The original documents are located in Box 43, folder "4/22/76 HR7988 Health Research and Health Services Amendments of 1976 (1)" of the White House Records Office: Legislation Case Files at the Gerald R. Ford Presidential Library.

S 4/22/76

APPROVED
APR 22 1976

THE WHITE HOUSE

WASHINGTON

DECISION
Last Day: April 24, 1976

Posted 4/23/76

Archives 4/23/76

MEMORANDUM FOR THE PRESIDENT

FROM: JIM CANNON

SUBJECT: Enrolled Bill H.R. 7988 - Health Research and Health Services Amendments of 1976

This is to present for your action H.R. 7988, which extends through FY 1977, with increased funding, heart, lung, blood and certain other research programs; bio-medical research training; establishes a national genetic diseases program; limits the authority of the FDA to regulate vitamins and minerals; and other miscellaneous provisions.

BACKGROUND

A detailed description of the major provisions of the bill and agency comments are included in Jim Lynn's memorandum attached at Tab A.

The bill passed the House by a vote of 375-5, and the Senate by a vote of 90-2.

RECOMMENDATIONS AND COMMENTS

Both OMB and HEW recommend approval of H.R. 7988. HEW, however, recommends a statement be issued indicating the President's objection to the limitation of the FDA's authority to regulate vitamins, minerals and dietary supplements.

It is the opinion of HEW that the restrictions imposed on the FDA will hamper its ability to assure that consumers are fully informed about the variety of vitamin and mineral products. Also, the Department is concerned that this represents an undesirable precedent for Congressional termination of federal agency regulatory jurisdiction on a piecemeal basis.

On the other hand, the freedom to purchase vitamins in varying potencies and quantities is an issue that is highly sensitive to a large number of Americans. This measure can be viewed as a reasonable effort to strike a balance between protecting the consumer from unsafe or dangerous products, while at the same time recognizing the rights of consumers

who desire to purchase and utilize vitamin, mineral and dietary supplements which are not specifically dangerous to one's health.

Also, as House Minority Leader, you supported similar legislation. On May 3, 1973, you co-sponsored H.R. 7473, legislation introduced by Representative Hosmer to amend the Food, Drug and Cosmetic Act to include a definition of food supplements which would exclude them from FDA control.

It is essential to note that the legislation does not effect the authority of HEW to take action against products based on safety considerations, nor against products that are represented for use by children under 12 or by pregnant or lactating women, or that are used for treating specific diseases or as conventional food substitutes. Also, HEW would still retain authority to initiate enforcement action against a food or vitamin product if its labeling or advertising is false or misleading. The Department is also being granted new authority over the advertising of vitamins, minerals, and other non-prescription drugs.

RECOMMENDATIONS

Jim Lynn and I recommend that you approve H.R. 7988 without a signing statement. Bill Seidman, Max Friedersdorf, and Counsel's Office (Lazarus) recommend approval of the enrolled bill.

DECISION

Sign H.R. 7988 at Tab B.

APF Approve no signing statement

_____ Disapprove

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

APR 19 1976

MEMORANDUM FOR THE PRESIDENT

Subject: Enrolled Bill H.R. 7988 - Health Research and Health Services Amendments of 1976
Sponsor - Rep. Rogers (D) Florida

Last Day for Action

April 24, 1976 - Saturday

Purpose

Extends through fiscal year 1977 and increases the authorizations for the heart, lung, blood disease and national research service awards programs; modifies authorizations for the arthritis program; authorizes grants for new programs, i.e., genetic diseases and visiting scientist awards; and limits authority of FDA to regulate vitamins and minerals.

Agency Recommendations

Office of Management and Budget	Approval
Department of Health, Education, and Welfare	Approval (Signing statement attached)
National Science Foundation	No objection (informally)
Federal Trade Commission	No objection (informally)
Department of Justice	Defers to other agencies (informally)

Discussion

H.R. 7988 is an omnibus health research and training bill that would extend, enlarge, or modify the appropriations authorizations for a number of health research programs--heart and lung diseases, blood diseases, arthritis and genetic diseases. The bill would also extend authorizations for national research service awards (biomedical research

training), the physician shortage area scholarship program, and the health professions student loan program, and would authorize new categorical grants for genetic diseases and visiting scientist awards. H.R. 7988 would significantly limit the authority of the HEW Secretary to regulate vitamins and minerals, a provision which HEW finds highly objectionable.

The bill was passed in the House by a vote of 375-5 and in the Senate 90-2. Its major provisions are discussed below.

Heart, lung and blood research program; National Research Service Awards. The appropriations authorizations for the National Heart and Lung Institute (NHLI) and the National Research Service Awards Program expired on June 30, 1975. H.R. 7988 would extend and increase these authorizations through fiscal year 1977. Further, in the heart, lung and blood research area, H.R. 7988 would:

-- provide explicit and broadened authority for the NHLI to conduct programs with respect to the use of blood products and the management of blood resources,

-- redesignate the Institute as the National Heart, Lung and Blood Institute, and

-- provide that the 30 research centers currently authorized in law be divided equally among the heart, lung, and blood research areas.

In testimony and reports on H.R. 7988, HEW stated that it had no objection to the provisions extending the heart, lung, and blood research programs or the National Research Service Awards program as long as (1) no new activities were mandated and (2) the appropriation authorizations were consistent with the administration's budget requests.

Genetic diseases. H.R. 7988 would repeal the present categorical authorities for research and other activities relating to sickle cell disease and Cooley's anemia and substitute a more comprehensive categorical program for genetic diseases testing, counseling, information, and education. The bill would include at least nine different genetic diseases as eligible for funding, but would require that priority be given to sickle cell and Cooley's anemia projects. HEW opposed this provision as interfering with the orderly and efficient administration of health research programs concerned with genetic diseases.

Restrictions on vitamin and mineral regulation. H.R. 7988 would limit the authority of the HEW Secretary to regulate vitamins, minerals, and other dietary supplements--in effect, largely removing FDA's regulatory authority to prescribe potency and combination standards.

These provisions represent a congressional response to regulations published by FDA proposing that most vitamins and minerals with a potency of 150% or more of FDA's recommended daily allowances be classified as drugs. The regulations were initially published in 1962 and, after a long history of hearings and public comments, were published as final regulations in 1973 to become effective on January 1, 1975. A court order stayed the effective date of the regulations until June 30, 1975.

Under the provisions of H.R. 7988, the HEW Secretary would be prohibited from (1) imposing maximum limits on the potency of vitamins and minerals and other dietary supplements, (2) specifying only limited combinations of vitamins or minerals which can be marketed, and (3) classifying a vitamin or mineral as a drug solely because it exceeds the level or potency that HEW determines is nutritionally rational or useful. The restrictions in H.R. 7988, however, would not affect the authority of HEW to take action against products based on safety considerations, nor against products that are represented for use by children under twelve or by pregnant or lactating women, or that are used for treating specific diseases or as conventional food substitutes.

HEW would still retain authority to initiate enforcement action against a food or vitamin product if its labeling or advertising is false or misleading. HEW would also be granted new authority over the advertising of vitamins, minerals, and other non-prescription drugs. This authority is much the same as that already exercised by the Federal Trade Commission (FTC), although the bill requires FDA to allow FTC 90 days before taking its own enforcement actions concerning non-prescription drug advertising.

HEW has strongly opposed legislation which would limit the authority of FDA to regulate vitamins, minerals, and dietary supplements.

Other provisions. H.R. 7988 includes numerous miscellaneous provisions related to health research and health services. Briefly, the enrolled bill would:

-- direct both the President's Biomedical Research Panel and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research each to undertake a study on the implications of disclosure to the public of information contained in research proposals submitted to HEW,

-- redistribute the appropriations authorizations for arthritis centers between 1976 and 1977 and make certain technical amendments to the National Arthritis Act (P.L. 93-640),

-- extend the expiration date of the National Diabetes Commission to September 30, 1976,

-- add ambulatory surgical services as a supplemental health service which may be offered by migrant and community health centers,

-- permit the Indian Health Service to utilize non-profit recruitment agencies to assist in obtaining personnel,

-- prohibit the consideration of political affiliation in making appointments to advisory committees under the Public Health Service Act and related laws,

-- extend the provisions of the Soldiers and Sailors Civil Relief Act of 1940 to the Commissioned Corps of the Public Health Service,

-- authorize HEW to make awards to enable outstanding scientists to serve as visiting scientists at colleges with high enrollments of disadvantaged students, and

-- extend through fiscal year 1976 the appropriations authorizations for the physician shortage area scholarship program and the health professions student loan program for which the Administration specifically proposed no new funding.

The Administration did not have an opportunity to take a position on most of these provisions.

Budget impact

H.R. 7988 would authorize $614 million for fiscal year 1976 and $638 million for fiscal year 1977. These amounts exceed the budget by $174 million for 1976 and $197

million for 1977. Specific program appropriations authorizations are shown in the table below.

($ in millions)

	1976		1977	
	Budget request	H.R. 7988	Budget request	H.R. 7988
Heart, lung, and blood research and control	1/288	349	330	403
Research Service Awards	132	165	111	185
Genetic diseases	--	30	--	30
Arthritis centers	--	8	--	20
Health Professions Student Loans	20	60	--	--
Physician Shortage Area Scholarships	--	2	--	--
	440	614	441	638

1/ Already appropriated.

If the Congress appropriates funds for these programs at their authorization levels, there would be an outlay increase over the budget of approximately $40 million in 1976 and $165 million in 1977.

Arguments in favor of approval

1. H.R. 7988 would extend specific appropriation authorizations for two major health programs which the Administration supports - the National Research Service Awards (research training) program and heart, lung, and blood research. Funds for both programs are included in the budget and HEW has given them relatively high priority.

2. Except for the provisions limiting HEW authority over vitamins and minerals, the other provisions in H.R. 7988 are relatively minor in importance and would not adversely affect the Administration's health research programs.

3. Although the appropriations authorizations for the health research and training programs exceed the President's budget, actual funding may be held to lower levels in the appropriations process.

Arguments in favor of disapproval

1. The appropriations authorizations for the research and control programs are not necessary and they are excessive. This will create pressures for some budget add-ons, even if not the full amount authorized. Moreover, the research activities proposed in H.R. 7988 can be funded under the general authorizations of the PHS Act.

2. H.R. 7988 authorizes a new categorical grant program for genetic diseases, e.g., testing and counseling, and a new program to support visiting scientists at institutions with significant enrollments of disadvantaged students. These proposals run counter to the Administration's objective of eliminating categorical grant programs and to curb the initiation of new programs.

3. The limitations imposed by H.R. 7988 on FDA authority to regulate vitamins and minerals will limit FDA ability to assure that consumers are fully informed about the effectiveness of vitamins and minerals. Moreover, they represent an undesirable precedent for congressional termination of Federal agency regulatory jurisdiction on a piecemeal basis.

4. The extension of Soldiers and Sailors Civil Relief Act (SSCRA) benefits to PHS Commissioned Corps officers tends to perpetuate special benefits for a separate personnel system. The SSCRA was intended to apply only to Federal personnel engaged in national defense and frequently rotated for the convenience of the Federal Government. Neither condition applies to members of the PHS Commissioned Corps, whose conditions of service are virtually undistinguishable from those of regular civil service employees. The proposed new benefit for the Corps will make it that much more difficult to integrate that system into the General Schedule.

Recommendation

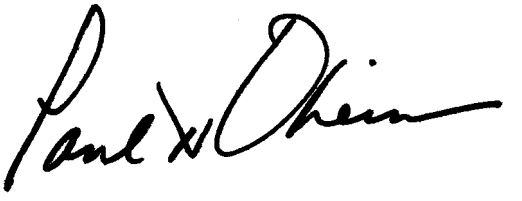
HEW reluctantly recommends approval of H.R. 7988. In its attached views letter on the enrolled bill, HEW states

that it believes the Administration's commitment to a strong program in the areas of health research training and heart, lung, and blood research outweighs, on balance, the undesirable restrictions placed on FDA's authority to regulate vitamins, minerals and other food supplements. HEW recommends that a signing statement be issued which would make clear the Administration's objections to the bill's restrictions on FDA's authority to regulate these areas.

* * * * * * * *

As indicated above, we believe H.R. 7988 has several undesirable features.

However, on balance, we recommend approval of H.R. 7988 because we consider it highly unlikely that a significantly better bill could be enacted by this Congress even if the bill was vetoed and the veto was sustained. Given the fact that the bill contains so many undesirable provisions, however, we recommend against the issuance of a signing statement, as proposed by HEW.



James T. Lynn
Director

Attachments

NATIONAL SCIENCE FOUNDATION
WASHINGTON, D.C. 20550

OFFICE OF THE
DIRECTOR

April 16, 1976

Mr. James M. Frey
Assistant Director for
Legislative Reference
Office of Management and Budget
Washington, D.C. 20503

Dear Mr. Frey:

This is in response to your communication of April 14, 1976, requesting the comments of the National Science Foundation on Enrolled Bill H.R. 7988, the "Health Research and Health Services Amendments of 1976."

The Foundation has no objection to approval of the bill by the President. In view, however, of strong expressions of concern voiced by representatives of the scientific community and groups such as the American Institute of Nutrition, we suggest that the following language be used in the signing message:

> "While I am pleased to sign into law H.R. 7988, the "Health Research and Health Services Amendments of 1976," I must express grave concerns about one portion, Title V. Title V amends the Food, Drug and Cosmetic Act and is completely unrelated to the main purpose of the bill. As a consequence of Title V, the Food and Drug Administration would no longer be permitted to exercise appropriate controlling influence over the addition of vitamins and minerals to the food we eat. Over the years, we have come to depend heavily upon the Food and Drug Administration to prevent fraudulent practices and to protect us from harmful substances. This Title represents an important reversal and, in my view, will not serve the best interests of the Nation."

Sincerely yours,

H. Guyford Stever
Director

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

ADVANCE

DRAFT

The Honorable James T. Lynn
Director, Office of Management
and Budget
Washington, D. C. 20503

Dear Mr. Lynn:

This is in response to your request for a report on H.R. 7988, an enrolled bill "To amend the Public Health Service Act to revise and extend the program under the National Heart and Lung Institute, to revise and extend the program of National Research Service Awards, and to establish a national program with respect to genetic diseases; and to require a study and report on the release of research information."

Although the enrolled bill would encumber the Food and Drug Administration with highly undesirable restrictions in the area of vitamin and mineral regulation, we nevertheless recommend that the President sign the enrolled bill, because the bill would extend our authorities to make National Research Service Awards and to carry out research and other activities in relation to heart, lung, blood vessel, and blood diseases and blood resources.

The major provisions of the enrolled bill are summarized at Tab A.

The main shortcoming of the bill is the restrictions imposed upon the Food and Drug Administration (FDA) in the area of vitamin and mineral regulation.

These restrictions are an overreaction to regulations published by the FDA. The present version of the regulations would merely create categories for various vitamin and mineral combination products, and would prescribe the components and potency levels for each of those product categories. The combination product categories are subject to further revision;

upon petition, components and component potency levels within each category may be changed, and additional combination product categories may be provided. These regulations appear to be modest and useful. They would help consumers, not hinder them.

At present, there is much confusion in the marketplace about vitamins and minerals and dietary supplements in general. An incredible array of combination products is available, and one would have to an expert to determine which is the best value, nutritionally and economically. With regulations such as the FDA has developed, the average American consumer who seeks a multinutrient product for "nutritional insurance" against deficiencies would be assured of getting what the vast majority of scientific opinion agrees is an appropriate product. These regulations would help the consumer to compare the cost of products since the nutritional value of various brands would be reasonably close to one another within each product category.

The speculative use of unnaturally high doses of vitamins and minerals could be dangerous. Although much remains to be learned about how nutrition and diet affect the human body, enough is known to indicate that a cautious approach to the ingestion of large doses of vitamins and minerals is required. It is best to learn about the potential dangers of new products in the laboratory, not in the marketplace. To the extent the enrolled bill would permit the sale of imbalanced and needlessly high doses of vitamins and minerals, it is not good legislation.

The restrictions in the enrolled bill, however, at least do not affect the authority of the FDA to take action against products based on safety considerations, nor against products which are represented for use in relation to specific diseases, by children under twelve, or by pregnant or lactating women, nor against products represented as conventional food substitutes or for use as the sole item of a meal or diet.

The enrolled bill, moreover, also extends two vital health programs of this Department. First, our authority to make National Research Service Awards would be continued through fiscal year 1977. This authority is the basis for our support of research training in the health area. Secondly, our authorities for activities in the area of cardiovascular, lung, and blood diseases and blood resources would be extended through fiscal year 1977.

The Administration is committed to a strong program in the areas of health research training and cardiovascular, lung, and blood diseases and blood resources. We feel that, on balance, our commitment to these areas outweighs the undesirable restrictions placed on the FDA by the enrolled bill. We reluctantly recommend that the President sign the enrolled bill, but that he also issue a signing statement explaining his displeasure with the imposition of restrictions upon the FDA. A draft signing statement may be found at Tab B.

Sincerely,

Secretary

Enclosures

DRAFT

Major Provisions of H.R. 7988, An Enrolled Bill

The enrolled bill would--

-- authorize appropriations of $165 million for fiscal year 1976 and $185 million for FY 1977 for National Research Service Awards (the Budget requests were $132 million for FY 1976 and $111 million for FY 1977; $140 million is being spent for FY 1976 under a continuing resolution),

-- authorize appropriations of $349 million for FY 1976 and $403 million for FY 1977 for research and other activities in relation to cardiovascular, lung, and blood diseases and blood resources (the Budget requests were $288 million for FY 1976 and $330 million for FY 1977; $349 million is being spent for FY 1976 under a continuing resolution),

-- repeal the present categorical authorities for research and other activities in relation to sickle cell disease and Cooley's anemia, and substitute instead (1) a genetic diseases testing, counseling, information, and education program, with appropriation authorizations of $30 million for each of the fiscal years 1976 through 1978 (present activities in this area are subsumed under the National Heart and Lung Institute budget), and (2) require the Secretary, in making grants in the area of genetic diseases, to give priority to sickle cell disease and Cooley's anemia projects,

-- prohibit the Secretary from using his authority under the Federal Food, Drug, and Cosmetic Act, in relation to "standards of identity" and "misbranding", to limit the potency of vitamins and minerals, or the combinations of vitamins, minerals, and other food ingredients, which may be sold; but these restrictions do not apply to preparations which are represented for use in relation to specific diseases, by children under twelve, or by pregnant or lactating women, nor to products represented as conventional food substitutes or for use as the sole item of a meal or diet; the enrolled bill would not affect the Secretary's authority to take action based on safety considerations,

-- authorize the Secretary, in coordination with the Federal Trade Commission, to take action in relation to misleading advertising of products to which the prohibition above would apply,

-- direct the President's Biomedical Research Panel and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research each to undertake a study concerning the disclosure of information in research proposals submitted to the Department,

-- reduce the appropriation authorization for comprehensive arthritis centers from $13 million to $8 million for FY 1976, but increase the FY 1977 authorization from $15 million to $20 million (the Budget does not provide for these centers, and no funds are currently being spent under this authority),

-- prohibit the consideration of political affiliation in making appointments to advisory committees under the Public Health Service Act and related laws,

-- extend the Soldiers' and Sailors' Civil Relief Act of 1940 to the Commissioned Corps of the Public Health Service.

-- permit the Secretary to make health research and related grants to any suitable Federal institution, rather than only to certain institutions currently specified in law,

-- authorize the Secretary to make awards to enable outstanding scientists to serve as visiting scientists at colleges with high enrollments of disadvantaged students,

-- authorize an appropriation of $2 million for FY 1976 for Physician Shortage Area Scholarships; current law authorizes only continuation scholarships (the Budget does not request any funds for new scholarships of this kind, nor are funds currently being spent for new scholarships of this kind), and

-- authorize an appropriation of $60 million for FY 1976 for Federal capital contributions to the student loan funds
-- reduce the appropriation authorization for cimprehensive

of health professions schools; current law authorizes only contributions for continuation loans (the Budget does not request any funds for capital contributions, except for continuation loans; funds have been spent for FY 1976 only for continuation loans).

DRAFT

Draft Signing Statement

Of particular concern to me is title V of H.R. 7988, which restricts the Food and Drug Administration's (FDA's) regulation of vitamins, minerals, and other dietary supplements. I have been following the development of this legislation with great interest. Along with Congress, I have received much mail about it. I understand the fears of some that the FDA regulation of dietary supplements could unduly restrict their freedom of choice. However, I am not convinced that this particular section of the bill is entirely in the public interest. I am reluctant to pass it into law without first voicing my reservations.

Title IV of this bill is a reaction, I think an overreaction, to regulations published by the FDA. These regulations appear to be modest and useful. They would help consumers, not hinder them. The present version of the regulations would merely create categories for various vitamin and mineral combination products, and would prescribe the components and potency levels for each of those product categories. The combination product categories are subject to further revision; upon petition, components and component potency levels within each category may be changed, and additional combination product categories may be provided. This seems to be a reasonable regulation, for which there appears to be a need.

At present, there is much confusion in the marketplace about vitamins and minerals and dietary supplements in general. An incredible array of combination products is available, and one would have to be an expert to determine which is the best

value, nutritionally and economically. With regulations such as the FDA has developed, the average American consumer who seeks a multinutrient product for "nutritional insurance" against deficiencies would be assured of getting what the vast majority of scientific opinion agrees is an appropriate product. These regulations would help the consumer to compare the cost of products since the nutritional value of various brands would be reasonably close to one another within each product category.

The speculative use of unnaturally high doses of vitamins and minerals can be dangerous. Although all agree that much remains to be learned about how nutrition and diet affect the human body, enough is known to indicate that a cautious approach to the ingestion of megadoses of vitamins and minerals is required. It is known, for example, that high doses of vitamin A or vitamin D are toxic; it is known that virtually all minerals will become toxic at some level; and it is known that the body requires some, not yet fully understood, balance of vitamin and mineral levels. It is best to learn about the potential dangers of new products in the laboratory, not in the marketplace. To the extent this legislation would encourage the sale of imbalanced and needlessly high doses of vitamins and minerals, it is not good legislation.

Current law gives the FDA the responsibility and the power to establish standards for food and to require adequate labeling of food. These are vital government functions which assure the maintenance and improvement of the nutritional quality of our nation's food supply and which help consumers make intelligent selections in the marketplace. I question

the wisdom of carving out from the FDA's regulatory jurisdiction a special exemption for "food supplements."

The FDA regulations would not limit the availability of products on the grounds that they are determined to be "not nutritionally rational or useful." Any substance currently available would be available under the pending regulations. Substances of no known nutritional value, such as bioflavinoids, could still be freely marketed--they just could not be labeled as a "dietary supplement" or be included as part of the aforementioned vitamin and mineral products. Furthermore, any individual vitamin and mineral could be marketed in any potency recognized as safe. For example, those who wish to sell or buy high dosages of vitamin C for use as a dietary supplement would be free to do so--even if the product greatly exceeds the potency needed for good nutrition.

In summary, to the extent this legislation serves to perpetuate consumer confusion and confounds intelligent and selective shopping, to the extent it endorses public experimentation with needlessly high doses of vitamins and minerals, or with other food-derived products not normally part of the diet and about which little is known, and to the extent it will protect and encourage nutrition misinformation and fraud, it is not legislation which I can wholeheartedly support.

Therefore, I have concluded that the fears expressed about the FDA regulations are unfounded, that title ~~IV~~ V of the bill is unnecessary to preserve individual freedom of choice in selecting dietary supplements, and that the FDA regulations would be beneficial to the consumer in exercising that freedom of choice.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

DATE: 4-19-76

TO: Bob Linder

FROM: D. Evans

Attached are the HEW and NSF views letters on H.R. 7988, for inclusion in the enrolled bill file. Please substitute the HEW letter for the "Advance" copy which was attached to the file. Thanks.

OMB FORM 38
REV AUG 73

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

APR 19 1976

The Honorable James T. Lynn
Director, Office of Management
and Budget
Washington, D. C. 20503

Dear Mr. Lynn:

This is in response to your request for a report on H.R. 7988, an enrolled bill "To amend the Public Health Service Act to revise and extend the program under the National Heart and Lung Institute, to revise and extend the program of National Research Service Awards, and to establish a national program with respect to genetic diseases; and to require a study and report on the release of research information."

Although the enrolled bill would encumber the Food and Drug Administration with highly undesirable restrictions in the area of vitamin and mineral regulation, we nevertheless recommend that the President sign the enrolled bill, because the bill would extend our authorities to make National Research Service Awards and to carry out research and other activities in relation to heart, lung, blood vessel, and blood diseases and blood resources.

The major provisions of the enrolled bill are summarized at Tab A.

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These restrictions are an overreaction to regulations published by the FDA. The present version of the regulations would merely create categories for various vitamin and mineral combination products, and would prescribe the components and potency levels for each of those product categories. The combination product categories are subject to further revision;

upon petition, components and component potency levels within each category may be changed, and additional combination product categories may be provided. These regulations appear to be modest and useful. They would help consumers, not hinder them.

At present, there is much confusion in the marketplace about vitamins and minerals and dietary supplements in general. An incredible array of combination products is available, and one would have to be an expert to determine which is the best value, nutritionally and economically. With regulations such as the FDA has developed, the average American consumer who seeks a multinutrient product for "nutritional insurance" against deficiencies would be assured of getting what the vast majority of scientific opinion agrees is an appropriate product. These regulations would help the consumer to compare the cost of products since the nutritional value of various brands would be reasonably close to one another within each product category.

The speculative use of unnaturally high doses of vitamins and minerals could be dangerous. Although much remains to be learned about how nutrition and diet affect the human body, enough is known to indicate that a cautious approach to the ingestion of large doses of vitamins and minerals is required. It is best to learn about the potential dangers of new products in the laboratory, not in the marketplace. To the extent the enrolled bill would permit the sale of imbalanced and needlessly high doses of vitamins and minerals, it is not good legislation.

The restrictions in the enrolled bill, however, at least do not affect the authority of the FDA to take action against products based on safety considerations, nor against products which are represented for use in relation to specific diseases, by children under twelve, or by pregnant or lactating women, nor against products represented as conventional food substitutes or for use as the sole item of a meal or diet.

The enrolled bill, moreover, also extends two vital health programs of this Department. First, our authority to make National Research Service Awards would be continued through fiscal year 1977. This authority is the basis for our support of research training in the health area. Secondly, our authorities for activities in the area of cardiovascular, lung, and blood diseases and blood resources would be extended through fiscal year 1977.

The Administration is committed to a strong program in the areas of health research training and cardiovascular, lung, and blood diseases and blood resources. We feel that, on balance, our commitment to these areas outweighs the undesirable restrictions placed on the FDA by the enrolled bill. We reluctantly recommend that the President sign the enrolled bill, but that he also issue a signing statement explaining his displeasure with the imposition of restrictions upon the FDA. A draft signing statement may be found at Tab B.

Sincerely,

Marjorie Lynch

Under Secretary

Enclosures

Major Provisions of H.R. 7988, An Enrolled Bill

The enrolled bill would--

-- authorize appropriations of $165 million for fiscal year 1976 and $185 million for FY 1977 for National Research Service Awards (the Budget requests were $132 million for FY 1976 and $111 million for FY 1977; $140 million is being spent for FY 1976 under a continuing resolution),

-- authorize appropriations of $349 million for FY 1976 and $403 million for FY 1977 for research and other activities in relation to cardiovascular, lung, and blood diseases and blood resources (the Budget requests were $288 million for FY 1976 and $330 million for FY 1977; $349 million is being spent for FY 1976 under a continuing resolution),

-- repeal the present categorical authorities for research and other activities in relation to sickle cell disease and Cooley's anemia, and substitute instead (1) a genetic diseases testing, counseling, information, and education program, with appropriation authorizations of $30 million for each of the fiscal years 1976 through 1978 (present activities in this area are subsumed under the National Heart and Lung Institute budget), and (2) require the Secretary, in making grants in the area of genetic diseases, to give priority to sickle cell disease and Cooley's anemia projects,

-- prohibit the Secretary from using his authority under the Federal Food, Drug, and Cosmetic Act, in relation to "standards of identity" and "misbranding", to limit the potency of vitamins and minerals, or the combinations of vitamins, minerals, and other food ingredients, which may be sold; but these restrictions do not apply to preparations which are represented for use in relation to specific diseases, by children under twelve, or by pregnant or lactating women, nor to products represented as conventional food substitutes or for use as the sole item of a meal or diet; the enrolled bill would not affect the Secretary's authority to take action based on safety considerations,

-- authorize the Secretary, in coordination with the Federal Trade Commission, to take action in relation to misleading advertising of products to which the prohibition above would apply,

-- direct the President's Biomedical Research Panel and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research each to undertake a study concerning the disclosure of information in research proposals submitted to the Department,

-- reduce the appropriation authorization for comprehensive arthritis centers from $13 million to $8 million for FY 1976, but increase the FY 1977 authorization from $15 million to $20 million (the Budget does not provide for these centers, and no funds are currently being spent under this authority),

-- prohibit the consideration of political affiliation in making appointments to advisory committees under the Public Health Service Act and related laws,

-- extend the Soldiers' and Sailors' Civil Relief Act of 1940 to the Commissioned Corps of the Public Health Service,

-- permit the Secretary to make health research and related grants to any suitable Federal institution, rather than only to certain institutions currently specified in law,

-- authorize the Secretary to make awards to enable outstanding scientists to serve as visiting scientists at colleges with high enrollments of disadvantaged students,

-- authorize an appropriation of $2 million for FY 1976 for Physician Shortage Area Scholarships; current law authorizes only continuation scholarships (the Budget does not request any funds for new scholarships of this kind, nor are funds currently being spent for new scholarships of this kind), and

-- authorize an appropriation of $60 million for FY 1976 for Federal capital contributions to the student loan funds

of health professions schools; current law authorizes only contributions for continuation loans (the Budget does not request any funds for capital contributions, except for continuation loans; funds have been spent for FY 1976 only for continuation loans).

Draft Signing Statement

Title I of this Act extends through FY 1977 authorizations for the National Heart, Blood Vessel, Lung, and Blood Program and changes the name of the Institute at NIH to the National Heart, Lung, and Blood Institute. I want to register my enthusiastic support for the activities being conducted by the newly renamed National Heart, Lung, and Blood Institute.

Heart, blood vessel, lung, and blood diseases currently cost this nation approximately $58 billion annually. However, it is most gratifying to note that substantial progress is being made in our attack on them,

- For the past several years deaths from heart attacks have been declining by about 2% per year resulting in a decrease in the number of deaths from heart attacks by about 14,000 per year.

- Through the efforts of the National High Blood Pressure Education Program, which is coordinated by the Institute, some five million Americans have sought treatment for their high blood pressure and the number on effective treatment has doubled since the Program was initiated in 1972.

- In the area of lung diseases, major advances have been made in our understanding of the performance of the lungs and their response to such important respiratory diseases as chronic bronchitis and emphysema. Application of these results offers, for the first time, the potential for primary prevention and, if detected early, of effective treatment for these diseases. Another accomplishment has been improvement in the treatment of respiratory distress of the newborn, especially newborns of low birth

weight. In the past 80 to 85% of these infants died soon after birth. Application of these results will reduce this death rate to perhaps 10 to 15% thus reducing deaths due to this condition from about 50,000 per year to perhaps 6,000 to 10,000 per year.

- Important progress is also being made in the area of blood diseases and blood banking. The implementation of the National Blood Policy which is aimed at providing an adequate and safe supply of high quality blood and blood products for transfusion where and when they are needed is progressing. In the near future we expect to be able to store blood in blood banks for longer periods. This will result in a reduction in wasting due to outdating and will thus further improve the blood supply. Methods for further reducing the number of cases of hepatitis following transfusion are also being developed and show promise for the future.

In continuing our attack on heart, blood vessel, lung, and blood diseases, I would emphasize the Administration's commitment to support the best research and research approaches available. The formal addition of "Blood" to the name and the responsibilities of the Institute is in recognition of work now being done and will in no way lessen our research efforts in the areas of heart and cardiovascular disease or lung and respiratory disorders.

Title II of this bill will extend through FY 1977 our training programs for biomedical and behavioral scientists. I am pleased to sign it into law because, first, by extending

the authority it will end the current uncertainty about the status of the National Research Service Award Program for the training of health scientists. Second, the provision will permit us to do the planning necessary to use our national resources for training most effectively.

(more)

Of particular concern to me is title V of H.R. 7988, which restricts the Food and Drug Administration's (FDA's) regulation of vitamins, minerals, and other dietary supplements. I have been following the development of this legislation with great interest. Along with Congress, I have received much mail about it. I understand the fears of some that the FDA regulation of dietary supplements could unduly restrict their freedom of choice. However, I am not convinced that this particular section of the bill is entirely in the public interest. I am reluctant to pass it into law without first voicing my reservations.

Title V of this bill is a reaction, I think an overreaction, to regulations published by the FDA. These regulations appear to be modest and useful. They would help consumers, not hinder them. The present version of the regulations would merely create categories for various vitamin and mineral combination products, and would prescribe the components and potency levels for each of those product categories. The combination product categories are subject to further revision; upon petition, components and component potency levels within each category may be changed, and additional combination product categories may be provided. This seems to be a reasonable regulation, for which there appears to be a need.

At present, there is much confusion in the marketplace about vitamins and minerals and dietary supplements in general. An incredible array of combination products is available, and one would have to be an expert to determine which is the best

value, nutritionally and economically. With regulations such as the FDA has developed, the average American consumer who seeks a multinutrient product for "nutritional insurance" against deficiencies would be assured of getting what the vast majority of scientific opinion agrees is an appropriate product. These regulations would help the consumer to compare the cost of products since the nutritional value of various brands would be reasonably close to one another within each product category.

The speculative use of unnaturally high doses of vitamins and minerals can be dangerous. Although all agree that much remains to be learned about how nutrition and diet affect the human body, enough is known to indicate that a cautious approach to the ingestion of megadoses of vitamins and minerals is required. It is known, for example, that high doses of vitamin A or vitamin D are toxic; it is known that virtually all minerals will become toxic at some level; and it is known that the body requires some, not yet fully understood, balance of vitamin and mineral levels. It is best to learn about the potential dangers of new products in the laboratory, not in the marketplace. To the extent this legislation would encourage the sale of imbalanced and needlessly high doses of vitamins and minerals, it is not good legislation.

Current law gives the FDA the responsibility and the power to establish standards for food and to require adequate labeling of food. These are vital government functions which assure the maintenance and improvement of the nutritional quality of our nation's food supply and which help consumers make intelligent selections in the marketplace. I question

the wisdom of carving out from the FDA's regulatory jurisdiction a special exemption for "food supplements."

The FDA regulations would not limit the availability of products on the grounds that they are determined to be "not nutritionally rational or useful." Any substance currently available would be available under the pending regulations. Substances of no known nutritional value, such as bioflavinoids, could still be freely marketed--they just could not be labeled as a "dietary supplement" or be included as part of the aforementioned vitamin and mineral products. Furthermore, any individual vitamin and mineral could be marketed in any potency recognized as safe. For example, those who wish to sell or buy high dosages of vitamin C for use as a dietary supplement would be free to do so--even if the product greatly exceeds the potency needed for good nutrition.

In summary, to the extent this legislation serves to perpetuate consumer confusion and confounds intelligent and selective shopping, to the extent it endorses public experimentation with needlessly high doses of vitamins and minerals, or with other food-derived products not normally part of the diet and about which little is known, and to the extent it will protect and encourage nutrition misinformation and fraud, it is not legislation which I can wholeheartedly support.

Therefore, I have concluded that the fears expressed about the FDA regulations are unfounded, that title V of the bill is unnecessary to preserve individual freedom of choice in selecting dietary supplements, and that the FDA regulations would be beneficial to the consumer in exercising that freedom of choice.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

DATE: 4-20-76

TO: Bob Linder

FROM: Jim Frey

Attached is the Justice views letter on H.R. 7988 for inclusion in the enrolled bill file.

Also attached is the NSC recommendation on S. 3056. Please have it included in the enrolled bill file. Thanks.

OMB FORM 38
REV AUG 73

ASSISTANT ATTORNEY GENERAL
LEGISLATIVE AFFAIRS

Department of Justice
Washington, D.C. 20530

April 19, 1976

Honorable James T. Lynn
Director, Office of Management
and Budget
Washington, D.C. 20503

Dear Mr. Lynn:

In compliance with your request, I have examined a facsimile of the enrolled bill HR 7988, "To amend the Public Health Service Act to revise and extend the program under the National Heart and Lung Institute, etc."

Only Title III of the enrolled bill is of interest to the Department of Justice. Title III requires the President's Biomedical Research Panel and the National Commission for the Protection of Human Subjects of Biomedical and Behavorial Research to investigate and report upon the implications of disclosure to the public of information contained in research protocols, hypotheses and designs obtained by the Secretary of Health, Education and Welfare in connection with applications for grants, fellowships and contracts during 1975.

We understand that this Title is intended to provide a means for reviewing the implications of the decision in Washington Research Project Inc. v. Department of Health, Education and Welfare, 504 F.2d 238 (D.C. Cir. 1974) in which the court held that the fourth exemption in the Freedom of Information Act (5 U.S.C. §552(b)(4)), which allows agencies to withold commercial confidential information and trade secrets obtained from persons outside the Government,

did not apply to information obtained from non-profit associations such as universities. We believe that this decision was wrong and that the study provided for in Title III should be useful in assessing the need for further legislation in this area.

Because Title III is a minor feature of the enrolled bill and because it merely provides for a study rather than any change in substantive law, we do not believe that it is important in assessing the bill as a whole. Accordingly, the Department of Justice defers to those agencies more directly concerned with the subject matter of the bill as to whether it should receive Executive approval.

Sincerely,

Michael M. Uhlmann

Michael M. Uhlmann
Assistant Attorney General
Office of Legislative Affairs

4/21

Judy —

Will you file and add
to the file. Thanks.

Katie

FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

OFFICE OF THE CHAIRMAN

April 20, 1976

The Honorable James T. Lynn
Director, Office of Management
and Budget
Executive Office of the President
Washington, D. C. 20503

Dear Mr. Lynn:

This is in response to your invitation of April 14, 1976, for the Commission's views on an enrolled bill, H.R. 7988, the Health Research and Health Services Amendments of 1976.

Ten of this bill's eleven titles pertain to health research and would have no impact on this agency. However, Title V contains amendments to the Federal Food, Drug and Cosmetic Act relating to the labeling and advertising of natural or synthetic vitamins and minerals which would affect the Commission. Under these provisions these products would be deemed misbranded under the Food, Drug and Cosmetic Act if their advertising were false or misleading in a material respect. Except in instances where immediate action is necessary to eliminate an imminent health hazard, H.R. 7988 requires the Secretary of Health, Education and Welfare to notify the Federal Trade Commission of his intention to initiate a misbranding action regarding allegedly false or misleading advertising. After notification by the Secretary, the Commission has up to 90 days in which to take specific enforcement action under the Federal Trade Commission Act before the Secretary may commence a misbranding action.

The notice by the Secretary must contain: (1) an outline of the Secretary's proposed action; (2) a description of the advertising alleged to amount to misbranding and (3) the rationale underlying the misbranding charge. The Secretary must also forward to the Commission documents relevant to

the alleged misbranding. Within 30 days after the receipt of the notice and supplemental information from the Secretary the Commission must inform the Secretary if it has initiated or intends to initiate any enforcement action. The Commission must notify the Secretary if an investigation of the advertising is underway or if a civil action under Sections 5, 13 or 19 of the Federal Trade Commission Act has commenced or is contemplated. The Secretary must be advised if the Commission has issued or plans to issue a Section 5(b) complaint or if this advertising has been the subject of a Section 16(b) certification to the Attorney General.

If the Commission notifies the Secretary that one of these four enforcement procedures has begun, the Secretary may not take any action against the advertising for 60 days. However, if the Commission informs the Secretary within 30 days that this agency plans no enforcement action against that advertising, or, if the Commission fails to respond in writing to the Secretary within the requisite 30 days, the Secretary may proceed with his misbranding action.

Although procedures outlined in Title V of this bill would alter the traditional framework for the regulation of vitamins and mineral advertising, they would have no budgetary effect on this agency. The Commission informed the Congress by letter of October 3, 1975, that we were not aware of any inadequacies in the existing mechanism governing vitamin and mineral advertising. However, since the requirements of Title V of the enrolled bill are not unreasonable, the Commission does not oppose enactment of Title V.

By direction of the Commission.

Calvin J. Collier
Chairman

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

To: J. Cavanaugh
4-19-76
4:45 p.m.

DATE: 4-19-76

TO: Bob Linder

FROM: D. Evans

We have attached the "Advance" copy of the HEW views letter. As soon as the signed letter is received, it will be forwarded.

OMB FORM 38
REV AUG 73

THE WHITE HOUSE

ACTION MEMORANDUM WASHINGTON LOG NO.:

Date: April 19, 1976 Time: 4:50 pm

FOR ACTION: Spencer Johnson
Max Friedersdorf
Ken Lazarus
Bill Seidman
Robert Hartmann

cc (for information): Ed Schmults
Jim Cavanaugh
Jack Marsh

FROM THE STAFF SECRETARY

DUE: Date: April 20, 1976 Time: 5:00 pm

SUBJECT:
Enrolled Bill H.R. 7988-Health Research and Health Services Amendments of 1976

ACTION REQUESTED:

____ For Necessary Action ____ For Your Recommendations

____ Prepare Agenda and Brief ____ Draft Reply

__X__ For Your Comments ____ Draft Remarks

REMARKS:

Please return to Judy Johnston--Ground Floor--West Wing

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

K. R. COLE, JR.
For the President

THE WHITE HOUSE

ACTION MEMORANDUM WASHINGTON LOG NO.:

Date: April 19, 1976 Time: 4:50 pm

FOR ACTION: Spencer Johnson
Max Friedersdorf
Ken Lazarus
Bill Seidman ✓
Robert Hartmann

cc (for information): Ed Schmults
Jim Cavanaugh
Jack Marsh

FROM THE STAFF SECRETARY

DUE: Date: April 20, 1976 Time: 5:00 pm

SUBJECT:

Enrolled Bill H.R. 7988-Health Research and Health Services Amendments of 1976

ACTION REQUESTED:

____ For Necessary Action
____ For Your Recommendations
____ Prepare Agenda and Brief
____ Draft Reply
__X__ For Your Comments
____ Draft Remarks

REMARKS:

Please return to Judy Johnston--Ground Floor--West Wing

approval

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

James M. Cannon
For the President

THE WHITE HOUSE

WASHINGTON

April 20, 1976

MEMORANDUM FOR: JIM CAVANAUGH

FROM: MAX L. FRIEDERSDORF M.L.F.

SUBJECT: H.R. 7988 - Health Researchand Health Services Amendments of 1976

The Office of Legislative Affairs concurs with the agencies that the bill be signed. The Conference Report passed the Hous e by a vote of 360 - 0..

Attachments

THE WHITE HOUSE

ACTION MEMORANDUM WASHINGTON LOG NO.:

Date: April 19, 1976 Time: 4:50 pm

FOR ACTION: Spencer Johnson
Max Friedersdorf
Ken Lazarus ✓
Bill Seidman
Robert Hartmann

cc (for information): Ed Schmults
Jim Cavanaugh
Jack Marsh

FROM THE STAFF SECRETARY

DUE: Date: April 20, 1976 Time: 5:00 pm

SUBJECT:

Enrolled Bill H.R. 7988-Health Research and Health Services Amendments of 1976

ACTION REQUESTED:

_____ For Necessary Action _____ For Your Recommendations

_____ Prepare Agenda and Brief _____ Draft Reply

_X_ For Your Comments _____ Draft Remarks

REMARKS:

Please return to Judy Johnston--Ground Floor--West Wing

Recommend approval and suggest the issuance of a signing statement (other than the draft attached to this package) in order to meet the legitimate concerns of consumers. The signing statement should also be coordinated with the regulatory reform groups.

Ken Lazarus 4/20/76

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

James M. Cannon
For the President

THE WHITE HOUSE

ACTION MEMORANDUM WASHINGTON LOG NO.:

Date: April 19, 1976 Time: 4:50 pm

FOR ACTION: Spencer Johnson
Max Friedersdorf
Ken Lazarus
Bill Seidman
Robert Hartmann ✓

cc (for information): Ed Schmults
Jim Cavanaugh
Jack Marsh

FROM THE STAFF SECRETARY

DUE: Date: April 20, 1976 Time: 5:00 pm

SUBJECT: 4/19 - 5:10 pm

Enrolled Bill H.R. 7988-Health Research and Health Services Amendments of 1976

ACTION REQUESTED:

____ For Necessary Action ____ For Your Recommendations

____ Prepare Agenda and Brief ____ Draft Reply

__X__ For Your Comments ____ Draft Remarks

REMARKS:

Please return to Judy Johnston--Ground Floor--West Wing

RTH
Recommend no signing statement — certainly not the one attached
RD

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

James M. Cannon
For the President

THE WHITE HOUSE

ACTION MEMORANDUM WASHINGTON LOG NO.:

Date: April 19, 1976 Time: 4:50 pm

FOR ACTION: Spencer Johnson ✓
Max Friedersdorf
Ken Lazarus
Bill Seidman
Robert Hartmann

cc (for information): Ed Schmults
Jim Cavanaugh
Jack Marsh

FROM THE STAFF SECRETARY

DUE: Date: April 20, 1976 Time: 5:00 pm

SUBJECT:

Enrolled Bill H.R. 7988-Health Research and Health Services Amendments of 1976

ACTION REQUESTED:

____ For Necessary Action ____ For Your Recommendations

____ Prepare Agenda and Brief ____ Draft Reply

__X__ For Your Comments ____ Draft Remarks

REMARKS:

Please return to Judy Johnston--Ground Floor--West Wing

Recmd that Pres. sign w/out statement. The vitamin issue is very sensitive to large #'s of Americans who demand the right to buy vit. for health reasons w/o restrictions. It is this tremendous pressure over the last 3 yrs that has caused the Congress to act. Also as House Minority Leader the president supported such legislation. This does not prevent the FDA from acting in instances of safety or toxicity. Although some might say this is backing away from consumer health and safety issues -- the availability of vitamins is also a consumer issue of free access.

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

James M. Cannon
For the President