70 kg subject can handle with ease in the normal or physiological reservoirs of the body the metabolites from about 12,000 mg of vitamin B-17 (nitriloside). I believe that one may superimpose upon this the injection intravenously of 50,000 mg of pure vitamin B-17 (nitriloside) without toxic effect to make a non-toxic total of about 60,000 mg of vitamin B-17 (unmetabolized as well as metabolized) that the body can handle.

Our concern here is not in the question of non-toxicity of vitamin B-17. The non-toxicity of it is obvious. We are interested in the physiological consequences of the dietary intake of vitamin B-17 at levels of ,2000 mg or more a day found in the normal diets of aboriginal populations. Consider the fact that the metabolic products of at least 12,000 mg of vitamin B-17 are non-toxic in the 70 kg subject. This means, for example, that such a concentration could well introduce 3,000 mg or more salicylic acid isomer - p-hydroxybenzoic acid - or benzoic acid into the 70 kg organism. This is equivalent to 50 grains of these antiseptic, antirheumatic substances. This intake is in excess by 10 fold of the therapeutic doses of these substances.

The benzoic acid as well as salicylic acid isomer in the dietary rations described present a level 5 times in excess of that which is medically antirheumatic, for example. IN concentrations of 1:1000 the benzoic acid will prevent food fermentation in packaged food.. In a 5 to 10 fold greater concentration in the intestinal and urinary tracts this metabolite is not without effect. In brief, it should come as no surprise that the cancer-free aboriginal populations also showan impressively low incidence of rheumatoid arthritis.

There is a physiological and nutritional mainland China that has been overlooked in our overlooking the existence and essentiality of vitamin B-17 (nitriloside).

There are, of course, a few systematisations or conventions to be determined in the matter of nomenclature. The Vitamin B-17 (nitriloside) category is divisible into the glucosides of mandelonitrile, on the one hand, and the glucosides of acetone cyanohydrin on the other. Both divisions are susceptible to hydrolysis by beta glucosidase. When we see the vitamin B-17 content of a plant reported in terms of HCN, we obviously must use the conversion factor appropriate to the nitriloside in question to convert the cyanide into the related quantity of vitamin B-17.

It would seem a little awkward to designate the mandelonitrile nitrilosides as nitrisolide-a (Vitamin B-17$_a$) in contrast to the acetone cyanohydrin nitrilosides which could be designated as vitamin B-17$_b$ (nitriloside-b).. Perhaps we could designate the mandelonitrile glucosides as simply vitamin B-17 (nitriloside) and reserve the subscript a for the acetone cyanohydrin nitrilosides - vitamin B-17$_a$.

Any suggestions that you have on this would greatly be appreciated.

I believe that after reading Dr Oke's brilliant monographs you will probably agree with me that he is the top living authority on nitrilosides. It is gratifying that he recognizes their vitamin status.

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Mr G Edward Griffin
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26 December 1971

Dear Mr Griffin:

We all enjoyed very much your excellent and impressive TV presentation over San Francisco Channel 5 on 26 December 1971 !

As you say, "perhaps it is a blessing that we can not move too rapidly" in the case of Aprikern. In this movement our only major concern is state and federal bureaucracy. With the PREVENTION article (December 1971) " a tremendous amount of interest in this subject is being developed", as you say. We have two levels to consider for Aprikern production. The first is the simple production facility and the second is the machinery of distribution. These two steps are confronted with only a single major problem: bureaucracy. The bureaucrats have the power to order a plant closed on any one of a thousand or more different ruses or excuses. They are always prepared to make such a move at the impelling request of any well heeled lobby that pays the going price.

The production facility for Aprikern requires a simple food license. No true problem here except that such a license gives bureaucracy the address and 'phone number. The bureaucrat is now prepared to strike at the plant level as well as at the level of distribution, though at the first level usually where distribution may obviously be automatically aborted. In the absence of full licensure, then the first and second levels become targets for even more effective strikes.

The enemies of things like Aprikern recognize that it is a product with a continuing or recurrent market, and this very continuity factor makes the product a dangerous competitive threat to non-recurrent goods and services in this field . Aprikern is a food and the uneaten ration of yesterday can not be deferred for ingestion to-morrow since to-morrow has its own Aprikern requirement.

Were Aprikern to be allowed by bureaucracy to enter the market as the pure food it is, I am confident that its sales, conservatively estimated, would surpass $750,000 a month within 2 months of introduction. Bureaucracy, however, precludes phenomena like this from occurring very often. Monopoly has its custodians of the valves of commerce in the regulatory agencies of state and federal government. These valves are quickly shut off when and if a newcomer threatens to preempt any substantial market area.

Who needs the primitive old fashioned form of graft in government when a division of H EW can aseptically award Hoffman La Roche with a $1,250,000 contract for 5-FU

for "clinical investigation" of this patented drug when without patent protection the same amount of the chemical could be produced for about $17,000? While doing this, Laetrile (nitriloside) was denied clearance for clinical investigations to be supported not by government but by private individuals. That the 5-FU "study" produced nothing concerns no one. In fact, there is little evidence that a pretense at a "study" of this useless and highly poisonous compound was ever made. The patent on 5 FU is shared equally between the American Cancer Society and Hoffman La Roche.

Were the FDA to permit the "clinical investigation" of Laetrile (nitriloside) this permission in one stroke would wipe out the market for such useless and dangerous preparations as 5 FU. Patients and physicians desperately seek to do something in the face of terminal cancer and their options are obviously limited by what is legally open to them.

The full awareness of the significance of vitamin B-17 (nitriloside) is now registering in the minds of our bureaucrats and those whom they serve. The attitude is becoming obvious even to us that these people feel vitamin B-17 (nitriloside) is too good and too valuable for the Indians. Just as in the past when valuable minerals or oil were discovered on Indian lands, government bureaucracy would move the Indians away to "better land" so attempts are being made now to move all innovators and pioneers on vitamin B-17 (nitriloside) away from the development - through the invocation of one legal ruse or another - until it "cools", and then allow monopoly supporting the involved bureacracy to preempt the field.

For example, should General Foods and American Home Products decide to market Aprikern products to-morrow and Laetrile under another brand name federal and state bureaucracy could "clear" such products for these giants while denying clearance for any of us on any imagined grounds from adequacy of plant facilities to suspected subversion, or "conspiracy".

We are not dealing with theory but with actuality. Recall that one minor league company was making inroads into the condensed soup business when it was disocvered that 2 or 3 cans of vihysoisse had been infected with botulinus. This incident bankrupted the company involved.

In the Old World power and economic stratifications seemed more fixed or permanent than in America. Corruption in government seemed more extensive there. In America the same stratifications are maintained with much greater adroitness and sophistication Here bag men are fewer in the cruder sense of the term. But a general who behaved properly finds himself after government retirement in an all-pay-no-work position in a munitions outfit. Ex-FDA help find similar places in the major drug and food companies.

II

In view of all this, it is obvious that these requirements of surviving government bureaucracy are so overwhelming that discussion at this time of price for supplies, etc is almost irrelevant. We want to keep clearly in mind that the strategy of bureaucracy in areas such as ours is often to tolerate for varying periods of time

technically evasive acts so that those involved may be contained and then terminated at a time propitious for the interests of bureaucracy. On the other hand, a heavy and direct confrontation of bureaucracy would be less profitable to bureaucracy through broadening opportunities beyond those directly favored by bureaucracy while gaining for the "direct actionists" no special advantage. When this threatens bureaucracy then turns to tactics of economic attrition: the unlimited wealth of government against the limited wealth of free enterprise.

Were we aware of effective defensive tactics we would be employing them. The one even partially effective defensive tactic is fragmentation. The more autonomous groups that appear at a given time the less capable bureaucracy is of subverting them; but, even more important, the less profit or incentive bureaucracy finds in attempting such subversion because the appearance of multiple autonomous groups automatically destroys the political-economic basis that makes bureaucratic concern profitable.

Please keep in mind that the potential or waiting market for Aprikern is at least as great as that for all the other vitamins, including C. To-day bureaucracy can make or break a billion dollar market within a few days with merely a few pronouncements or edicts. A Surgeon-General, bought just like fresh beef (but not as intrinsically valuable), can say "yes" or "no" on phosphate or non-phosphate detergents on evening TV. He reads his lines as they are given to him and the markets move accordingly. Despite a few twists and turns for window trimming, monopoly is almost always sustained in this game.

Nixon has just signed the bill giving HEW's NCI $1.6 billion as a starter for cancer research. Can we expect HEW's FDA to allow a situation to develop from which vitamin B-17 (nitriloside) in the prevention and management of human cancer could obviate the need for this $1.6 billion and billions to come?

Sincerely,

Ernst T Krebs, Jr
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Mr Edward Griffin
American Media
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Dear Mr Griffin: 23 September 1973

Thank you for your letters of 28 August and 17 September as they pertain to my educational background.

I enclose a photocopy from a current issue of WHO'S WHO IN THE WEST, in which I've been listed for the past 17 years. This accurately reflects the nine years of formal collegiate training taken at Hahnemann Medical College, University of Illinois, and University of California. It omits about another two years taken , in part, at University of Mississippi and at various summer sessions.

The reason that these institutions withheld the M D and Ph D should not be difficult to guess. (The dean at Hahnemann, Dr Cameron, was the medical director of the American Cancer Society) I was explicitly instructed to renounce Laetrile, pull off it, or be denied an earned doctorate in the institutions involved. (My brother touched Laetrile after completing his course of studies; he spent $1,000 with Mr Harry Segal, Esq, Los Angeles, in a successful suit to win his M.D., which was being withheld if he did not promise to abandon Laetrile. Our father and his brother were also M.D.s involved in Laetrile, though the latter withdrew in order to remain in good standing with the AMA)

Despite all this, I could not be prevented from taking whatever graduate work I chose because I certainly had demonstrated competence for such. This general situation brought me in 1959 to seek through one Harry Goodfriend an honorary doctorate in science from the University of Panama. This was obtained, but Mr Goodfriend subsequently proved to be less than a reliable person and for this and many other good reasons I have felt it wise not to refer to the Panamannian degree.

It so happend that a small university in Nevada on March 22, 1973 granted me an earned Ph D (a photocopy of the diploma is enclosed). This is an academically poor institution but an operative and legally chartered one. In this step I have further technically subverted the original and admitted conspiracy against my progress with Laetrile and against the unitarian or trophoblastic thesis of cancer. The conspiracy was particularly vicious because its- grim intent was to trade on the fact that there were 3 Krebs in Laetrile with MDs while the fourth, and by far, the most active, myself, was denied a doctorate. The technics of obfuscation to which this situation lent itself at the hands of the enemy must be obvious.

As my work continued, there were academic spin -offs. The work that I pioneered on Leptotaenia dissecta (leptonin) was subsidized through the efforts of the late Mr Edward Spicer and myself at the University of Southern California and brought Daniel Everett Johnson an M A in microbiology. We obtained further subsidy for leptonin at UCLA and this brought him a Ph D there in microbiology with leptonin the subject of his thesis. This initially attracted considerable attentionuntil the late Ian Macdonald, whom you will probably remember, visited UCLA and persuaded them to "black out" the entire leptonin matter lest it advance the cause of the Krebs in matter of Laetrile.

Arnold Lowman obtained both his M A and Ph D in the Department of Pharmacology at University of California on the early Laetrile extracts. Less than two years ago my stepson obtained his Ph D from University of California, in pharmacology and biochemistry, for his studies on my patented discovery of diisopropylammoniumdichloracetate. Peter also obtained his M A from University of San Francisco on the same discovery. So far there have been at least 8 or 9 graduate degrees issued on the basis of theses directly and explicitly representing my work and discoveries. Further work on Laetrile, after Lowman, was specifically disallowed.

The USSR Academy of Sciences and about 27 universities over the world account for approximately 400 papers based on my discovery and synthesis of vitamin B-15 (pangamic acid). I will not go into the impressive list of domestic and foreign patents that have issued on at least half a dozen or my discoveries. Incidentally, I enclose a photocopy from page 424 of the July 23, 1973 (Vol 225, No 4) issue of the Journal of the American Medical Association entitled " Vitamin B-15.. - To Live Longer and Happier". It quotes Vasili Bukin, MD, head of the Biochemistry Research Institute of the Academy of Medical Sciences of the USSR, to the effect that a new book will shortly be published in the USSR on vitamin B-15 (pangamic acid)

I was assured by my academic mentors that if I refused to obey, conform and be controlled- be a member of the club - I would pass into oblivion. I would be denied academic recognition, degrees, jobs, institutions, etc. My answer in the vernacular was for them to stuff the entire business because we still had enough freedom in this country for me to go out to establish my own research foundation - John Beard Memorial Foundation - under the despised doctrine of free enterprise.

It was tough as hell for a time, but I have never for a moment regretted my original decisions in behalf of freedom. One atom of freedom is more powerful than a continent of slavery. Forge the chains in platinum and encrust them with emeralds and diamonds and they still remain chains. Human achievement is the history of those who will never wear chains.

We have won, but I can't take the time here to give you the details of the great events that are occurring now in the de facto validation of Laetrile and the unitarian or trophoblastic thesis of cancer.

We are realistic enough to know that there will be some frantic but unsuccessful efforts to preempt and annex what has been achieved. We do not like conspiracies against the public welfare nor those who so conspire. I would find an wholesome delight in shafting those forces who in the past in such petty and unsuccessful ways attempted to destroy or control me and my work because of their antipathy against individualistic enterprise.

Accordingly, I would like very much to see such institutions as Bob Jones University, American Christian College, University of Plano , Lubbock Christian College, and the like (listed in "The Review of the News") extend formal invitations to me to accept doctorates in science (honoris causa) before university convocations at which I would present scholarly but lucid and explicit accounts of the solution to the cancer problem. Such presentations would be so prepared as to lend themselves to scholarly publication under the imprimatur of the institution involved.

We would want the citations, in every case, to include the explicit claim of the solution to the cancer problem as involving the identification of cancer as trophoblast "out of phase" and B-17 as the specifically surveillant amtineoplastic vitamin. Such citations could also mention the USSR Academy of Sciences, their publications and books, on the validation of the American discovery of vitamin B-15 (pangamic acid) while saluting free enterprise - so often accused by its enemies as being possessed by money but bereft of imagination and discovery. The recommended acts by the various institutions should be given the widest publicity at ALL LEVELS. Such acts are ones that can not be erased or obscured. Eggs can not be unscrambled. By "risking" a few months of historical prematurity, the reaction of initial criticism (if it came) would itself give such institutions a priority for vision and intelligence that would serve them well and long.

All this is something that obviously calls for immediate flat out action. I believe that it is of such import that I am forwarding a copy of this entire communication to Mr George W Kell, Esq since I believe that somehow I was first inspired by him along the expressed general course. It is pointless to be coy when engaged in mortal combat. There are no prizes for losers.

I'm intensively engaged in the details of the final stagesprior to the universal announcement and acceptance of the work. Who and what forces will be identified with this victory? I shall be prepared upon a week's notice to take a plane anywhere that it is necessary to go, mount a podium and spell out word-for-word in clear compelling language the solution to the cancer problem and have the guest university ratify the claim by granting it s scientific doctorate (h.c.) with an explicitating citation of the achievement. In fact, I would rather see the FIRST recognition come from such as Bob Jonea University than even the Rockefeller University of New York.

Obviously, I believe that the confidentiality of this communication should be strictly respected.

ETK,JR

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Mr Andrew R L McNaughton
The McNaughton Foundation
315 Montgomery Street, Room 1610
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2 August 1971

Dear Andrew:

I have read Professor Navarro's letter of 24 June, which you so kindly forwarded on 29 June.

Conceptually his proposal of using the presumptive CGH extracted from cancer urines as an antigen to produce an antiserum against which to test for (and titrate) CGH from any source is brilliant. It is obvious that if CGH is actually the antigen that the CGH antiserum detects when it is added to an extract of cancer urine, the detected CGH itself may serve as an antigen from which to prepare an antiserum that is specific because the testing antiserum of the CGH immunodiagnostic pregnancy kit was itself prepared by the use of CGH as an antigen.

In my opinion, the major problem in Dr Navarro's proposed study is that of obtaining from cancer urine CGH or CGH-like antigen of sufficient purity. If the cancer CGH (the phrase "cancer antigen" is too much) is recovered in a mixture of contaminating proteins and other molecules and then used as an antigen the resulting antiserum is going to be actually a collection of antisera and so "polyvalent" that it will probably yield a general mammalian reaction in every specimen of human body fluid tested for CGH. If foreign antigens can be excluded from the cancer CGH in a quantity sufficient to provide an antiserum to CGH of a titer much higher than the titers to the admixed antigens in the (polyvalent) antiserum it will be possible to use the "CGH antiserum" for the purpose of detecting CGH.

The advantage one has here is that the proposed antiserum may be used against high concentrations of stock CGH antigen (which should be sufficiently pure to assay about 8,000 I.U./mg or more). The object of the whole project is, of course, to demonstrate that cancer does carry a CGH antigen - even though it sometimes be in such very small quantities as to provide a low titer antiserum. This is in a degree corrected by titrating such antiserum against high concentrations of very pure stock CGH.

Of course, the CGH antigen when used to make the antiserum need not be too pure if one takses the associated antigens - free from cancer CGH - and proceeds to make a high titer antiserum from them. Such antiserum added to a solution of "cancer CGH" will, of course, adsorb from it all the non-CGH antigens. The resulting antigen-antibody complexes may then be removed from the solution and thus leave an almost pure CGH antigen in solution. This is the old "antigen-antibody adsorption technic" - a classical one in immunology.

All of this is very elementary to Dr Navarro, but I am repeating it here to be sure that we are all generally agreed on the proposed project.

While it is usually important that one personally conduct all steps of his experiment from A to Z, there is much to be said for having the proposed "cancer CGH antiserum" prepared independently by a good laboratory working in immunology. The technics involved are among the most commonplace in immunology, especially in the field of commercial serum production.

Dr Navarro's question is good but rhetorical - " Now, if we test the urine of pregnant women with this anti-serum, should we not get the same positive result? We should". I say we would. We would also get the same results from testing placental tissue. The intensity of the reaction - the CGH titer in the placental tissue - would decrease as the placenta approaches term. Very high CGH concentrations would obviously be found in association with chorionepitheliomas in both sexes - genital ones as well as extra-genital.

A detailed project on the "possible proof of the trophoblastic thesis of cancer" might include preparing an antiserum of whole placenta-free human embryos of various stages of development. Such antiserum would be checked against (a) stock CGH and (b) presumptive cancer CGH. Both reactions should be negative because the definitively embryo contains no trophoblast. Both reactions should be positive if either stock CGH antiserum (prepared from pregnancy urine) or antiserum prepared from CGH cancer antigen be used.

A further refinement - or extension - would involve preparing antisera from the respective organs of the definitive embryos and even infants. Such antisera would then be checked against stock CGH. The reactions should be negative. The same against "cancer CGH"... We would, of course, commence picking up the carcinoembryonic antigen or fetal antigen, so-called, of Phil Gold of Montreal et al. We would pick these up from normal definitively embryonic gut (trophoblast-free).

Then as we found these respective organs neoplastic (i.e., hybridized by definitive trophoblast) we would find: (1) each organ immunologically identifiable by its corresponding antiserum (e.g., antiserum against kidney forming antigen-antibody (antiserum) combinations with non-neoplastic kidney, etc.); (2) possessed of a disidentity with an unrelated antiserum (e.g., antiserum against gastric tissue failing to form an antigen-antibody combination with kidney antigen); and (3) running through ALL of the respective organs with tissue in trophoblastic or neoplastic hybridization an antigen that would combine with specific stock antiserum CGH as well as with cancer CGH antiserum.

This would, of course, be the common denominator of neoplasia that would run throughout all trophoblast-hybridized tissues or organs - this cancer CGH. Moreover, we would want to show a gravimetric identity between CGH from pregnancy urine and placental tissue, on the one hand, and CGH from cancer. This would involve titrating weighed amounts of the two CGHs with CGH antiserum to show that a milligram of each carried the same number of International Units. The CGHs would be purified by chromatographic adsorption, electrophoreses, etc.

II

We are discussing this far beyond the simple level of "diagnostic tests" because in this country the greatest single criticism of the proposed Nixon program to spend billions on cancer research is that science lacks an unified concept

It is a new record in tautology to remind oneself that there is only one unity. For this reason any attempt to "solve the cancer problem" outside of its actual solution in the unitarian or trophoblastic fact of cancer is a total waste of time and money whether we spend $10 or ten billion dollars. In the UTTC we have the science. All that we require from government are the funds for technological demonstration.

This demonstration along immunological lines would involve the basic procedures suggested for CGH but they would go far beyond CGH to embrace trophoblastic ACTH (t-adrenocorticotropin), trophoblastic ADH (t-antidiuretic hormone), trophoblastic TSH (t-thyroid stimulating hormone), and other trophoblastic hormones. A full profile of trophoblastic hormones would be utilized in such studies.. Then beneath these common trophoblastic protein hormones we would seek (through the use of very primitive trophoblast - possibly from the 84-cell stage of an human conceptus) the common protein denominator as an antigen. 4 p.9

Quantification would be expressed in terms of micro I.U.s. That is, we would divide the present International unit for CGH into units of 0.001 the present units. We would use starting urines of a specific gravity adjusted to a level low enough to cover all urines (with the possible exception of diabetes insipidus). We would probably want to use blood serum specimens for obtaining the initial reading which would be correlated with the urinary reading at an adjusted specific gravity.

III

Even one molecule of CGH in the male or in the non-pregnant female is certain evidence of cancer however "preclinical" or "subclinical" it be.

Under our present vitamin B-17 (nitriloside)-deficient dietary it would not be at all surprising to find almost 100 per cent of the population showing some quantity or other of trophoblast antigen in the body-fluids.

If our quantification of trophoblast antigen or hormone be precise enough, it is almost obvious that we shall be able to demonstrate the practical antineoplastic action of vitamin B-17 (nitriloside) from the start as reflected in a decrement in trophoblast hormone titer that correlates with the quantity of pure vitamin B-17 ingested or injected or with the quantity of concentrated food sources of vitamin B-17 such as the fat-free meal of seeds of apricots, peaches, apples, etc.

Carcinogens, Viruses, etc. While preliminary reviews of cancer epidemology leave little doubt that the total number of cases of cancer - morbidity and mortality rates - in age-adjusted civilized populations is practically the same country-for country, the site incidence varies widely in various populations. Cigarets, for example, supply the carcinogens that largely determine the pulmonary system as the site for neoplastic induction. In the absence of the carcinogens of cigarets in a given modern population (e.g., Seventh-Day Adventists) the site incidence in terms of cancer of the lungs is extremely low as compared to smoking populations. But the total incidence of cancer in this population is practically identical with that of smoking as well as other non-smoking populations.

The dietary deficiency in vitamin B-17 (nitriloside) is a constant. The occurrence of specific carcinogens is a variable. The vitamin B-17 deficiency is so constant or uniform as to account for an almost identical mortality rate in the most varied ethnic groups living under standard environmental conditions.

Since the origin of all cancer shares a basic morphogenetic process - the proliferation and ultimate differentiation of normal body or somatic cells - those agents which foster cellular proliferation and differentiation for prolonged periods of time and to an extreme degree are carcinogenic.. Keep in mind that the morphogenetic events leading to malignant induction, as well as malignant induction itself, are fostered by carcinogenic agents (whether estrogen, polycyclic hydrocarbons, radiation, viruses or the like separately or additively); and that malignant induction occurs whether there is a plethora of vitamin B-17 (nitriloside) in the diet or a total deficiency of B-17.

In the presence of B-17 the emergent trophoblast (neoplast) is sheared off before a clinical neoplastic lesion may develop. This does not mean that the carcinogen fails completely to express its cytopathogenic harm to the host - sometimes expressed in benign dysplasias or minor tumefactions.

Because certain viruses, if not the majority, are cytopathogenic and in foreign hosts will stimulate cellular proliferation and often ultimately neoplastic differentiation (meiosic of a diploid totipotent cell with the introduction of trophoblast) viruses can obviously under certain conditions bring about malignant induction. In the dietary absence of vitamin B-17 - especially in a host with pancreatic enzyme deficiency and depressed lymphocytic defense - the induced neoplasm may come into clinical bloom.

Are there cancer viruses? At one time cancer virologists looked at cancer as the common expression of extremely uncommon viruses. To-day they see the picture more clearly as that of cancer being an extremely uncommon expression of the presence of extremely common viruses. It is about as silly scientifically to talk of cancer viruses or oncogenic viruses, as such in man, as it is to label a given automobile as "the leg-break factor" because it ran down Mr Jones and broke his leg.

IV

One of the most urgent needs that the technological implementation of the UTTC would meet is that of demonstrating the qualitative malignancy or lack of it in a given lesion.. Too many clinical oncologists look at "lumps and bumps" in absolutistic terms. They are either benign or they are cancer to such men. If they be cancer it matters little whether they be 99.85 per cent somatic or hostal - which they not infrequently are - or whether they be 90 per cent truly neoplastic, which they seldom are. The former produce very large tumefactions, as a rule, while the latter show little or no tumefaction.. Yet it is "the index of tumefaction" that misguides the therapist to radiate or cut away what is essentially defensive or reactive somatic or hostal tissue while producing a relative concentration of definitively malignant tissue.

For at least three to four years after the universal prophylactic and/or therapeutic use of vitamin B-17 (nitriloside) there will be a dwindling number of patients with "burned out" or erstwhile neoplastic lesions. These will represent sometimes large, indolent fibrous masses for the greater part. Some of them may show ulceration and open drainage. They will look horrible. All of the vitamin B-17 injected and/or ingested won't change them much. They are biologically benign. In time the generation so affected will die off, but in the meantime it is to be hoped that idiocy of cautery- be it x-ray, cobalt or linear accelerator - will be withheld mercifully from such victims. Surgery will have its mechanical indications in association with neoplasia persisting from the pre-vitamin B-17 era.

One can not expect to burn or cut away a chronic dietary deficiency disease nor restore the tissue damage done by toxins or carcinogens by the use of the knife or radiation. The present morbidity and mortality rates for cancer are dramatic proof of the futility of such measures.

The CGH project Dr Navarro outlines is of fundamental importance to problems extending well beyond cancer. Consider the action of the pancreatic enzymes in digesting the pericellular coat of pregnancy trophoblast and thus rendering it vulnerable to destruction by hostal lymphocytes. The divestment of the pericellular coat from trophoblast exposes its underlying antigens which then invite lymphocytic attack that destroys the trophoblast. These enzymes, incidentally, selectively digest CGH and other trophoblastic protein hormones. Hertig and other years ago reported how normal or intact pregnancy trophoblast repels lymphocytes. Hertig says that he never saw the trophoblast of a threatening abortion in situ that was not infiltrated by lymphocytes while he has never seen normal pregnancy trophoblast that did not repel lymphocytes.

We have long known from substantial independently published studies (i.e., studies conducted in a context oblivious to the UTTC) that CGH is a very powerful inhibitor of rhodanese.. We know what this means in terms of the antineoplastic activity of the extrinsic factor or dietary factor vitamin B-17 (nitriloside) in confrontation of a beta-glycosidase-rich-rhodanese-rich trophoblast or neoplast. We have now just run into indpendently published studies reporting the powerful effect of CGH in repelling lymphocytes!

For three-quarters of a century classical immunology has, in effect, been pounding its head against a stone wall in the vain quest for "cancer antigens", the production of cancer antibodies, etc., etc. The cancer or trophoblast cell is non-antigenic because of the pericellular sialomucin coat.

From the perspective of classical immunology countless hundreds of experimenters have vainly tried to use cancer cells as antigens. Dr Navarro's suggested experimentation is, among many other reasons, very good because it for probably the first time allows classical immunological procedures - simple antigen-antibody reactions - to be fruitfully employed in at least the diagnosis if not the adumbration of cancer. While the coating of the trophoblast or neoplastic is immunologically priveleged - non-antigenic - the diffusible hormone produced is of necessity antigenic to a mild degree.. Certainly not so antigenic as to produce hostal antibodies that might persist to interfere with a subsequent pregnancy. But just possibly antigenic enough to provide CGH antibodies in the new mother to clean up through antigen antibody combination persisting CGH.

V

As you know, immunology is almost as big a thing in modern cancer research as are viruses. Both obviously find their niches in the UTTC. It is stupid to persist in attempting to find "cancer vaccines", "cancer therapeutic antisera", etc.; or vainly seeking specific "cancer viruses" against which to prepare vaccines or sera.

The total factors in the normal governance of trophoblast in the life-cycle are: intrinsic - function of the pancreatic enzymes and strong immunological defense through largely lymphocytic function; and extrinsic - vitamin B-17 (nitriloside) as the specific antineoplastic vitamin (within the context of totally adequate nutrition).

Vigorous repair and tissue regenerative processes are indispensable to multicellular life. These involve cellular proliferation and cellular differentiation.

Vitamin B-17 (nitriloside) has been naturally selective as surveillant against the possibility of a persistent neoplastic or trophoblastic differentiation overwhelming the host. Pancreatic and immunological function are adjunctive. The assurances or protections are at least triple.

We do not commence to comprehend the fantastic upheaval that has occurred within the last century in the ecology that determines man's destiny. This last century is barely a minute in the history of human evolution. But consider this so well put by Aviva Wiseman (Roy. Soc. Health, J., 91 (2):134-138, May-June 1971:

> " The fact that more men, women and children are alive today than the total of all human beings born before the beginning of this century is difficult enough to grasp.. "

The total solution to cancer was naturally resolved among that minority of mankind born in the century of our parents. The majority of all men who have ever lived now await the studied reapplication of this solution. It is here in this already established science that but requires technological application. John Beard at the turn of the century told us that there is no other road but the trophoblastic fact of cancer and all its infinite implications, and he was right. If we don't recognize and implement this fact quickly we can have as the ignoble achievement of this century the fact that more human beings will have developed cancer and died from it than the total of all human beings born into existence in all time up to this century that for its full span held the solution to cancer in its printed scientific records.

Sincerely,

Ernst T. Krebs Jr

Ernst T Krebs, Jr
JOHN BEARD MEMORIAL FOUNDATION

ps - I have just received the paper " Immunological Engineers" by Graham Chedd, New Scientist and Science Journal, 13 May 1971, pp 396-397, which you so kindly forwarded. This extract from the paper is well phrased:

> " The infantry consists of the well-known soluble antibodies, sent out into the blood in response to invasion by the great majority of the microbes to which we are susceptible. The heavy armour is made up of the cytotoxic lymphocytes, the class of white blood cells that attack and destroy parasitic organisms, that are largely responsible for rejecting grafts of foreign tissue, and whose main job is to patrol the body on the continual look-out for cancer cells ".

Incidentally, the CGH antigen produces the "infantry antibodies". The conceptus is obviously a "parasitic organism" in the biological sense - a graft of genetically foreign tissue. The immunologically priveleged pericellular coat of the neoplast or trophoblast protects the conceptus from the rejection reaction (aided by hostal lymphocytes) so long as the coat remains intact.

Chedd is quite glib in his observation - ' the cytotoxic lymphocytes .. may be to patrol the body on the continual look-out for cancer cells". This is true in a limited sense, but it means nothing until the pericellular coat is broken either through pancreatic or other enzymes (intrinsic) and/or through the extrinsic dietary factor, vitamin B-17 (nitriloside). When the beta glycosidase releases the HCN-benzaldehyde cytotoxins at the neoplast cell they kill at least some such cells and cripple (render necrobiotic) the other neoplast or trophoblast cells. THEN the surveillant action of the hostal lymphocytes come into play as they converge toward "the parasitic cells" whose coat of immunological privelege has been impaired or destroyed.

I note your check mark on the following in Chedd's paper -

> " Not surprisingly, the possibility that the body's own immunological defence system can be stirred into more effective action against tumors received a great deal of discussion... Injection of BCG vaccine into a tumor can in some instances cause tumor regression, for example".

Injection of the protein of the tuberculosis organism (BCG vaccine) will elicit an invasion of lymphocytes into the injected area. The injected protein not only impairs neoplastic elements but somatic cells as well. Lymphocytes move in to destroy such necrobiotic cells. The clinical potential of manipulating lymphocytes - zero.

Chemical Week for July 28, 1971 just brought this -

> " AN ISRAELI DIAGNOSTIC TEST FOR CANCER WILL GET A LONG LOOK IN THE U.S. J T Baker Chemical has licensed the system developed by Chloe Tal, an immunologist at Hadassah-Hebrew University Medical Center (Jerusalem) Evaluation will be carried out by Baker and Merrell-National Laboratories another division of Richardson-Merrell. Developer Tal found a protein, T-globulin, in the blood of persons with cancer and in pregnant women. She suggests that the cancer cells cause the body to form a specific antigen, which in turn causes production of T-globulin as an antibody. She further theorizes that primitive cells in the placenta stimulate production of T-globulin in the same way cancer cells do. The method scored high in Israeli tests.. "

You will recall that we have discussed this work elsewhere. The "primitive cells in the placenta" are, of course, trophoblast cells. The antigen concerned is protein below the ontogenic level of the "highly differentiated" glycoproteins of trophoblast such as CGH.

Tal's work is all to the good. There are at least a dozen distinct trophoblastic antigen any one of which by itself will produce a specific antiserum. In one exhibition of cancer we may see some of these antigens predominate over others and in some exhibitions some of these antigens of the trophoblast may be missing. But all of them are never missing. The more of these various antigens that are present, the more malignant the process is biologically. For example, all of these antigens are present in chorionepithelioma. The more differentiated the trophoblast, the more virulent.

Quantified polyvalent antiserum would increase our chances of identifying the presence of the most vestigial quantity of trophoblast. With the presence so

determined we could proceed to titrate the positive specimen with each of 7 or so various antisera each specific for a given trophoblast or neoplast antigen. This would provide us an excellent profile of the neoplasm with which we are dealing.. All of this would be mainly of academic value in view of the fact that vitamin B-17 (nitriloside) - and the pancreatic enzymes will destroy the trophoblast with an efficiency directly proportional to the differentiation and concentration of trophoblast.

Nevertheless, such high sophisticated technics would be very valuable in leaving no doubt at to the benignity, for example, of an indolent somatic mass remaining as a formidable or even lethal mechnical problem after B-17 "washed out" all the dfinitively malignant elements , neoplast or trophoblast. Such quantitation would also be especially valuable at this stage in the vitamin B-17 management of acute leukemia in children. It would provide the therapist with the courage of knowledge to persist in the realm of rationality by avoiding indiscriminate cytotoxins that kill primitive WBCs, RBCs, and all other rapidly dividing somatic cells while leaving trophoblast or neoplast untouched.

**

" New Wave of Cancer from Hiroshima Bomb", Ibid, p 368 (NSSJ) :

> " .. This showed that exposure to a small dose of neutrons reduced the incidence of lymphosarcoma in mice ".

A "small dose" of radiation is one that is insufficient to produce a material immunosuppressive effect. Thus the organism remains resistant to neoplasia through its immunological system.. But neoplast comes from the meiosis of a a diploid totipotent cell. We have frequently been reminded that diploid totipotent cells are selectively susceptible to radiation. This is well known. If the dose of radiation is just sufficient to impair if not sterilize such "germ cells" but not sufficient to produce the immunosuppression that causes the host to accept trophoblast, one might expect such radiation to reduce the incidence of experimentally induced cancer in experimental animals relevantly manipulated.

As we have pointed out elsewhere, heavy radiation is carcinogenic largely through its profound immunosuppressive effect. It allows the host to retain transplanted kidney or heart that the unirradiated system through its lymphocytic system would reject. It similarly allows the host to retain trophoblast or neoplast that it would otherwise reject through lymphocytic action.

Recall that trophoblast at the right time and place is received by a maternal host that has undergone the preparatory immunosuppression in the uterine decidua to receive the trophoblast which then proceeds to produce by way of further immunosuppression its own prednisone and related immunosuppressive steroids.

The roughly seven times greater incidence of cancer (than among unirradiated populations) reported for the Hiroshima victims reflects an abiding immunosuppressant damage that allows trophoblast to escape the lymphocyte surveillance which Chedd suggests.

This occurs in the presence of a relative or absolute dietary deficiency in vitamin B-17 (nitriloside). A dietary sufficiency, even though the pancreas be impaired, would provide its own and direct surveillance against such emergent

[redacted]

trophoblast. The mass screening of populations such as the exposed in Hiroshima for trophoblast antigens would find some justification. But obviously better than this would be the routine daily administration of upward of 25 mg of vitamin B-17 (nitriloside) [redacted], or the ingestion of nitrilosidic foods carrying this equivalence.

**

I shall reply on the other matters included with the clippings [redacted] in a day or so

Krebs to (name of doctor deleted), March 9, 1971

JOHN BEARD MEMORIAL FOUNDATION
POST OFFICE BOX 685
SAN FRANCISCO, CALIFORNIA 94101
(415) 824-1067

[redacted]

9 March 1971

Dear Dr [redacted]

We all greatly appreciate the goodness you and your staff reflect, and your attitude evokes a nostalgia for an America that was.

You have summarized the "Laetrile controversy" perfectly in your statement: " Certainly what happened was instigated by far more than a cloying and over protective bureacracy".

The fact of a limited conspiracy against Laetrile and Beardianism is something with which we all live . The pattern of this "limited conspiracy" is obvious. A purportedly objective report on Laetrile was planned by NBC. The program was to appear on the first Tuesday in February. It was put over a month. In the meantime the Federal and State health establishment hysterically conspired to subvert the possible affirmative effect of this program on 30 million viewers. For this reason they obtained search and arrest warrants against at least five members of the Laetrile project 96 hours before the show, and then induced NBC to include this information in the closing portion of the show.

I was certain that the opposition were going to strike against the show in some fashion. I expected a last minute cancellation. Up to 72 hours before the telecast Mr Delaney, the producer, informed us that "all was well". The fix was put in so that after Delaney was forced to change the program not enough time remained for an attempted correction.

We are not complaining. In the words of Harry Truman, if one can't stand the heat he gets out of the kitchen.

As you know, the politicians at the moment are intensively involved in the political potential of cancer. It costs this country over $15 billion a year, directly and indirectly. There is going to be a multibillion dollar pie for those at the public trough to cut - unless the country should discover that the whole problem has already been basically solved. The specialists and bureaus threatened by this solution will reflexively turn to other branches of government to do anything necessary to prevent the private subversion or preemption of the wealth and power the projected national cancer "effort" promises the chosen ones.

All of this is very pedestrian and is clear to the majority of those who wrote to me in recent days - about 114 .

The view of the "limited conspiracy" is something with which we all can live. This holds that government has unwittingly been used as a tool in behalf of powerful special interests.

Those of us who live with the view of the "limited conspiracy" treat it as something as real and the air we breathe. We look at it as the citizens of Chicago once looked at gangsterism in a city in which the police, courts, and the whole establishment were bought and controlled by gangster power. These people, as a whole, never lost faith in the general integrity of their Federal government.

In contrast to this theory (or fact) of limited conspiracies is that of the total or all-pervasive conspiracy that embraces the world itself. This is one so horrible to contemplate that most Americans turn from it reflexively.

If there be the larger conspiracy, we would expect it to be manifest in a way much more subtle than is this limited conspiracy. As my secretary will tell you, since she was with me, five hours after presenting a rather effective lecture on cancer before an audience of about 400 in Los Angeles the windshield was shot out of my car on the road back to San Francisco. The next night the glass window in the tail gate was shot out (300 miles removed from the first shooting). The police said, " Maybe someone is trying to tell you something".

We do not want to dwell on the matter of physical violence, but the late Arthur T Harris, M D was threatened by two black men with assassination if he continued to use Laetrile. Since that time we have decentralized the work so that if any two of us are shot out of the saddle it will have only a slighty negative effect on the program.

II

I appreciate what you say about Mr Welch. He is a gut fighter in his sector just as I am in cancer. I get the strong impression that he is not too preoccupied with the Bill of Rights, though I may be wrong. He is certainly free to "take a dim view of vitamins curing anything", but this places an additional obligation upon him. As John Stuart Mills so ably points out in his Essay on Liberty, it is more incumbent upon us to fight for the freedom of others to act and to believe contrary to us than it is to fight for their right to agree with us. No tyranny has ever found any difficulty with the latter.

Similarly, Mr Welch's preoccupation so far as Laetrile is concerned need not be relevant to its efficacy or inefficacy. What is at stake here is the sovereignty of the individual in the disposition of his body: his right to use any and all means he chooses to fight for his life in the face of a mortal illness. As I may have mentioned to you, a deputy minister of health of the USSR in a meeting in Montreal explained to me that in a free country - such as the USSR - no one would dare restrict a citizen from handling his body in any way he chose in fighting a mortal disease. It is a simple fact of life that a cancer victim in the USSR has sovereignty over his body. In the USA at this moment he does not own his body since it is legally denied a substance less toxic than vitamin C.

If there is the Conspiracy that Mr Welch claims, the effect of his program to date has been such as to be quite congenial to the practical ends of such a Conspiracy. We've seen this demonstrated on the other end of the spectrum in the case, for example, of Trotzkyism and a dozen other sects far to the left of Moscow. They are all tolerated with ease by the more sophisticated elements of the Power Structure because these radicals are talkers rather than doers.

I would qualify your statement that the Conspiracy fears more than anything else the Truth to read - the Conspiracy fears more than anything else the implementation of the truth.

As you know, organized medicine itself tolerates a few staff heretics - in fact, cultivates them. I have many friends among these people. They use vitamin B-15 (pangamic acid) and even talk the unitarian or trophoblastic thesis of cancer as well as the theory of Laetrile (vitamin B-17). A bottle of B-15 vs a bottle of ascorbic acid. Who cares? But let the most respected internists in the community go over to Laetrile so that 50 to 75 cancer patients pack their offices each day with the result that one patient is lost to a $3,000 piece of surgery, another to $1,500 worth of cobalt radiation (the machine and technician are there as current used is relatively slight), and another to half a dozen departments at the community hospital and then hell breaks lose. The doctors are first called to appear before the County Society. If they do not foreswear Laetrile here their hospital priveleges are suspended. If this does not work, they are raided by state and federal officers and smeared in all the media as cancer quacks. If they still survive with their licenses, they are actually threatened with assassination.

The Inquisitors involved in all this very often find no difficulty whatever in allowing vitamin B-15 (pangamic acid) research in their institutions. (University of California Medical School has granted 3 graduates degrees on our work; University of San Francisco, one; UCLA Med School, one; and USC Med School, 1)

We have been on both sides of the street. Whether it is a limited trade conspiracy or the big Conspiracy, the practical effects are the same.for those who invade the cancer or Laetrile jungle. There are fine Americans, physicians and others, who comfortably live and die completely innocent of the cancer conspiracy. These people may belong to the ACLU, Americans for Democratic Action, the AAACP, the John Birch Society, various societies for friendship with the USSR, the Goethe Beer and Chowder Club (reconverted Bund), nudist societies, and even homosexual organizations and still enjoy American freedom.

Cancer is where the action is. The innocents who touch Laetrile experience a traumatic syndrome unparalleled in American life. This is why we so strongly counsel many fine and dedicated doctors to refrain. Of course, every society always has a few who can not live fully without walking the highest wire in the tent.

Those of us deep in Laetrile and the unitarian or trophoblastic thesis of cancer know what Martin Luther meant when he said, in effect, here I stand ; I can not do otherwise. While we are inexpressibly grateful to those who stand with us, nothing could cause us to be anywhere except where we are. The most that the enemy can do is to kill us, and in the process we are going to take a few with us. For every one that falls two will rise. In a rotten and septic society there is nothing greater than to have something so good that death is a cheap price for its preservation. We find an euphoria that evil can not know as we welcome the privelege of battle.

All of this has been a rather lengthy way of saying that we believe your proposed paper for AMERICAN OPINION is in concept wonderful. It should be polished even well beyond its present excellence, and then reprints should be distributed to the health professions.

It is only fair to emphasize, however, that once a physician has embarked upon such a path he is given no way to escape his printed words. These can have a devastatingly destructive effect upon his professional status, upon his wife and family, and even upon his personal safety.

At the lecture at Sheraton-West in Los Angeles last Thursday a sincere and obviously intense woman (whom I had previously met) arose during the question and answer period. " I was a physician in the USSR, but I left for what I believed was a free country. But now I am told by the County Society that if I dare use Laetrile they will get me and my license. I want to follow your work. What should I do?"

I replied, " You have a great responsibility as a doctor in a society in which there is a great shortage of physicians. Forget Laetrile and do your very best where you are, and in doing this you may be much more effective than joining a battle for which you are possibly not prepared.. Trained in dialetical materialism as you were, you may smile at this: It is possible that the Lord has not touched your shoulder for service on this front. I know only that He has touched mine".

Thank you all again for your loyalty. If I can contribute anything constructive, I shall be pleased to meet with Mr and Mrs Welch.

Cordially,

Ernst T Krebs, Jr

JOHN BEARD MEMORIAL FOUNDATION

This photocopy was sent to me by ET Krebs
This note on p. 2 apparently was part of the fax of.

24-A The Arizona Republic Phoenix, Sunday, Feb. 28, 1971

Cancer clinic ring seized in California

New York Times Service

IMPERIAL BEACH, Calif., — California food and drug agents moved this week to break up what they described as an "underground railroad" that has been transporting cancer victims into Mexico for treatment with a drug that is banned in the United States and Canada.

Charges of criminal conspiracy and fraud were lodged against Mrs. Mary C. Whelchel whose boarding house has been a haven for cancer patients from all parts of the United States en route to Mexico for treatment with the so-called wonder drug.

Three other persons were arrested in San Francisco. Dr. Ernst T. Krebs Jr., a biochemist and head of the John Beard Memorial Foundation, who developed the drug, was charged with sale and distribution of a prohibited drug and with practicing medicine without a license. Conspiracy and fraud charges involving alleged drug sales were placed against his brother, Dr. Byron Krebs, a physician, and the biochemist's secretary, Miss Malvina Cassesse.

to be "of no value in the therapy, treatment, alleviation or cure of cancer."

Deputy District Attorney James Lorenz said a search of Mrs. Whelchel's boarding house turned up a quantity of the contraband drug as well as stacks of literature extolling laetrile's curative powers.

The Mexican authorities are also looking into the operation of the cancer clinics.

For many who cross the border it is a pilgrimage of desperate last hope, for their malignancy has reached its terminal stage, and they have been told that they have only a few months to live. Some are too weak to walk. Surgery, radiation and other standard therapies have given way to pain-relieving palliatives.

Tale of miraculous recoveries attributed to laetrile are spread with evangelistic zeal by many of those who have visited the Mexican clinic, by a newsletter Mrs. Whelchel sends to the several hundred men and women she has shepherded across the border and by a magazine that goes to 3,000 members of an organization called the International Association of Cancer Victims and Friends.

"Cancer Ring Seized in California," Ariz. Republic 28 Feb 71

Clinic

The drug, named laetrile by the Krebs[illegible] apricot pits [illegible]. The United States Food and Drug Administration prohibited its use in 1965, declaring it a nostrum of no demonstrated value. Since then between 3,000 and 4,000 Americans are believed to have been treated with laetril — many of them against the advice of their doctors back home — at cancer clinics in Tijuana and other Mexican border cities.

A few hours before her arrest, as she has almost every weekday morning for six years, Mrs. Whelchel loaded a group of her lodgers aboard a small bus and drove them eight miles across the border to receive laetrile injections at Dr. Ernesto Contreras' Good Samaritan Clinic outside Tijuana.

Also charged in the conspiracy with Mrs Whelchel, but immune from arrest by the United States because of his Mexican residence, was the Harvard-trained Contreras, who has treated some 1,800 patients with laetrile since it was outlawed in the United States.

Grant Leake of the California Bureau of Food and Drugs described the arrest of Mrs. Whelchel as "the start of a crackdown on the whole network of laetrile operations." Other arrests are being contemplated, he said, under a seven-year-old California law that holds laetrile

The American Cancer Society and the American Medical Association have never said that laetrile is injurious or has produced harmful side effects. They nevertheless regard it as dangerous because they say, cancer sufferers are lured into rejecting or abandoning conventional therapy that might save their lives.

The drug's defenders, in rebuttal, say that 80 to 85 per cent of those who turn to laetrile have already exhausted such conventional treatment without obtaining relief.

Contreras acknowledged that the drug had some limitations. He said that he had found it ineffective against brain tumors, and sometimes it was of marginal value in stomach and ovarian malignancies. The most astounding results, he said, were in the treatment of lung and breast cancer.

The drug's principal promoter is the McNaughton Foundation of Sausalito, Calif. The foundation is a private research organization set up by Andrew R. L. McNaughton, son of the commander of Canada's armed forces in World War II. He manufactured laetrile in Montreal after it had been banned in the United States and before the Canadian government took similar action against it

IT CAN HAPPEN HERE: In the USSR people are prevented from fleeing the country because their masters tell them they are not fit to choose the political system under which they are to live. The choice must be made for them... In the USA cancer victims are prevented from fleeing for their lives for Laetrile in foreign countries because their government tells these people they are not fit to decide such matters for themselves.. Those who feed the refugees from the USSR are prosecuted.. Those who feed the cancer refugees from the USA with admittedly harmless accessory food (vitamin B-17) are similarly prosecuted and persecuted.

IT IS HAPPENING HERE. Tyranny knows no boundaries. Unopposed it flourishes malignantly. How great it would be if even a very small society of patriotic American physicians, banding together, could invoke the Nurenberg principles of defying government in its evil or murderous ends and defiantly use laetrile

ETK, JR

Interesting Concept!

BEARD MEMORIAL FOUNDATION
POST OFFICE BOX 685
SAN FRANCISCO, CALIFORNIA 94101
(415) 824-1067

3 August 1971

The enclosed is not yet responsive to your recent and very valued communication in which you enclosed an excellent general summary on cancer from Vital Speeches. I am also mindful of a brilliant paper you wrote a number of months past as well as important data you forwarded from Mrs W.

A procedure I commonly follow with the consent of those addressed is to send copies of some definitive replies to those whose interests are specifically relevant to the replies. Accordingly, I have enclosed a photocopy of my general reply to a letter Mr McNaughton received from Dr Navarro in which he asked that my opinions on a research project proposed for the St Tomas University group be elicited. The details of all this are in the enclosed.

As you read this stuff it will bring to mind some of the elementary principles that you mastered long ago in immunology. A subsequent photocopy that you will receive will carry a detailed reply to specific questions on the vitamin B-17 management of breast cancer as raised by a surgeon in Louisiana.

You may find the enclosed photocopy of a letter by Dr Miles H Robinson to your name sake, Elliot L Richardson, interesting. Robinson has the courage to tell the head of HEW of the obvious "moral decay in the FDA". In contrast to Dr Robinson's courage look at the photocopy of a letter sent by an unidentified Laetrile (nitriloside) authority in Germany through Dr Keizer of Osnabrück, Germany. We have certainly reached a disgraceful state when German scientists without fear of contradiction can tell our major bureaucracies in Washington just how rotten they are. The writer may be right that the Laetrile scandal will "unfortunately become more harmful for the USA than the Vietnam affair." It is significant that such a comparison is so matter of fact.

I like Dr Nieper's letter to Mr Richardson: " The circumstances of the Laetrile affair may rather soon become a very important burden for the moral integrity of the United States", etc. When you witness our so-called leaders in Washington no longer even making a pretense at moral behaviour but accepting the insults of truth with indifference, one finds the conspiratorial theory quite plausible. It would seem that only men who are acting on orders under a plan would continue to flaunt their corrupt practices before the world. Such men can have no real concern or interest in the welfare of their country, which they openly degrade.

In another communication I shall reply in detail to the valuable commentary by William L Aitken (Vital Speeches of the Day, 1 July 1971), which you so kindly sent me.

As you know, the sophistication of your political insights are beyond the average reader. However, I believe that the publication of your paper in the journal you suggested is an excellent idea. I shall shortly make some specific suggestions as I return your MS with my annotations.

I am quite sure that people like Dr Miles H Robinson are truly mystified by what has been happening in Washington, and do not see it as a part of a larger plan. Robinson, as he says, has no ax to grind for Laetrile per se. I have never met him, written to him or 'phoned him. He is obviously shocked to witness corruption ~~which~~ now which no one even bothers to hide or deny. I have met Dr Nieper. He knows the score politically.

Note Dr Thurston's letter of 7 July to Mr Richardson, who has lied all over the place.

Malvina is away on a trip but will return by Thursday.

Thank you again for your interest and cooperation. I trust that all this is not too depressing.

Sincerely,

Ernst T Krebs, Jr
JOHN BEARD MEMORIAL FOUNDATION

encl

1. Photocopy of reply to ARLMcN, 9 pages
2. Dr Thurston's letter to Mr Richardson
3. Dr Nieper's letter " " "
4. Dr Miles H Robinson's letter to Mr Richardson, 4 pages

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

July 22, 1975

State of California
Board of Medical Examiners
Sacramento, California 95814

Gentlemen:

This is a formal complaint concerning what we submit is unlawful, unprofessional, and unethical conduct on the part of John A. Richardson, M.D., 514 Kains Avenue, Albany, California, a physician licensed to practice in the State of California.

As is fully disclosed in the enclosed, certified, Investigative Report, the U.S. Food and Drug Administration charges that Dr. Richardson has been a party to unlawful traffic in amygdalin. Amygdalin, which is also known as Laetrile, is an unproven cancer remedy. Representation that it has any established value in the treatment or prevention of cancer are a fraud on the public. Dr. Richardson is selling the drug to cancer victims he claims are his patients. He is also furnishing cancer victims with pangamic acid, also known as Pro-vitamin B15, which is allegedly a nutritional supplement but actually has no established nutritional value.

The amygdalin distributed by Dr. Richardson is in the form of tablets and ampules which are labeled as containing a 15% solution of SIDUS amygdalin. SIDUS is a German supplier of the drug. Amygdalin is a new drug within the meaning of Section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)) for which there is no approved New Drug Application (NDA) nor any Notice of Claimed Exemption for an Investigational New Drug (IND) on file. (See enclosed certificate). Neither the safety nor the effectiveness of amygdalin has been established. Therefore, it is not possible to write adequate directions for its use as is required by Section 502(f)(1) of the Act (21 U.S.C. 352(f)(1)). Consequently, the drug is misbranded within the meaning of Section 502(f)(1). Amygdalin is also misbranded since the label of the ampule does not state the name and address of the manufacturer, packer, or distributor of the solution as required by Section 502(b) (21 U.S.C. 352(b)) of the Act.

The pangamic acid distributed by Dr. Richardson consists of capsules labeled as containing 50 mg. of Pro-vitamin B15 and described as a water soluble accessory food factor. It is misbranded within the meaning of Section 403(a) of the Act (21 U.S.C. 343(a)) since it is not a pro-vitamin, and since there is no scientific evidence establishing it has any nutritional value.

Dr. Richardson is shipping amygdalin and capsules of pangamic acid to individuals outside of the State of California who he claims are his patients. In February, United States Marshals in Minnesota, Alabama, Washington, and Oregon seized five such consignments of these products shipped by Dr. Richardson.

The FDA submits that Dr. Richardson is violating (1) Section 301(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(c)) when he receives, directly or indirectly, misbranded amygdalin injection containing amygdalin of German manufacture; (2) Section 301(a) of Act (21 U.S.C. 331(a)) when he introduces into interstate commerce foods or drugs that are misbranded; (3) Section 301(d) of the Act (21 U.S.C. 331(d)) when he ships amygdalin to persons outside of the State of California because shipment of the drug is prohibited by Section 505 (21 U.S.C. 355). There are no exemptions in the Act which permit a physician to ship in interstate commerce either foods that are misbranded or unapproved new drugs for clinical use. This is true whether the consignees are his patients, physicians, or members of the public.

Dr. Richardson is well aware of the fact that distribution of amygdalin is contrary to the provisions of the Federal Food, Drug, and Cosmetic Act. Although he claims a special privilege as a practitioner licensed by California law to practice medicine, and asserts that his distribution of the drug is protected by that privilege we believe no such privilege exists. Even if there were a question of privilege, Dr. Richardson could not claim it in those cases in which he has sold and shipped the drug to individuals he has never examined, who use the drug in attempted self treatment. (See Investigative Report concerning the dentist, Dr. Burmeister pp 4 and 5, and the optometrist's son pp 8 and 9). The FDA charges that Dr. Richardson has been and is engaged in conduct prohibited by law, unfounded in scien and without medical justification. We submit that such conduct is unethical and unprofessional, particularly so when it furthers the distribution of a remedy that has no established value, the promotion of wh

is a fraud on the public. We call the Board's particular attention to the irresponsible and dangerous advice on the treatment of cancer in which Dr. Richardson urges patients to delay surgery and avoid radiation treatment in favor of treatment with Laetrile. (Exhibit 2, p.5). This advice, if followed, has an obvious potential for disasterous consequences.

For these reasons the Food and Drug Administration respectfully urges that this Board revoke Dr. Richardson's license to practice medicine in California and that his privileges not be reinstated unless and until the Board is satisfied Dr. Richardson will:

1. Cease violating the Federal Food, Drug, and Cosmetic Act as alleged above;

2. Cease any practice involving use of any misbranded food or any unapproved new drug except as may be explicitly authroized in a Notice of Claimed Exemption (IND), approved by the Food and Drug Administration.

FDA has been unable to determine the identity of the persons supplying amygdalin to Dr. Richardson or the means by which it entered the count. Amygdalin intended for clinical use may not legally enter the United States in the absence of any approved NDA or IND. Should the Board secure any information bearing on this matter we would appreciate being advised of its findings.

The Board of Medical Examiners is charged with the principal responsibility of regulating the practice of medicine in California. As such, the Board possesses the requisite authority, and is the most appropriate instrumentality, to regulate the medical conduct of Dr. Richardson, a physician licensed to practice medicine in the State of California. Moreover, the revocation remedy available to this Board is the most effective and prompt means available to prevent Dr. Richar son from distributing Laetrile, and to provide necessary protection of the public health.

To facilitate and expedite the Board's consideration of this complaint Mr. Ronald G. Fischer of the Food and Drug Administration's district office in San Francisco has been authorized to appear before the board to testify as to all investigations involving Dr. Richardson's actions conducted by the Food and Drug Administration, and to the results thereof. He will arrange for the appearance of any other

fact witnesses the Board may deem it necessary to hear in connection with consideration of this complaint. Mr. Fischer may be reached at (415) 556-0780. His address is:

Ronald G. Fischer, Director
Compliance Branch
U. S. Food and Drug Administration
50 Fulton Street
San Francisco, California 94102

A copy of this complaint, with enclosures, is being sent to Dr. Richardson's office today by certified mail.

The following are enclosed:

1. Certified Investigative Report of the Food and Drug Administration
2. Certificate covering the status of amygdalin
3. Federal Food, Drug, and Cosmetic Act, as amended August, 1972

We respectfully request this matter be given the earliest possible attention.

Sincerely yours,

Carl M. Leventhal

Carl M. Leventhal, M.D., Deputy Director for
J. Richard Crout, M.D.
Director
Bureau of Drugs

Enclosures:
Investigative Report
Certificate on Status of Amygdalin
Copy of Federal Food, Drug, and Cosmetic Act
3 cc this letter with enclosures

Cover letter for Leventhal to Calif. Board of Medical Examiners, July 22, 1975

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

July 24, 1975

CERTIFIED MAIL

John A. Richardson, M.D.
514 Kains Avenue
Albany, California

Dear Dr. Richardson:

Please find enclosed the letter of complaint submitted to the California Medical Examiners on July 22, 1975.

Sincerely yours,

T. E. Byers
Associate Director for Compliance
Bureau of Drugs

Enclosures:
Investigative Report
Cy of Certificate on Laetrile
Federal Food, Drug, & Cosmetic Act

THE COMMITTEE FOR FREEDOM OF CHOICE IN CANCER THERAPY
146 MAIN STREET • SUITE 408 • LOS ALTOS, CALIFORNIA 94022 • (415) 948-9?

Dear Doctor:

I'm certainly pleased that you are interested in obtaining information on L-mandelonitrile-Beta-glucouroniside or Laetrile.

Ed Griffin is coming out with a tape by E. T. Krebs on cancer, which is a disease not unlike scurvy or pellegra or pernicious anemia in that it is a deficinecy of the pancreatic enzyme chymotrypsin and the vitamin B17, Laetriel, (a contraction formed by the use of the above underlined letters. Nitrile means, as you know, cyanide). The trophoblast which is the first production of the zygote grows by fermentation and is identical with the cancer cell which is the trophoblast when out of phase with time and place. The trophoblast produces many hormones including HCG which is useful in the rabbit test for pergnancy and in determining the presence of cancer in the male and the non-pregnant female. There is a great deal of information available now which you may order from the enclosed reading list. I am, also, enclosing a brochure.

We, generally, say that a patient who has clinical cancer will be regulated or controlled with 50 grams of Laetrile. That is about 17-20 injections of 3gms each. You may give 9 grams one day, I.V. q 3 days or 3 gms qd and have the patient take 500-1000 milligrams P.O. on alternate days. The vials contain crystals which are mixed with 8cc of distilled water. This forms a microsuspension of 10 cc. There are absolutely no side effects. The cancer cell contains Beta Glucuronidase, an enzyme which splits off the cyanide and Benzaldehyde both of which works at the cancer sight destroying the the cancer cells. The normal cells contain Rhodenase which with sulfur and any nascent CN forms thiocyanate which is a metabolic pool for the formation of B_{12}, a cyanide linkage with albumin - cyanacobalamin, as you know, and which is also some sort of a "natural" B.P. regulator - a further breakdown product, urea, prevents the painful nemolytic crises in sickle cell anemia. It is a good idea to obtain a 24 hour urine for the determination of trophoblast activity through the presence of human choriogonadotrophic hormone. The test can be repeated in six weeks and will be a guide to therapy. I will include directions for the urine test separately.

It is of great importance that the patient strictly adhere to the diet which follows:

Vegetable Kingdom. In the vegetable kingdom eat anything and everything that is edible and for which you have no idiosyncrasy. Eat everything whole: eat all of the edible parts of the food - especially the roughage. This food is preferably eaten raw; but when you can not tolerate it raw, cook the food just sufficiently to make tolerable or edible.

Animal Kingdom: Eat any or all fish as fresh as possible and lightly cooked in the absence of animal fats (vegetable oils may be used). Eat the skin-free meat of poultry. Whatever does not fall within this formula forget it. Don't eat it. The formula is all inclusive so it's not necessary to mention, no dairy products, beef, mutton, pork, bacon, ham, etc.

The liver is to neo plastic diseases what the heart is to circulatory diseases. The liver is central.

Adequate liquid intake with fresh fruit juices plain or carbonated.

Vitamin supplements: Vit C, 750 mg to 2,000 mg; 500 I.V. d. alpha tocopherol, 2 theragram a day or equivalent.

Toxius of all kinds to be avoided including tobacco, alcohol. Discourage coffee, tranquilizers, sedatives, analgesics.

Antibiotics, O.K.

Rest important while exercise should spare the affected area.

As with the quest of freedom, 90% of the battle will be up to the patient and 10% will depend upon the physician. If the patient does not show sufficient motivation actively to enter into the fight for his life, there is something to be said at this stage in our history for not discouraging the patient to return home for passive, irrational and rather siwftly lethal therapy.

You should include Vitamin B_{15}, pangamic acid, which detoxifies the liver as a transmethylating agent, and increases the oxygen uptake potential of the tissues, and since trophoblast lives by the fermentative process the rationale for the provitamin B_{15} is obvious.

Pancreatic enzyme supplementation: We find viokase tabs ii ẽid or T.I.D. to be the best and cheapest available in your drug store.

It is unfortunate if the patient has had radiation therapy. You will forgive me for being arbitrary about this but radiation has no part in the rational management of internal cancer. The more powerful the form - colbalt, linear accelerator - of radiation the greater are its hazards, uselessness, immunosuppressive, morbidity - increasing and life-shortening effects on the patient. The same generalizations are applicable to the alkylating agents and all other highly poisonous forms of cytotoxic therapy. These are properly called radiomimetic. They mimic the disastrous biological effects of radiation on living tissue. Both radiation therapy and attempts to "poison out" result in a profound hostal immunosuppression that greatly increases the susceptibility to metastases. How irrational it would be to attempt to treat cancer immunologically and/or physiologically and at the

same time administered immunosuppressants in the form of radiation of any kind, methotrexate, 5 FU Cytoxan or similarly useless and dangerous general cellular poisons. All of the modalities, as we know, have been used to depress the rejection phenomona associated with organ transplantation. The entire physiological objective in rational cancer therapy is to increase "the rejection phenomena" Even in the case of skin or superficial lesians the skilled application of "escharotics" is to be preferred in most cases to radiation. Some American dermatologists are especially skilled in this technic, and they sometimes employ topical applications of 5 FU, methotrexate or the like, which application is physiologically sound since the immunosuppressant effect is topical or limited. Radiation and/or radiomimetic poisons will reduce palpable, gross or measurable tumefaction. Often this reduction may amount to 75 per cent or more of the mass of the growth. These agents have a selective effect - radiation and poisons. They selectively kill everything but the definitively neoplastic cells. For example, a benign uterine myoma will usually melt away under radiation like snow in the sun. If there be neoplastic cells in such tumor, these will remain. The size of the tumor may thus be decreased by 90 percent while the relative concentration of definitively neoplastic cells is thereby increased by 90 per cent.

As all experienced clinicians know, or should know, after radiation or poisons have reduced the gross tumefaction of lesian the patients general well being does not substantially improve. To the contrary, there is often an explosive or fulminating increase in the biological malignancy of his lesians. This is marked by the appearance of diffuse metastases and a rapid deterioration in general vitality followed shortly by death. Some of the more naive therapists at the tumor conference reviewing the post mortem findings may express regret that there was not a more powerful source of radiation or a more lethal poison to destroy the 10 or 15 per cent of the so-called tumor that remained. This remaining portion is, of course, the expression of a relatively high concentration of neoplastic cells resulting from the selective destruction of the 85 or 90 per cent of the tumor that represented vascular tissue, connective tissue and other somatic or hostal elements that entered into the reactive hostal hyperplasia involved in the attempt to limit the definitively neoplastic or trophoblastic cells. If all this be so, why do such things remain in our armamentarium? Well, more on that later. In the meantime, consider the patent rights on 5 FU are shared between Hoffman, La Roche and the American Cancer Society.

Much of what has been said above regarding radiation and diet has been borrowed heavily from Dr. E. T. Krebs who is the co-discoverer of Laetrile and besides being a good friend, he is without a doubt one of the most brilliant men I've known in medical science.

The key to a proper use of Laetrile, pangamic acid, diet and the pancreatic enzymes is an understanding of the embryology behind the unitarian or Beardian trophoblast theory; and this information is readily available from the Committee for Freedom of Choice in Cancer Therapy if you should wish to review it.

I will answer your more specific questions in a separate memorandum.

Cordially,

John A. Richardson, M.D.

John A. Richardson, M.D.

J.A. Richardson to Griffin, December 2, 1972

JOHN A. RICHARDSON, M.D.
814 KAINS AVENUE
ALBANY, CALIFORNIA 94706
TELEPHONE 527-3020

Dec. 2, 1972

Dear Ed,

Of course we're looking forward to your return within a week or so. I think the film project is monumental. It could be the catalyst for motivating what's left of America. I doubt it but it will give us a good feeling to know that we hit them where it hurts and perhaps upset some of the Insider prospects of a completely one-sided victory.

I finally talked to Stout. He said the judge was keeping the papers for evidence in spite of the fact that we say we used it so what. Our next hearing or trial or whatever is to be sometime Thursday- think it's the afternoon. Again I have no idea what will be

(2)

happening. Presumably, the "Grand Father clause" again. Dean Burke has been contacted and I had Ralph send you a copy of his observations. Interesting. The last paragraph on Page 1 where he says Amygdalin was used + recorded in the French medical journals as early as 1845 and with such success that its disuse could not have been brought about except by some intelligence that phased it out.

You wanted substantiation on the arbitrary points which will allow the people to comprehend. We should hammer home the fact that there is a false premise which must be discarded + that is simply that Cancer is not "spontaneous generation" — strike from space sort of thing but a "cause and effect" relationship of pancreatic enzyme and accessory food factor to the physiological well being

(3.) of the human organism. Now let them pause & turn back the reel and tape recorder so this sinks in again and again and again.

Now then it will be easy to believe my findings that 99% of the people on a prophylactic dosage of 100 mgm — or more according to personal preference — lets say 100% for theoretical accuracy have not come down with clinical cancer in a two year period. Krebs says of 150 investigators likewise ingesting a prophylactic dose none have developed clinical cancer over a ten year period. On a theoretical basis, barring something like a severe pancreatic insufficiency or an unreasonable exposure to radiomimetic trauma + in answer to #1 none will come down with clinical cancer — None having been no clinical cancer diagnosed to start with.

Early detection cancer point # 2
presents two subcategories. Those
with a significantly positive HCG
test prior to the lump and bump
stage have also enjoyed a 100%
survival rate and will probably
continue to do so in my series
— subtracting a percentage point
or two for the few cases left
on that have some weird and
wonderful complication. In the
second category of early detection
— say the lump + bump stage
and without radiomimetic or
surgical interference will have a
75 to 85% survival (5 yr.) somewhat
less providing that the vital organs
have not been destroyed. With
radiomimetic + untimely surgical
intervention survival plummets to
from 0 to 20%

A few of my category 2
patients are still around but they
will die sooner than they and we
all things being equal in this demonstration

5.

I have some that are still alive after two years of therapy and they seem well But the radiomimetics will make their survival for longer than 5 years almost impossible. Your category 3 is unfortunate since they are hopeless.

But of the guy who has been operated upon, opened up & closed without molesting anything, he has a damned good chance of living to be an old man — provided important viscera have not been sacrificed. He'll probably make it. It's the cobalt that will kill not the cancer. A patient will be dieing and his HCG test will be down to a very low level. The cancer cells are almost all gone but there are too many holes in the liver lungs pancreas & kidney. I have some patients who have been paralyzed (2) by cobalt spine radiation and after

6. Vitamin treatment their HCG test is faintly positive. Lose at their weight but the iatrogenic manipulation is such that they can't walk.

But again if you want a figure Contreras says he's saving 15% of these category Threes. Moertel of the NCI says Orthodox medicine has a 7½% 5 yr survival but includes category 2 + 3 and only 15% have a 50% 5 yr. Survival.

Anyway Ed why fall into the enemy trap — you're welcome to look at the records of some 300 plus patients I have treated. But this is a vitamin + enzyme deficiency disease. We dare not talk about 5 year survivals when we are really talking about 100% survival with prophylaxis. When you start killing people with radiomimetic insults to their bodies — you're talking about radiation deaths.

There are several other

7) reasons for not using their false and misleading yardsticks. One is that this yardstick is not applick to vitamin deficiency diseases. Later on when B17 is accepted and your film will have been instrumental in having it widely accepted we may appear the fool by having swallowed our presentation by acquiescing in the use of the yardstick. Anyone who begins to see the vitamin aspect soon realizes that it is like measuring water and steel with the same clumsy apparatus.

I still think you should take adequate safeguards to avoid the confiscation, puttaining or destruction of your films. The premise that cancer has a mystique of its own has not found any reason to suppose differently. "They" undoubtedly know about it

(8) now. But in my experience, they don't count on our (your) being tricky or elusive. (Advice from one having passed his first fifty years).

Getting back to the use of the vitamin deficiency premise. Adequate examples of physiological distortion resulting in grotesque body appearances can be provided by perusing a textbook on vitamins. This then will place our cause and effect relationship squarely in the company in which it belongs.

Got a letter from Bill Veit who will return before Christmas. He's gotten all the rumors from other sources and has not dismissed pore ole Larry Abraham from being the top instigator of this nefarious plot. Stew said it had to be Larry who by dint of his own ruthless ambition allowed himself to employ linfame for merely selfish objectives. I think he was tired of using proper channels to get to the

5-18-92

Dear Dr. Krebs:

Thank you for giving me another birthday (May 17).

Please, again, remember November 15th 1979 when my Doctor and four other urologist gave me a maximum of 4 months to live with my prostate Cancer and they set up appointments for radiation and Chemotherapy, which I knew would kill me, if the Cancer didn't, and refused their treatment.

Then on a Sunday afternoon I contacted you by telephone and went with your simple program. (95 in Mex)

I am 71 years old and am in my 13th year. 3 of the 4 urologists have died with prostate cancer and 40 or 50 (now 90) people are alive today, and doing very well, because they followed my "Krebs simple program.

Thanks again for giving me back my life.

Your friend

H. Lynn "Bud" Robinson

4144 N. 38th St.

Phoenix 85018 AZ

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

March 21, 1973

Mr. G. Edward Griffin
American Media
P.O. Box 1365
Thousand Oaks, California

Dear Mr. Griffin:

Your request of March 8, 1973 to Dr. Rauscher for survival information for metastic cancer has been referred to me. We do not routinely collect data on non-melanomic skin cancers (since it is so common, so rarely fatal, so often treated outside hospitals, and often without histologic diagnosis). Survival information is available, however, for all other cancers among whites. Five year percent survivals by stage of disease at diagnosis are:

	Percent Surviving	
	Observed	Relative*
All cancers (both sexes)	33	40
Localized disease	56	67
Regional Spread	28	34
Distant Spread	7	9

* The relative survival rate adjusts for "normal" mortality from all other causes.

If you wish to combine disease with regional spread and disease with distant spread into your category "metastasized," then 5 year survivals are: observed = 17%, relative 21%. Common usage seems to be to call disease with distant spread "metastasized." The message I like to take from these numbers is that treating the disease early (while localized) at least doubles the chances for survival.

I hope this gives you the answers you need. If we can help you any further please do not hesitate to write.

Very truly yours,

Marvin A. Schneiderman, Ph.D.
Associate Scientific Director
for Demography, DCCP
National Cancer Institute

Bill Sykes open letter to friends, April, 1990

I Conquered CANCER

April 1990

Dear Friends

It's been 14 years since we first shared our experience of how I fought and conquered cancer. To answer your question, how am I feeling now, I want to assure you that I am in good health and the doctors can no longer find any trace of cancer. I am glad to share my experience, as we feel the wonderful recovery has come through the mercy and guidance of God.

In the fall and winter of 1975 to '76 I noticed a fullness and pressure on my left side. When the pressure increased, I went to a doctor for a check up. After examination he sent me to Ann Arbor for further tests. Extensive tests revealed lymphocytic leukemia and enlarged spleen. On March 24, 1976 the cancerous spleen, measuring 19x15x8 cm and weighing 1810 gms was removed. Cancer was found throughout my body.

A few days later the doctor called my wife to the office and told her that I had stage IV cancer. They had removed what they could, but, since the liver was honeycombed with cancer, there was little chance of my living more than a few months at best. The doctor suggested that with Chemotherapy my life might be extended a few extra months.

Stunned, my wife drove home that night. I had always been healthy, and now the doctor had said, "only a few months left". After years of cancer research, was Chemotherapy the best that could be offered? The doctor hadn't given any reassurance with that. There had to be something better! Next morning, after praying for guidance, she learned about Laetrile (also referred to as Amygdalin or B-17) and found a doctor who would administer it, but was told that he wouldn't be able to see me for three weeks. In desperation she said, "My husband can't wait that long"! She was told to bring me in as soon as I could travel and the doctor would somehow fit me into his busy schedule.

When we saw the doctor a week later, he explained how and why Laetrile was helping many cancer patients, and suggested that I have intravenous shots of 30cc's of Laetrile daily for the next three weeks. He also gave me enzymes and a diet to follow along with food supplements. In a few days I was feeling better, but, on our third visit the doctor said that he could no longer treat me. He had been told that his license would be revoked if he continued to use Laetrile. He showed my wife how to administer the Laetrile, sold us what he had, and gave us an address where more could be obtained.

The Next week I continued on the program and was feeling better each day. One afternoon the doctor from Ann Arbor called to ask why I had not returned for the Chemotherapy. He said I was playing "Russian Roulette" with my life. He finally persuaded me to return for Chemotherapy, so I went to Ann Arbor and started the treatments. Each day I felt worse. My eyes burned, my stomach felt like it was on fire. In just a few days I was so weak I could hardly get out of bed. The Chemotherapy was killing more good cells than bad! The "cure" was killing me faster than the disease! I couldn't take it any longer, so I stopped the Chemotherapy, returned to my supply of Laetrile and food supplements, and quickly started feeling better. It took longer this time as I was fighting the

effects of the Chemotherapy as well as the cancer. After that I faithfully stayed on the pancreatic enzymes and natural food supplements. Three months later I was feeling well enough to join in a game of racquet ball. I was given a diet that I still follow quite carefully. It emphasizes fresh fruits and vegetables, foods rich in nitrilosides, and forbids foods made with bleached flour or refined sugar.

We also purchased a juicer and I drank one or two glasses of fresh carrot juice each day. I also made what we called a "green drink". We went out in fields that had not been sprayed and picked dandelion leaves, plantain, shave grass and other herbs. We washed them, put water in a blender and added the herbs. I ate raw sunflower, pumpkin, and sesame seeds.

Enteric coated pancreatic enzymes played a major role as they help dissolve cancer cells and tumors if taken on an empty stomach. I took them late at night, in the night when I woke up, and first thing in the morning.

I'm not offering medical advice, but I used the following each day:

6	vitamin/mineral (2 each meal)	3	Assist-All (1 digest each meal)
2	1000 mg Vita C	4	Bee Pollen
2	Super C with Beta-Carotene A	3	Affect-Adophilus (1 each meal)
2	caps protein	6	Pancreatin (2 at time on empty stomach
2	Selenium	2	oz. Aloe Vera Juice
6	B-15	2	glasses Taheebo Tea

When we first learned that I had cancer we were using supplements of a company, which, at that time put out natural, organic products. After a time I noticed that I was not getting the same benefit from those supplements for I could not do the same amount of exercise without tiring. On checking the labels we found that the formulas had been changed and the products were no longer as natural or organic. After a great deal of research with labs, other researchers, and counseling with doctors, I chose and started using other natural products. I found them to be better formulated and the most complete natural/organic food supplements and herbs. In a short time I could again do all my push-ups and exercises without tiring. Now, at ~~nearly~~ 70-75 years of age I still play racquet ball twice a week. I feel fine and take no medication. At my yearly check-up the doctor remarked that he wished he was as healthy. I still use supplements daily for it has been said that "Disease cannot exist in a well nourished body".

Besides my daily program I clean my body every six months with special herb combinations. It took a lot of hard work and persistent effort to undo the harm cancer had done to my body, but the Lord blessed our efforts. One has to be diligent in living a healthful lifestyle. Those who are not, often regress.

If you want encouragement, or have questions, you are welcome to write or call. God has been very good to me and I am thankful to Him for my recovery. I hope and pray that, through my experience, others will find new hope and encouragement. May the day come when cancer will only be a word in the dusty pages of history.

Sincerely,
Bill Sykes

Bill & Hazel Sykes
P.O. Box 270145
Tampa, FL 33688 (813) 962-2639

P O Box 270145
Tampa, Fl. 33688
June 19, 1996

Ed Griffin
American Media
P O Box 4646
West Lake Village, Ca. 91359

Dear Malinda Wyman

After talking to you on the phone I looked for Bill's records, but could not find the operation papers. Maybe some of this discription will help. Am also, enclosing a couple pictures and you may be able to use one of them. Bill is 74 years old now and still plays a good game of racquit ball so he took his racquet with him. However, the picture only shows part of it so the picture is confusing. If you want another picture let us know.

We used laetrile for Bill, but I feel that there are many ways that diseases can be conquered. A friend of ours, who the doctors sent home to die couldn't even lift his head off the pillow. His mother went out and gathered herbs from the fields and woods and made him a "green drink" every day plus other natural things and today that man is a Doctor of natural medicine. That mother is the one who showed me what herbs to use for Bill.

There is no way to go in most cases but the natural way. There are so many stories we could tell you, but I will fill you in on just one.

After Bill had conquered cancer a doctor came to him one day. (This was an M.D. who gave chemotherapy in a well known hospital) He wanted to know how Bill had conquered his cancer because his wife was quite ill with cancer. Bill said, "Why don't you give her chemotherapy." His answer was, "I would never give chemotherapy to any of my friends or family."! He was not the only doctor who came to Bill with the same question.

I hope this will help some. Have a good day.

Hazel

Bill and Hazel Sykes

P S Last November we just celebrated our golden wedding anniversary. We would never have done that if Bill had done what the doctors wanted him to!

TATE OF CALIFORNIA—HUMAN RELATIONS AGENCY RONALD REAGAN, Governor

EPARTMENT OF PUBLIC HEALTH
51 BERKELEY WAY
RKELEY 94704

September 20, 1972

Ms. Carole Hagel, Secretary
American Media
P.O. Box 1365
Thousand Oaks, CA 91360

Dear Ms. Hagel:

Thank you for your letter of September 7, 1972.

The toxicology involved in apricot kernel poisoning is complex. At least several factors are involved in addition to the cyanide containing compounds present in the kernel (which vary widely in their cyanogen content). Two or more enzymes are required to split the cyanide containing molecule completely. Some of these enzymes are in the apricot kernel itself, others are in other foods, and still others are in the intestinal lining, and yet others may be in the colon bacteria. A discussion of these is in the book "*Toxicants in Natural Foods", a publication of the National Academy of Sciences.

The "British Medical Journal" for May 27, 1972, has an editorial on "Foods and Cyanide" pointing out neurological disorders from such substances. The "New England Journal of Medicine", vol. 270, May 21, 1964, No. 21, pp. 1113-1115, describes two deaths among nine children in Turkey poisoned by such kernels.

We regret that the confidentiality of morbidity reporting precludes interviewing the patients who were poisoned in Los Angeles.

Sincerely,

Ralph W. Weilerstein M.D.

Ralph W. Weilerstein, M.D.
Public Health Medical Officer
Bureau of Food and Drug

*Correct title is "Toxicants Occurring Naturally in Foods".

RWW:ve

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HOFFMANN-LA ROCHE INC.

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January 11, 1977

Mr. G. Edward Griffin
President
American Media
790 Hampshire Road
Suite H
Westlake Village, California 91361

Dear Mr. Griffin:

This is in answer to your letter of December 29, 1976 inquiring about the status of 5-FU.

The United States patent covering 5-FU was issued about twenty years ago to Dr. Charles Heidelberger and Dr. Robert Duschinsky as joint inventors. As you indicate, Dr. Heidelberger was then connected with the University of Wisconsin and was working with funds of the American Cancer Society. Dr. Duschinsky was then an employee of this company. Dr. Heidelberger assigned his undivided interest in the patent to the American Cancer Society, whereas Dr. Duschinsky assigned his undivided interest in the patent to this company.

Subsequently we read in the public press that the American Cancer Society had conveyed an undivided interest in the patent to the United States Government. Our understanding was, also from material in the public press, that the U.S. Government granted several licenses under its interest in the patent.

We do not feel that we are in a position to comment on what payments, if any, the American Cancer Society received on account of the patent.

We trust that this information will be helpful to you.

Yours very truly,

S. L. Welt

Samuel L. Welt
Assistant Vice President
and Chief Patent Counsel

SLW:BS