PROTEST

AGAINST PERSECUTION OF THE HEALTH MOVEMENT

by

THE FOOD AND DRUG ADMINISTRATION

Filed by

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Table of Contents

To the Congress of the United States:

This petition and protest is being filed with Congress against the campaign of persecution being carried on by the Food and Drug Administration against the health movement. This campaign is not called for by any harm being done to the public, nor is it legally justifiable by any law that has been passed by Congress.

By this campaign the FDA is attempting to withhold from the public certain vitamin preparations and foods which I believe are important for health. There is not a single bit of evidence that their use is harmful. The FDA is attempting to stop their use solely because the FDA believes they serve no useful purpose.

In a recent decision a Federal Court has ruled:

> "The provisions of the Federal Food, Drug and Cosmetic Act did not vest in the Food and Drug Administration, or any other federal agency, the power to determine what foods should be included in the American diet; this is the function of the marketplace." *U.S v. 119 Cases (Dextra Brand Fortified Sugar) S. D. Florida, Feb. 27, 1963*

It is on this sound statement of law that the present petition and protest is based.

My Interest in the Matter

I believe that anyone making a statement of this kind should explain fully any financial or other interest he may have in the subject matter, as well as any vested professional interest he may have in maintaining the status quo.

I am presenting this protest as a private citizen having no financial or other interest in any of the matters presented herein. I am, however, deeply interested in the basic problem of nutrition and its relation to health- my own health; the health of my family; and the health of the American people.

I am not writing as a representative of any organized group, but am presenting my own views. I have no connection with the sale of any health food or product.

I am a lawyer, and therefore have no vested interest in any particular school of medical opinion.

I believe the FDA has departed from the principles of Dr. Harvey Wiley, on which the Pure Food Law was originally founded,[1] and I urge that Congress take steps to see that the enforcement of the law be returned to those principles.

1. See p. herein

My Qualifications

The questions I will discuss lie in the field of the chemistry of the human body, which is basically the field called bio-chemistry. In college I majored in chemistry, and took a course in which our text was *Matthew's Physiological Chemistry,* a standard text in medical schools of that day. (1920) Since then I have kept fairly well informed of developments in this field, although I have branched off into patent law. I have in my library many books on nutrition, including *The Vitamins in Medicine* by Bicknell and Prescott. This book, which was last revised in 1952, is the only comprehensive book on the relation of vitamins to health and disease available in the English language. The Journal of the American Medical Association is reviewing this book and said that "every doctor should have one." I refer to this book solely as showing that I have endeavored to keep abreast of current scientific investigation and thought in the field of vitamins and and nutrition.

In presenting this protest I shall first refer to some criticisms of the health movement made by Commissioner George P. Larrick, which are either wholly unjustified or contrary to fact. I will then proceed to discuss certain enforcement actions taken by DFA which are justifiable neither by law nor by the facts of the situation.

A. Relation of Soil to Health

In referring to what he calls "The Soil Depletion Myth", Mr. Larrick has said:

> "The facts are that research has demonstrated that the nutritional values of our crops are not significantly affected by either the soil or the kind of fertilizer used." *(Summary Report of FDA, February 1962)*

In order to evaluate this statement by Mr. Larrick it is important to review a few of the outstanding facts relating to soil and fertilizers.

1. The first scientific study of the relation of soil chemistry to animal nutrition was made by the eminent German chemist Justis von Liebig about 1850. His studies indicated that for maximum nutritional value plants need not only the minerals present in large amounts in the soil, i.e., nitrogen, potassium, phosphorus and calcium, but also other minerals present in very small amounts, now called the "trace minerals".

2. The followers of Liebig, who attempted to apply his theories to practical agriculture, could not conceive that minerals present in almost microscopic amounts could be of any practical importance. They therefore ignored these "trace minerals" and concentrated on the "major minerals" present in large amounts. This misconception has been perpetuated down to the present day, and is the basis of current commercial fertilizer theory and practice.

3. During the last 50 years has come the discovery by modern scientific experts on nutrition that these "trace minerals" are just as necessary for human nutrition as the vitamins. In fact, the "trace minerals" form an important part of the chemical complexes in which the vitamins are found in nature.

These "trace minerals" are sometimes called the "minor mineral elements", but that is a misnomer, because their presence in minute amounts is just as essential as the presence of the major elements in larger amounts.

With these facts as background, let us turn to examine critically what Mr. Larrick calls "The Soil Depletion Myth."

Trace Minerals in the Soil Are Important

Mr. Larrick's statement that the nutritional values of crops are not affected by the soil is directly contradicted by the U. S. Department of Agriculture. Its yearbook of 1957 on "Soil" reflects a more modern view when it says:

> "Many of the minor [mineral] elements are associated in the plants with the vitamins or with enzyme systems and other

organic components. If the minor element in the soil is limited in amount, the plant does not grow normally. Such plants are usually less nutritious than normal plants." *p. 263*

This yearbook contains a number of maps showing which areas of the United States are deficient in specified minerals "as revealed by limited growth or other symptoms of nutritional troubles in specific crops." These maps show the localities where deficiencies of cobalt, copper, boron, magnesium, manganese, molybdenum, or zinc cause "mineral-nutritional diseases of animals."

The Heinz Handbook of Nutrition, a standard reference work, says that all of these minerals (except boron) have "definite demonstrable functions in the human body and metabolism." This handbook goes further and says "About 13 different minerals are known to be needed by the body, and all must be obtained from the diet." *(p. 106)*

As a specific example of the effects of trace minerals on animal nutrition, let us take magnesium. The technical literature on this subject was reviewed recently by M. L. Morris, et al, of the University of Wisconsin in the Journal of Nutrition for April, 1963 at *p. 437*. This article shows that as early as 1932 a report was made of the bad effects on dogs of a lack of magnesium. Since then a number of reports have been published showing bad effects on chickens, rats, rabbits and calves. Summarizing his own conclusions, M. L. Morris said:

> "In the dog low magnesium diets cause widespread calcification of the kidney, heart, bood vessels, larynx, trachea, lungs, and smooth muscle of the stomach and uterus, and degeneration of skeletal muscles."

In the face of this evidence, it would seem rash on the part of anyone to make a statement that a deficiency of magnesium does not affect the nutritional value of crops.

The yearbook of the U. S. Department of Agriculture mentioned above pays more attention to animal than to human nutrition. This is quite natural, since "agricultural experiment stations" sprang up all over the world soon after Liebig's work in 1850. Systematic application of scientific principles to human nutrition is more recent, and is not as far advanced. However, there is a large and growing body of evidence that many of the mineral deficiences that have bad effects on animals, have similar bad effects on humans.

Prof. W. Nicolausen, of Hanover, Germany says:

> "We have come to the conclusion that the signs of deficiencies in human beings rest on the same causes as they do in animals."

Prof. William A. Albrecht, Chairman of the Department of Soils at the University of Missouri, in discussing the importance of the trace minerals says:

"Recent research suggests the function of the trace, or minor, elements in stimulating the synthesis of essential amino acids. Trace-element deficiencies suggest deficiencies in the quality of protein, which in turn operate to exclude higher forms, or to provoke nutritional deficiencies and 'diseases' as degenerative ailments." *The Geographical Review, 1957, p. 95*

Organic Fertilizer Has Important Advantages

In discussing "The Soil Depletion Myth", Mr. Larrick says that "the nutritional values are not significantly affected...by the kind of fertilizer used." This statement is also refuted by the same yearbook of the U. S. Department of Agriculture. Page 673 of that yearbook contains this statement:

"Organic matter, especially manure or compost derived from a wide range of normally growing plants, furnishes the growing plants a balanced supply of slowly available nutrients, including the trace elements."

This fact has been established by many authorities well qualified in the scientific aspects of agriculture. Frank A. Gilbert, who has M.A. and Ph. D. degrees from Harvard, is at present a member of the Agricultural Sciences Research Division of Battelle Memorial Institute, of Columbus, Ohio, one of the leading research institutions of the country. In a book "Mineral Nutrition of Plants and Animals" he covers the importance of the "trace minerals" in human nutrition.

As one example, he points out the importance of zinc. This mineral is present in the liver, the pancreas and the thyroid. He says: "It has been found that animals getting ample zinc lived longer and grew better than those on a diet containing little zinc."

Another authority, Prof. Roger J. Williams, Director, Biochemical Institute, University of Texas, says:

" Zinc, to discuss this particular example, is an indispensable constitutent of an enzyme 'carbonic anhydrase'. This enzyme is in our bodies and needs to be there to hasten the decomposition of carbonic acid...Therefore the need for zinc in human nutrition has been established. Perhaps it has not been established in the eyes of untutored individuals; if it is established in the eyes of experts this should be enough. No competent biochemist can be found who has any doubt about the need for zinc in human nutrition." [1]

Having established the fact that zinc is important in human metabolism, let us turn to consider the relation of zinc to organic fertilizers. On this

1. Nutrition in a Nutshell, Dolphin Books, 1962, p. 100

point Mr. Gilbert says:

> "Organic fertilizers are higher in zinc content than inorganic fertilizers, and the increasing reports of zinc deficiency may arise from the reduced use of organic fertilizers and the increased use of inorganic fertilizers containing little or none of the element." *p. 73*

Summing up the importance of vitamins and minerals in the food supply he says:

> "Foods lacking the health factors, yet fresh and attractive in appearance, bring the same price on the market as the more nutritive foods; and little if any effort has been made by public-health organizations to provide laws governing the sale of such products. The producer of edible but inferior food of low mineral and vitamin content feels at present no social responsibility for increasing the value of his product, nor is he handicapped in its sale. The consuming public as individuals have no way of distinguishing the superior food from the poor, and for the most part are completely at the mercy of the growers and purveyors who, by reason of ignorance or for economic gain, grow or market inferior products." *p. 99*

I could quote many other reputable authorities who disagree with Mr. Larrick's statement that "the nutritional values of our crops are not significantly affected by either the soil or the kind of fertilizer used." But why should Mr. Larrick attempt to hand down a ukase on this subject, which is clearly outside of his competence or authority.

B. Many of Us Prefer Foods Organically Grown.

Many of us who are interested in modern scientific nutrition believe that the best foods are those grown "organically". By this term we normally mean that:

(1) The food is grown by the use of complete fertilizers that furnish, not only the major chemical elements advocated by Liebig in 1850, but also the essential "trace" chemical elements and organic matter. We believe that such fertilizers are important aids in producing foods high in protein, as well as in vitamins and minerals.

(2) The crops are raised without use of poisonous insecticides, thus avoiding the bad effects pointed out by Rachel Carson in "*Silent Spring*".

(3) The poultry and meats are raised without artificial fatteners such as stilbestrol (artificial sex hormone) and tranquilizers.

Mr. Larrick says that such foods are "no more wholesome than other foods". He is, of course, entitled to his own opinion on this matter, even

though he may be ill-informed, but why should he be permitted to voice his personal opinion as though it were the considered opinion of Uncle Sam?

He also says "it is questionable whether very many are actually grown and processed in the manner represented". On this point I will pit my personal experience against his. I doubt whether he or his organization has investigated a single source of organically grown foods. I have. And I can take him to visit the farms from which we obtain our poultry, vegetables, fruit, and beef. If he is interested in facts rather than in unsupported assertions, I urge him to accept this invitation.

C. Natural Vitamins Are Superior to Synthetics.

Unfortunately, most of the research work on vitamins has been done by chemists, who have been interested primarily in attempting to isolate the pure essence of a vitamin so that it could be used as a medicine to cure disease. Hence, as soon as a natural food was found to have some vitamin effect ("protective effect" it was originally called), the chemists have sought to isolate the vitamin by some chemical process, determine its chemical composition, and then imitate it by a synthetic product.

Let us take vitamin C as an example.

One of the earliest instances of the use of vitamin C to cure scurvy was the experience of Jacques Cartier, the French explorer in America, in 1536. A large number of his men were stricken with scurvy, which the Indians cured by a tea made from pine needles. Subsequent researchers confirmed the fact that numerous fresh vegetables and fruits contain a substance which cures or prevents scurvy, and has many other important functions in the complicated chemistry of the human body. They called the effective substance "vitamin C."

So, following the conventional procedure of vitamin research, the chemists thought they had identified the substance that produced these results. Albert von Szent-Gyorgi isolated a crystalline substance in 1927 and called it "ascorbic acid." But Gyorgi soon found that the natural vitamin complex also included a permeability factor which he called "vitamin P."

Subsequent developments (especially actual use on human subjects) have proven that the natural vitamin C complex includes the following:

Ascorbic acid
The enzyme tyrosinase (organic copper)
Rutin
Vitamin K
Vitamin J
Vitamin P
Ascorbigen

Now let us look at the actual use of vitamin C.

One of the signs of mild scurvy is pyorrhea, ("pink toothbrush"). Any good natural vitamin C complex (unless hindered by antagonists of this vitamin, such as coffee and tobacco) will promptly stop the bleeding gums. But actual tests have shown that synthetic vitamin C (ascorbic acid) does not have the slightest effect on this situation. It is the vitamin P in the natural vitamin C complex that cures the capillary fragility of the scurvy state.

These facts concerning vitamin C have been stated to show why those of us who have carefully studied the subject prefer natural vitamins. Similar facts have been established concerning other vitamins.

Yet Mr. Larrick says:

> "Laboratory and clinical research has proved that synthetic vitamins have the same biological response as the naturally occurring vitamins." *(FDA Summary Report, February 1962)*

This statement is directly contradicted by another agency of the U.S. Government. The U. S. Army Nutrition Manual (1949) says:

> "Whenever possible, the nutrient required should be obtained from natural foods rather than synthetic preparations. This is particularly true of vitamins. Synthetic vitamin concentrates, tablets or pills may not contain all the known nutrients, either as such or in optimal proportion. Furthermore, they obviously may not contain lesser known or unknown nutrients which are, however, provided by natural foods."

Many investigators have reported facts which agree with this statement by the U. S. Army.

As early as 1938 McBeath and Zucker found that synthetic vitamin D was less valuable than the natural complex for increasing the immunity of children to dental decay.[1]

Writing in the Journal of the American Medical Association in 1941, Dr. Norman Jolliffe said that he had obtained good results in treating neuropsychiatric disorders with natural vitamin-containing materials such as brewers yeast and wheat germ, and that these "are preferred to synthetic products in capsule form from which some factors as yet impossible to encapsulate are likely to be missing." [2]

In 1962 an article appeared entitled "Superiority of Natural Vitamins for Nutritional Purposes." [3] The author says, "Adequate vitamin C activity is assured only where sufficient oxidases (oxidizing ferments), along with vitamin C, are to be found, as in the case of salad greens, fresh vegetable juices, herbs and fruits."

A very recent example is contained in the Journal of Nutrition of March, 1963.[4] Researchers for the U. S. Army reported on tests made on

1. Journal of Nutrition, 1938, p. 570
2. Journal American Medical Assn., Nov. 1, 1941, p. 1496
3. Zeitschrift fur Artzliche Fortbildung, Feb. 1962, by H. Gronau
4. Journal of Nutrition, 1963, p. 340

guinea pigs to find out what food factors might furnish some protection against the effects of radio-active fallout. They found that natural alfalfa and broccoli did have a protective effect, but that synthetic vitamin A or synthetic carotene (a substance from which the body can form vitamin A) did not have any appreciable protective effect. They conclude that the "radioprotective agent" in these foods is a water-soluble factor not yet identified.

Many doctors have demonstrated by actual results on patients the superiority of natural vitamins. For example, Horace W. Soper, M.D., F.A.C.P., of St. Louis, Missouri wrote:

> "I find so many patients who have taken the synthetic vitamins for years and still suffer from malnutrition. All that is required to restore them is a diet of high vitamin content and brewers yeast powder. Few persons consume enough Vitamin B in their diet. The yeast powder contains all the Vitamin B complex. Furthermore, the yeast continues its fermentive action in the small intestine and facilitates the absorption of all other vitamins and end products of food digestion. It is a splendid nerve tonic and a good adjunct in all forms of anemia. I concluded that the synthetic vitamins could not be depended upon. This opinion was later confirmed by the research work of Prof. A. J. Carlson of Chicago and Prof. Drummond of England."
> *American Journal of Digestive Diseases, 1953, p. 227*

As a result of my study and experience, I agree with the U. S. Army and these other authorities concerning the deficiencies of synthetic vitamins. And under present-day methods of food production, preparation and transportation, which are not conducive to the formation or preservation of vitamins, I believe it is good nutritional insurance to take a vitamin supplement extracted from natural sources.

I am inclined to believe that Commissioner Larrick has been misinformed concerning the "laboratory and clinical proof" that synthetic vitamins have in all cases "the same biological response as the naturally occurring vitamins". But, in any event, why should he be permitted to use the weight of the U. S. government against natural vitamins?

D. The FDA is Operating Contrary to the Principles of Dr. Harvey Wiley.

The FDA is trying to fool the public into thinking that it is carrying on the work started by Dr. Harvey Wiley, the father of the Federal Pure Food Law. I have personally seen this effort in the public display room of the FDA (Room 3024 of the Health Education and Welfare Building). The fact is that many of the present activities of FDA are directly contrary to the principles of Dr. Wiley.

In a recent book, *The Legacy of Doctor Wiley,* Maurice Natenberg has told the story of the life of Dr. Wiley. He summarizes Dr. Wiley's principles as follows:

> "His fundamental principle was exceedingly simple: Foods should be grown, transported, processed, and prepared for the table so that natural nutritional properties would be conserved to the highest degree. This precludes the use of toxic chemicals for preservation, flavoring, or coloring to hide the absence of original nutritional elements or presence of decay. Ideal nutriment must therefore be close to its original state, consumed almost immediately after harvesting or slaughter. Where that is impossible, the next acceptable alternative is food preserved by natural methods and subjected to a minimum of processing, transportation, and storage." *p. 60*

After his struggle to obtain the passage of the Pure Food Law, Dr. Wiley set about to stop "the use of toxic chemicals for preservation, flavoring, or coloring to hide the absence of original nutritional elements or presence of decay." But the large food processing companies brought such pressure to bear against these efforts that Dr. Wiley resigned in disgust. He spent the rest of his life exposing the fact that the Bureau of Chemistry (now the Food and Drug Administration) had been diverted from its intended purpose of protecting the public, to the protection of the giant food corporations. This story he told in his book, *The History of A Crime Against the Pure Food Laws.*

It is clear from his writings that if Dr. Wiley were alive today he would be equally vocal in objecting to present practices of the FDA.

He would point out that the FDA permits 7 parts per million of DDT on nearly every fruit, vegetable, and portion of animal fat reaching the American table. Yet one of its officers has admitted that as little as 5 parts per million produces definite liver damage in rats.

He would point out that the FDA has permitted the use of stilbestrol (an artifical sex hormone) to fatten poultry and cattle. Yet Canada, after scientific tests, prohibited its use.

He would point out that the FDA has approved 16 coal tar dyes for use in food. Yet Dr. Arthur A. Nelson of FDA admitted in 1957 that 10 of the certified dyes – all in wide use – had produced cancer in rats when injected under the skin. Earl Ubell, noted science writer, estimated that "some people get twice as much by mouth as some of the rats got under the skin. . ." The International Union against cancer has said that not one of these dyes has been proved safe for use in food.

In 1956 an international symposium on food additives was held in Rome. Dr. W. C. Hueper, Chief of the Environmental Cancer Section, National Cancer Institute, U. S. Department of Health, Education and Welfare read a paper strongly condemning most of the commonly used food additives and

contaminants. This conference adopted unanimously a set of principles which included:

> "An additive should be permitted only if it fulfills these requirements:
>
> (a) It should conform to agreed official specifications.
> (b) It should be shown by adequate scientific evidence to be innocuous to the consumer.
> (c) Its use should meet a recognized need and should be in the interest of the consumer."

Dr. Harvey Wiley would applaud this statement as conforming to the principles he originally proposed for the U. S. Pure Food Law. He would also strongly condemn the present policies of FDA as failing to conform to those principles.

E. The FDA is Illegally Harassing The Health Food Movement.

We have seen above from Natenberg's summary that Dr. Wiley believed that foods should be

> "grown, transported, processed, and prepared for the table so that natural properties would be conserved to the highest degree."

We can therefore be sure that if Dr. Wiley were alive today he would be disgusted, but not surprised, to see how the FDA is illegally harassing the movement which is trying to carry out this basic principle. In view of the limits of time and space I will limit this discussion to several typical examples.

(1) The Case of Admiral Sea Salt

More and more of the recent scientific data emphasizes the importance of the so-called "trace" minerals in human nutrition. (See pages 5 & 6) Sea salt is a very fine source of these "trace" minerals. It is for this reason that many health-minded people prefer to use sea salt in the place of ordinary table salt. My own family has been using sea salt for a long time.

The reason I prefer sea salt is that it contains minute amounts of the "trace" minerals known to be important in animal nutrition, along with others which may be important for reasons not yet discovered by nutritional science. No one has ever found any harmful effects from the use of sea salt.

For years we purchased from sources specializing in health foods, a brand of sea salt under the name of "Admiral Sea Salt", which was produced by a small company. I am informed that the FDA threatened this small compa-

ny with prosecution under the Food and Drug Act. It proceeded against this company, not because of any impurities in the product, or harm done by the product, but solely because FDA does not believe that sea salt is any better than ordinary salt.

Under these threats by FDA the company changed the name of its product to "Admiral Seasoning". This, of course, was such a non-descript name that those who wanted to purchase sea salt would be thrown off the track. This was apparently the intended purpose of FDA. I am informed that this small company has been forced out of business by this action by FDA.

Fortunately, other larger companies that can afford legal counsel to protect their rights are still selling sea salt, so that those of us who prefer to use this form of salt can still do so.

Congress has not set up the FDA as an arbiter to decide the relative value of foods, with authority to suppress foods which it thinks are of lesser value. The U. S. Circuit Court of Appeals for the Third Circuit made this clear in the following language:

> "There is no evidence to indicate a legislative intent to bar from the market foods which are wholesome merely because they may in fact be of relatively little value. So long as they are not confused with more wholesome products, their presence does no harm." *(U.S. v. 88 Cases (Birley's Orange Juice) 187 F. 2d 967, 972 (1950)*

In spite of this court decision, the FDA continues to do by force of pressure on small concerns, the very thing the court said it had no power to do.

This is indeed bureaucratic despotism.

(2) The Case of the Test for Vitamin C.

I personally have had an encounter with the bureaucratic despotism of the FDA.

Several years ago I saw an advertisement by a Canadian concern of a simple test kit by which a person could check on whether he was obtaining an adequate amount of vitamin C. Being interested in the subject I ordered one of the kits.

Before long I received a notice from a U. S. Customs Office that the test kit was being denied entry into this country because the FDA made the following objections:

(1) The kit would not give an accurate check on vitamin C.
(2) There was no evidence that people were not getting adequate vitamin C.

When I wrote to the Customs Bureau on my legal stationary demanding to know by what law the FDA was assuming to hold up this shipment, the test kit was immediately released to me.

If I had been a layman not represented by a lawyer, the FDA would probably have gotten away with this illegal suppression of a perfectly harmless test kit.

(3) The Case of Walnut Acres.

We have in my home state of Pennsylvania a small business known as "Walnut Acres", which has been selling organically-grown foods. It was started, and is being operated, by Paul K. Keene, an ex-missionary, who is motivated primarily by a desire to share with his fellow men the benefits of healthful foods which he himself has found to be helpful.

My wife and I have been dealing with Walnut Acres for many years, and we have every reason to believe that they are honest and that their products have been truthfully represented and labelled.

Some time ago, as part of its persecution of the health movement, the FDA started to harass Walnut Acres. The first thing that happened was that FDA agents appeared and, without making any explanation as to what they were after, started making a Gestapo-like search of the premises. The company was forced to put up a substantial bond, and the agents seized a considerable amount of merchandise.

The real motive for the action against Walnut Acres came out later when Mr. Randolph of the Regulatory Division of FDA told Mr. Keene that in his opinion Walnut Acres should not be permitted to advertise that its produce was raised without chemicals and sprays, because that is claiming a superiority which in fact does not exist. Shades of *Silent Spring!*

Walnut Acres, being a small family-type enterprise, was not represented by an attorney, and therefore agreed voluntarily to many of the unreasonable demands made upon it by the FDA agents. For example, it agreed to change the name of its "Lecithin Granules" to "Soya Phosphatides". To understand how ridiculous that demand was we should review a few facts about lecithin.

Lecithin is one of a group of fatty substances widely found in nature. It was discovered in 1844 by N. T. Gobley, who name it "lecithin" (Greek lekithos, egg yolk) because he had isolated it from egg yolk. Lecithin is an organic compound which includes several of the B vitamins (choline and inositol) and phosphorus (essential for the production of energy and nerve impulses). Lecithin is an emulsifier for fat, and is believed by many authorities to be the best natural substance to prevent the deposit of cholesterol on the walls of the blood vessels. Practically all of the lecithin sold as a food supplement is derived from soy oil, which is rich in this substance.

"Lecithin" is the standard dictionary name by which this substance is known, and this name is used in all technical literature. Therefore it is not seen why anyone cannot sell granules of this substance as "lecithin granules". The FDA has no legal basis whatever for preventing the use of this name.

Apparently the FDA does not believe that lecithin has any dietary benefit, and hopes to discourage its use by forcing the adoption of the more technical name "soya phosphatides". No adequate reason was given to Mr. Keene for demanding this change, and his only explanation for this requirement was "the whims and desires" of FDA.

A parallel case, but one in which the FDA did not get away with these Gestapo tactics, is the recent case of Dextra Fortified Sugar. There the product was fortified with phosphorus, and the FDA tried to make the company use the unwieldly phrase "Phosphorus from Monosodium phosphate and/or monopotassium phosphate". The company resisted this requirement, along with others, and the case went to a Federal Court. In deciding against FDA the court said this requirement of an indication of the source of the phosphorus was "picayune", and said:

> "The basic flaw in the Government's case against the product is that it is seeking, under the guise of misbranding charges, to prohibit the sale of a food in the marketplace simply because it is not in sympathy with its use. But the Government's position is clearly untenable. The provisions of the Federal Food, Drug, and Cosmetic Act did not vest in the Food and Drug Administration, or any other federal agency, the power to determine what foods should be included in the American diet; this is the function of the marketplace." *U.S. v. 119 Cases (Dextra Brand Fortified Sugar) S.D. of Florida, Feb. 27, 1963*

(4.) The Case of Dr. Royal Lee

The case of Dr. Royal Lee deserves special attention, because Commissioner Larrick has mentioned this case as one of the great triumphs of the Food and Drug Administration. I have examined carefully the court records of the several cases FDA prosecuted against Dr. Lee, and I am convinced that this is another instance of harassment of the health movement. It is another chapter of FDA activity that would make Dr. Harvey Wiley turn over in his grave.

In considering this case it is again necessary to review some history.

Royal Lee received the degree of Doctor of Dental Surgery from Marquette University in 1923. During his senior year he prepared a paper reviewing all the scientific literature then available on the cause of tooth decay. This study led him to conclude that tooth decay was primarily caused by nutritional deficiencies – particularly by the loss of vitamins from natural foods as the result of refining and processing.

After graduation, Dr. Lee did not practice dentistry, but being of an inventive turn of mind, became interested in inventing and developing dental instruments. This inventing activity eventually led him into the field of electric motors, where he has made an outstanding contribution in the Lee speed control, which is still the best speed control available, and is used extensively where accurate control of motor speed is essential.

Meanwhile, his scientific curiosity having been aroused by his study of the cause of tooth decay, he continued his research in nutrition as a hobby. At this early date (1925-1930) the science of nutrition was in its infancy. Only a few vitamins were known, and no one had the barest glimmer of the incredible complexity of the human chemical factory. (See the current series running in *Life* Magazine, Part I, October 26, 1962)

But in spite of the rudimentary state of the science of nutrition, Dr. Lee, with the insight of a true scientist, decided that the sure way to obtain all the then-known vitamins, as well as others that remained to be discovered, was to preserve and utilize the nutritional factors present in natural foods. In adopting this principle he was following directly in the footsteps of Dr. Harvey Wiley, whose principles, as summarized by Natenberg, included a belief that:

> "Foods should be grown, transported, processed and prepared for the table so that natural nutritional properties would be conserved to the highest degree." (See p. 21 above)

Dr. Lee did not follow the conventional path of attempting to isolate the vitamins and then imitate them synthetically. Instead he chose the approach of finding the best ways of preserving and utilizing the vitamins provided by nature.

One of the first foods to attract his attention was wheat. He knew that the germ of the wheat contained vitamin B, and suspected that it might contain other important nutritional factors. In commercial milling practice the wheat germ is removed because it contains wheat-germ oil (later found to contain vitamin F) which causes whole wheat flour to become rancid very quickly after it is ground.

Dr. Lee decided that the way to preserve all nutritional factors of wheat was to make it possible for the baker or housewife to grind the whole wheat flour from the grain just before baking the bread. He therefore invented an electric flour mill which grinds the grain without overheating it, and made the mills available in sizes for use in households or in bakeries. Since the grain itself keeps indefinitely without danger of rancidity, this procedure insures that the bread contains all of the nutrients nature puts into the grain.

I can testify personally that this procedure is practical and that the resulting bread is delicious as well as nutritious. We have a Lee flour mill in our kitchen, and my wife makes from a combination of wheat and rye flour the best bread I ever tasted. The fact that everyone who tastes our bread says the same thing is refutation of the propaganda put out by the white-flour interests that the public prefers white bread to whole wheat bread.

Commercial whole-wheat bread, which is loaded with preservative, softeners, etc., is not to be compared in taste with real 100% whole wheat bread made from freshly-ground flour. Preserving the bread from rancidity after it is baked is no problem for those having a freezer-refrigerator.

At the same time that he was working on ways to conserve vitamin content of the grains, Dr. Lee turned to the problem of producing effective concentrates which the dentist and physician could use to quickly supply the vitamins needed by those suffering from deficiencies.

Here again, he decided to follow the principles of conserving the vitamins provided by nature, instead of attempting to isolate a particular constituent and then make it synthetically. In following this principle he was pioneering the idea later stated in the U. S. Army Nutrition Manual of 1949 (see page 10) that:

> "Wherever possible, the nutrient should be obtained from natural foods rather than synthetic preparations."

Knowing that some of the vitamins are destroyed by heat, he developed methods of extracting the vitamins (known and unknown) without the use of heat, and he was granted several patents by the U. S. Patent Office on his new methods of extracting vitamins.

By using these methods, he soon developed a concentrate which he tried on himself and his friends. He found that it was effective in building up resistance against colds. He then offered it to some dentists and doctors, who reported good results in the treatment of many deficiency situations. Some doctors reported astonishing benefits to persons with indications of heart disease.

Dr. Lee called his vitamin concentrate "Catalyn" because vitamins have a catalytic action in the human body. This was one of the first multiple-vitamin-mineral preparation placed on the market, and was without doubt the first such preparation obtained from natural souces. It is still believed by many persons, including many doctors of medicine, to be the best vitamin preparation available.

After receiving favorable reports from many doctors, Dr. Lee began selling Catalyn. It was sold with a statement that it "produces results in two ways - by regulation of metabolism (an immediate effect), and by building up the vitality and resistance." The circular which accompanied it said "we earnestly request that if you have any of the diseases or conditions listed below, you consult your physician as to the advisability of using Catalyn either alone or as a supplementary treatment according to the schedules given." Then followed a list of ailments for which doctors had found Catalyn to be beneficial.

In 1934 the FDA brought suit in a federal court against Dr. Lee and his company, The Vitamin Products Company. The chief ground for the suit was that Catalyn was "mis-branded" because according to the "concensus of

medical opinion", it was not an effective remedy for the ailments for which it was recommended. The case was tried in 1939.

I have examined the records of that suit, and in my opinion, as a lawyer with some knowledge of biochemistry, it was one of the greatest miscarriages of justice I have ever seen. To explain all of the errors of the government's case would fill a volume, so I will merely point out a few of the more outstanding errors and inconsistencies.

A basic difficulty with this kind of a case, is that it goes before a jury for trial. Since the average citizen is unable to understand the technical facts about vitamins and body chemistry, the jury must decide a case of this kind solely by general impressions.

The FDA itself admits the fact that a jury is ill-equipped to decide a case involving technical questions in the field of medicine. At the National Congress on Medical Quackery held on October 6, 1961, William F. Goodrich, Assistant General Counsel for FDA said:

> "We must all agree that a jury is poorly equipped by training and experience to answer medical questions about cancer and arthritis. Any one of many possible trial incidents could well control their decision." *(Proceedings, p. 22)*

The same is of course true of technical questions concerning biochemistry and nutrition.

It is no wonder then, that a jury is often unduly impressed by the mere fact that the U. S. Government has brought suit against the defendant. When the trial is presided over by a judge who shares this view, the defendant is as good as convicted before the trial starts.

Let us examine a few of the grosser errors committed during the trial of Dr. Lee.

1. The government tests of Catalyn were made several years after the Catalyn had been seized. It is now known that many of the vitamins oxidize and are destroyed upon exposure to air. Yet the government tried to prove that its tests of Catalyn on guinea pigs failed to show the presence of any vitamins A, C or D and only a trace of vitamin B. The government did not attempt to show that proper steps had been taken to protect the Catalyn from moisture and air during the two-year interval between the seizure and the tests.

2. The government was permitted to introduce testimony that Catalyn had failed to produce good results on guinea pigs, but when Dr. Gerald M. Stevenson, testifying for the defendant, attempted to tell about beneficial effects on a dog, the judge said, "I don't care about your dog."

3. Fred W. Irish, a FDA employee, testified about making vitamin tests, but when the defense attorney asked him whether the same amount of vitamin B might have different effects on two different individuals, the court

ruled that this question was irrelevant and immaterial.

The defense attorney was trying to bring out the fact that because Catalyn did not cure one ailment in a particular patient was no reason for concluding that it was worthless. Modern investigators have verified the fact which the defense attorney sought to bring out. Prof. Roger J. Williams, a competent authority, states that different individuals differ widely in their need for the B vitamins. *(Biochemical Individuality, p. 149)*

4. Dr. Gerald M. Stevenson, an osteopathic physician, testified that he had used Catalyn on 700 patients, and was well satisfied with the results. He said that for two years he had placed expectant mothers on Catalyn, and found that it prevented the injury to teeth that often results from mineral deficiency. He said he believed that for babies Catalyn supplied "more and varied vitamins than if I prescribed cod liver oil." He told of using Catalyn successfully to improve the blood-clotting time before nose and throat surgery.

5. Dr. J. P. Kanoky told about excellent results from the use of Catalyn in a number of diseases. He said he preferred Catalyn, made from natural sources, to synthetic vitamins. In an attempt to belittle his testimony the Court asked, "Did you ever analyze that Catalyn tablet, Doctor?" Obviously the answer was "No", as it is unheard of for a doctor to personally analyze the medicines he prescribes.

6. Dr. William D. Olmstead, testified that he had tried every vitamin preparation made by the large pharmaceutical houses, and he finally concluded that he obtained the best results from Catalyn, and other products made by Dr. Lee's company.

7. Numerous individuals testified to benefits they had personally received from Catalyn. There was not a shred of evidence that Catalyn had ever had any bad effects on anyone. The best the FDA could do was to show that in a few instances Catalyn had not cured certain diseases.

8. As against this solid evidence of good results from Catalyn, the FDA relied on witnesses who testified to the general effect that the "concensus of medical opinion" was not favorable to the use of a multiple-vitamin preparation. This was undoubtedly true, as the average medical doctor has made little study of nutrition, and in 1939 the average doctor laughed at vitamins as a passing fad. I know this from my own personal experience.

9. One of the witnesses presented by the FDA to establish the "concensus of medical opinion" was Dr. Walter Brussock, Part of his testimony reads as follows:

"Ques. Doesn't vitamin deficiency cause degenerative changes in the human system?
Ans. It does not.

Ques. How about scurvy?
Ans. Scurvy is not a degenerative disease.

Ques. Are not vitamins necessary to the proper functioning of the human being as a constituent element of food intake?

Ans. They are necessary food factors, yes.

Ques. Then if they are deficient, why can't they cause functional disturbances?

Ans. I don't know."

If this testimony accurately represented the "concensus of medical opinion" in the year 1939, it certainly did not represent the concensus of government opinion. The U. S. Department of Agriculture Yearbook for 1939, "Food and Life", directly contradicts this testimony of Dr. Brussock in the following passage:

> "...there are probably thousands of people in this country who are suffering from an unrecognized deficiency of vitamin C. Many vague symptoms of ill-health, such as restlessness and irritability in infants and children and a run-down feeling in adults, particularly in the early spring (spring fever), are probably due to lack of vitamin C. In fact, even where there is not a single outward symptom of trouble a person may be in a state of vitamin C depletion more dangerous than scurvy itself. When such a condition is not detected and continues uncorrected, the teeth and bones may be damaged and, what may be even more serious, the blood system may be weakened to the point where it can no longer resist or fight infections not so easily cured as scurvy." *pp. 235-36*

If this government document had been introduced at the Lee trial it alone would have effectively rebutted most of the evidence against Dr. Lee.

Some of the witnesses for the FDA said that the average diet contains all of the vitamins needed. But in *Food and Life* the Department of Agriculture said:

> "The chief fault of many American diets is that they provide too little of the essential minerals and vitamins. This fault is due in large measure to the fact that refined foods are consumed in such amounts that the intake of minerals and vitamin-rich natural foods is lower than it should be." *(p. 104)*

But regardless of the correctness of the "concensus of medical opinion" in 1939, the consummate folly of trying to confine the new science of nutrition within any current "concensus of medical opionion" is clearly shown by Commissioner Larrick's own statement:

> "For centuries the approved medical theories of one generation have become outmoded in the next. What was accepted medical 100 years ago, or 50 years ago, to a large extent would be

quackery today." *National Congress on Medical Quackery– October 6-7, 1961, p. 12*

10. With the full weight of the U. S. government thrown behind this ill-informed and warped testimony, it is no wonder that the unlearned jury returned a verdict against Dr. Lee and The Vitamin Products Company. And it is certainly no great credit to our legal system that this verdict was upheld on appeal by the U. S. Court of Appeals for the Seventh Circuit.

11. In 1962 the FDA brought a second action against Dr. Lee, but in this case Dr. Lee pleaded "no contest" and accepted a consent decree. It can be easily understood that Dr. Lee foresaw a second trial weighted against him on the ground of an atiquated "concensus of medical opinion".

12. The real reason for the venom in the FDA persecution of Dr. Lee must be found behind the scenes. Dr. Lee has been a most vocal critic of the manner in which the FDA has departed from the principles of Dr. Harvey Wiley.

When Dr. Lee found that Wiley's book criticizing the operations of FDA was out of print, he attempted to obtain rights to re-publish it. But the widow of Dr. Wiley refused to give permission, saying that she was satisfied that the FDA was carrying on the work of her husband. That her naive faith in the FDA was unjustified can be verified by anyone who will take the trouble to read the book.

But Dr. Lee nevertheless did republish *The History of A Crime Against the Food Laws* because he thought the public was entitled to know the complete history of the FDA. This act was the equivalent of high treason in the minds of the FDA bureaucrats.

F. Conclusion

Supervision over Vitamins and Food Should be Removed from FDA and Placed in the Public Health Service.

It seems clear that in the Case of Dr. Lee, as in the other cases mentioned above, the FDA was doing exactly what the court said it was not authorized by law to do; namely,

> "...seeking, under the guise of misbranding charges, to prohibit the sale of a food on the marketplace simply because it [the FDA] is not in sympathy with its use."

While the FDA has been spending its money and manpower on these persecutions of the health food movement, it has complained to Congress that it does not have adequate manpower to enforce its regulations (all too liberal) against poisonous insecticides, or to police dangerous drugs like Thalidomide.

It is to be expected that the health food movement should be opposed by the large pharmaceutical drug houses which manufacture and sell synthetic vitamins. But what is not so well known is the close connections between these drug houses and the FDA. Some of those connections come to light in the notorious Dr. Welch case. Another interesting bit of evidence is the fact that Commissioner Larrick is to receive an honorary membership in the American Pharmaceutical Association at its meeting in May, 1963.

Unfortunately, the FDA has departed so far from the principals of Dr. Harvey Wiley, that there is no way apparent to reverse its course. It would seem quite logical and proper to split off its supervision over vitamins and foods and place it in the U. S. Public Health Service. In that bureau there seem to be scientists like Dr. W. C. Hueper (See p. 23 above) who are more dedicated to the principles of Dr. Wiley than to the interests of the food processors and the pharmaceutical industry.

And any bureau given supervision over the important field of the health of the American people should be prohibited from employing anyone having a connection with a vested interest; such as concerns selling food or health products; pharmaceutical houses; or the corporations which make their profits from processed foods, such as the food packers or the millers of flour.

In the conclusion of his book, *The History of A Crime Against The Food Law,* Dr. Harvey Wiley said that if the law had been enforced as originally intended:

> "No food product in our country would have any trace of benzoic acid, sulphurous acid or sulphites, or any alum or saccharin, save for medicinal purposes. No soft drink would contain any caffein, or theobromine. No bleached flour would enter interstate commerce. Our foods and drugs would be wholly without any form of adulteration and misbranding. The health of our people would be vastly improved and their life greatly extended. The manufacturers of our food supply, and especially the millers, would devote their energies to improving the public health and promoting happiness in every home by the production of whole ground, unbolted cereal flours and meals.
>
> "The resistance of our people to infectious diseases would be greatly increased by a vastly improved and more wholesome diet. Our example would be followed by the civilized world and thus bring to the whole universe the benefits which our own people had received." *p. 401*

I urge upon Congress the fact that what is needed most in the food and drug field is a return to the principles of Dr. Harvey Wiley.

KARL B. LUTZ

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