The original documents are located in Box 7, folder "Medical Devices" of the Spencer C. Johnson Files at the Gerald R. Ford Presidential Library.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

DRAFT

The Honorable Harrison A. Williams, Jr.
Chairman, Committee on Labor and
Public Welfare
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

We would like to offer our comments on the House and Senate versions of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (H.R. 11124 and S. 510).

These bills are similar in substance and would require premarket approval of certain medical devices and authorize establishment of performance standards for others. The bills would also strengthen the authority of the Food and Drug Administration (FDA) to take regulatory action against hazardous or deceptive medical devices, to prescribe good manufacturing practice regulations, to inspect records, to register device manufacturers, and to require maintenance of records and submission of reports concerning these products.

During Congressional consideration of these bills, the Department presented a number of statements and Departmental reports supporting medical device legislation. These bills would remedy weaknesses in FDA's present authority that have prevented the Agency from keeping pace with safety and effectiveness questions posed by increasingly complex new medical equipment.

In general, the Department prefers H.R. 11124, which is better drafted and, in most respects, provides FDA with better authority to protect consumers. However, we recommend that the conferees consider adoption of the following changes in H.R. 11124, which represent compromises between the Senate and House versions. We offer no suggestion concerning the premarket approval provisions of the bills since we perceive no significant substantive differences between them in this respect, except that H.R. 11124 contains preferable provisions for statutory classification of unique new devices into the premarket approval category.

Custom Devices

The custom device provisions of S. 510 allow use by practitioners of custom devices which fail to comply with standards or premarket approval requirements, but not as a course of conduct on many patients. H.R. 11124 contains custom device provisions that lack a prohibition of use of a

DRAFT

custom device as a course of conduct; the House committee report explains that some practitioners need to use custom devices routinely and that abuse can be prevented by other provisions of the Federal Food, Drug, and Cosmetic Act. A possible compromise would be to provide that custom devices shall only be used as a course of conduct under conditions prescribed in FDA regulations.

Good Manufacturing Practice Regulations

S. 510 offers a simpler procedure for promulgation of good manufacturing practice regulations than H.R. 11124. While both bills call for an opportunity for a hearing on good manufacturing practice regulations, H.R. 11124 also requires review by a special advisory committee. Because there would be ample opportunity for industry, consumers, and scientists to express their views on these regulations through comments on the proposal, participation in any hearing, and FDA workshops and meetings, the special advisory committee is unnecessary and, indeed, its review would unnecessarily delay implementation of good manufacturing practice regulations.

Records and Reports

Although we generally prefer the records and reports provisions of H.R. 11124, the bill should omit the special criteria for recordkeeping and reporting on class I (general controls) devices. No such limitation appears in S. 510, which requires any device manufacturer to submit to the Secretary, upon request, technical data and other data or information applicable to its devices as may reasonably be required to carry out the Federal Food, Drug, and Cosmetic Act. As a compromise, we suggest that the provisions of H.R. 11124 be adopted but that the limitation on records and reports concerning class I devices apply only to distributors and not to manufacturers of these devices.

Restricted Devices

The "restricted device" provisions of H.R. 11124 are generally better than the "prescription device" provisions of S. 510. However, H.R. 11124 specifically precludes FDA from restricting distribution or sale of a device to a category of physicians based on special training or experience. Under S. 510, FDA could differentiate between categories of licensed physicians if necessary to assure safe use of the device taking into account its potentiality for harmful effect or the collateral measures for its use. With the increasing sophistication of medical devices, it is important that FDA be able to consider the skill of intended users

when it establishes conditions for marketing of a device. Accordingly, we recommend that the conferees not adopt the language in H.R. 11124 that prevents FDA from restricting devices to a category of physicians possessing certain training or experience.

Proceedings of Advisory Committees

We question the advisability of the requirement in H.R. 11124 that panels and advisory committees maintain transcripts of their proceedings. We believe that maintenance of transcripts should be optional rather than mandatory, to promote full and frank discussion. We therefore recommend that this provision of H.R. 11124 be deleted.

Office To Assist Small Manufacturers of Medical Devices

The Department is opposed to the statutory establishment of a separate office within the Department of Health, Education, and Welfare to provide technical and other non-financial assistance to small manufacturers of medical devices, as proposed in H.R. 11124. Legislative mandates of organizational structure result in rigidity and overlapping functions and limit the Secretary's ability and discretion to organize the Department in the most effective manner to achieve its objectives.

The Department strongly favors enactment of medical device legislation and urges that the conferees adopt H.R. 11124, subject to the recommendations in this letter.

We were advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

Secretary

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D. C. 20201

09 MAR 1976

The Honorable Harley O. Staggers
Chairman, Committee on Interstate
and Foreign Commerce
House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

Your Committee, on January 21, 1976, ordered reported H.R. 11124, a bill "To amend the Federal Food, Drug, and Cosmetic Act to provide for the safety and effectiveness of medical devices intended for human use."

We have previously, by a letter dated February 5, 1976, provided our general views in support of this legislation. A copy of that letter is attached for your reference. We promised at that time to provide you with a more detailed analysis outlining some of the specific concerns we have with the bill. That analysis is enclosed for your information. We would appreciate it if our earlier letter as well as the enclosed analysis can be made a part of the permanent record of your Committee's consideration of this bill.

We recommend that the bill, amended as we have proposed in the accompanying analysis, be favorably considered by the Congress.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

Marjorie Lynch

Under Secretary

Enclosures

ANALYSIS OF H.R. 11124

1. Classification of Devices Intended for Human Use

We favor the provisions of the proposed new section 513 to the Federal Food, Drug, and Cosmetic Act which would provide for classification by the Food and Drug Administration (FDA) of all medical devices intended for human use. The proposed classification system is consistent with the 1970 recommendations of the Committee established by this Department, and chaired by Theodore Cooper, M.D., the present Assistant Secretary for Health, to make recommendations on the most appropriate means to assure the safety and effectiveness of medical devices.

Shortly after the Cooper Committee Report, FDA was requested by former Secretary Elliot Richardson to initiate the proposed medical device classification process. To date, FDA has classified approximately 3,000 devices. This work will be of significant value in classifying devices under this legislation.

2. Performance Standards

H.R. 11124 would add a new section 514 to the Act which would establish a procedure for promulgating performance standards for those devices for which general controls are insufficient to assure their safe and effective performance, and for which sufficient information exists to establish standards.

We believe that the procedure for the promulgation of a performance standard as set forth in this section could be improved. The present procedure would require the publication of two separate notices for comments: one publication of a notice for the submission of comments concerning the establishment of a standard (proposed section 514(b)), and a second publication requesting submission of offers to develop a proposed standard (proposed section 514(c)). We recommend that the two steps be combined into one publication providing for the solicitation of both comments on the need for a standard and the submission of offers to develop a standard.

In our testimony, we also expressed concern that the section providing for review of a device standard by an independent advisory committee should be amended. Under proposed section 514(g)(5)(B), as well as under proposed section 515(g)(2)(B), the Agency cannot use the panels (who advise on classification and premarket approval) as the independent advisory committee used for administrative review of proposed standards and of premarket approval decisions. We urged that section 514(g)(5)(B) be amended to allow FDA to merely disqualify those panel members who may have prejudged an issue from service on an independent review advisory committee. The Subcommittee staff has assured us that provisions in

section 514(g)(5)(B) are intended merely to prohibit the use of the entire classification panel that had considered a device as the independent advisory committee for review of a device standard or premarket approval decision and that the provisions do not bar use of individual members of a panel as members of the independent advisory committee. We agree with this interpretation and, if it is correct, agree that the bill need not be amended.

3. Premarket Approval

Premarket approval would be required under proposed section 515 for devices that are of substantial importance in supporting, sustaining or preventing impairment of human life or health, or present a potential unreasonable risk of illness or injury, and for which insufficient information exists to provide reasonable assurance of safety and effectiveness under general controls, or general controls and performance standards, alone.

We believe that the requirement for premarket approval in H.R. 11124 is too broad and that the criterion of unreasonable risk to health and the substantial importance of supporting, sustaining, or preventing the impairment of human life or health should be met before requiring premarket approval. Accordingly, we recommend that the word "or" be changed to "and" in section 513(a)(1)(C)(ii)(I).

In our testimony, we recommended that the provision for opportunity for a formal evidentiary hearing, as an alternative to independent advisory committee review of premarket approval decisions, be amended to provide instead for an opportunity for an informal hearing (as defined in section 3 of the bill). This recommendation was based on FDA's experience in removing unsafe and ineffective drugs from the market under a similar requirement in current drug law. However, during Subcommittee markup of the bill, Subcommittee staff explained that orders which are subject to review under section 515(g)(1) of the bill would take effect upon issuance, after merely an informal hearing and pending further proceedings. Thus, withdrawal orders would take effect prior to the formal evidentiary hearing or the review by an independent advisory committee. This understanding, coupled with the substitution of "questioning" for "cross-examination" at informal hearings, addresses our concerns about unwarranted delays in terminating marketing of devices subject to section 515.

4. Banned Devices

We support the change in proposed new section 516 to provide that, under specified circumstances, the ban of a device shall take effect upon publication and pending any further proceedings.

5. Records and Reports

At the hearing, we urged that the records and reports section (section 519(a)(1)) be simplified by deletion of the provision barring "requirements unduly burdensome to a device manufacturer, importer or distributor taking into account his cost of complying with such requirements and the need for the protection of the public health and the implementation of this Act." This language is unnecessary, would engender controversy, and would not add any real safeguards to assure that burdensome requirements are not imposed. We also expressed concern that the restrictions in section 519(a)(5) upon FDA's authority to require reports for devices subject only to general controls may be misunderstood. We read these requirements as only restricting use by FDA of the reporting authority to require that research be conducted that will generate data meeting FDA reporting requirements, or to require routine periodic reporting unrelated to public health needs, except where necessary to determine if the device should be reclassified or if the device is adulterated or misbranded. While the records and reports provisions of H.R. 11124 are superior to those in S. 510, the Senate version of the legislation, we believe they can be further improved by the amendments we suggest.

Although we also recommended amending section 519(b)(2) to provide that researchers and teachers who directly import devices for their own use be subject to section 519 recordkeeping and report requirements, such an amendment is no longer necessary because of clarifying amendments to the investigational provisions of the bill which assure recordkeeping and reporting by researchers.

6. Custom Devices

We support the objective of the provision allowing marketing of custom devices, under proposed new subsection 520(b), that necessarily deviate from requirements which would otherwise be applicable under a standard or the premarket approval provisions of the bill. However, it is essential that the custom device provisions not become a loophole that will allow the marketing of dangerous or deceptive products. Section 520(b) would not, as we read the bill, exempt any device from otherwise applicable regulations for investigational devices, banned devices, or restricted devices. It should also be made clear that FDA would be able to take necessary action to curb a practitioner's use of a custom device on several patients, where this use is repeated to such an extent that the practitioner is in effect conducting unsupervised experiments, or allowing the marketing of a product that would otherwise be unlawful. We recognize the difficulty of drafting a provision limiting use of custom devices as a course of conduct that prevents abuses, but does not prevent use of custom products where justified by medical need. FDA will endeavor to strike the necessary balance in its regulations implementing section 520(b).

7. Restricted Devices

We are seriously concerned about a provision adopted during Subcommittee markup of the bill which would curb FDA's authority to restrict use of a medical device to a subcategory of physicians based on training and experience when necessary to provide reasonable assurance of a device's safety and effectiveness. This provision will seriously undermine the Agency's ability to reduce public exposure to medical devices that may be unsafe in the hands of practitioners who lack the training or experience to use them. Also, the effect of H.R. 11124 may be to discourage FDA approval for commercial marketing of products that will provide great benefits to patients when used by skilled practitioners, but which present unreasonable risk to patients if used too widely by the untrained. FDA may have to retain investigational controls over devices for a lengthy period of time, since section 520(g), unlike section 520(e), authorizes FDA to distinguish between categories of physicians based on qualifications. To assure that a device can be marketed safely and effectively, FDA may also have to resort to its present authority under section 502(f) of the Act, to require adequate directions for use and promulgate conditional exemptions from this requirement. We therefore recommend deletion of the phrase "(other than any condition which would limit the use of a device to a particular category or categories of physicians based on their training and experience)." This matter is a serious concern with the increasing sophistication of medical devices.

8. Good Manufacturing Practice Advisory Committee

We still believe that it is unnecessary to require establishment of a separate advisory committee to advise FDA concerning good manufacturing practice regulations. FDA's present procedures provide ample opportunity for industry, consumers, and scientists to make known their views in this area. If a specific advisory committee on good manufacturing practice regulations seems desirable, we will establish one. Moreover, the Department is opposed generally to the statutory establishment of advisory committees since it tends to result over time in the existence of unnecessarily rigid committees which have outlived their usefulness. We note that Congress supported this view in the Federal Advisory Committee Act.

9. Proceedings of Advisory Panels and Committees

We question the advisability of the amendment adopted by the Subcommittee, new subsection 520(i), that advisory panels and committees maintain transcripts of their proceedings. It is FDA's policy to allow its committees to decide for themselves whether they wish to have transcripts or tapes made of their meetings as an aid to preparation of minutes, as set forth in proposed section 2.313 of Title 21, Code of Federal Regulations in FDA's proposed procedural regulations (Federal Register of September 3, 1975, 40 FR 40748). This policy has been maintained to

protect the free interchange of ideas by these advisors. This concept that internal communications of Government employees may be exempted from public disclosure so as to promote full and frank discussion is set forth in the Freedom of Information Act as incorporated into the Federal Advisory Committee Act. We believe it consistent with this policy that maintenance of transcripts be optional rather than mandatory. We therefore recommend that this provision be deleted.

10. HEW Office to Provide Technical Assistance to Small Manufacturers of Medical Devices

The Department is opposed to the statutory establishment of a separate office within HEW to provide technical and other nonfinancial assistance to small manufacturers of medical devices. Legislative mandates of organizational structure result in rigidity and overlapping functions and limit the Secretary's ability and discretion to organize the Department in the most effective manner to achieve its objectives.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

The Honorable Harley O. Staggers
Chairman, Committee on Interstate
and Foreign Commerce
House of Representatives
Washington, D. C. 20515

FEB 5 1976

Dear Mr. Chairman:

There is before your Committee, as reported by the Subcommittee on Public Health and Environment on November 13, 1975, H.R. 11124, the "Medical Device Amendments of 1975." The reported bill is a clean bill in lieu of H.R. 5545 as amended by the Subcommittee.

The Department of Health, Education, and Welfare supported legislation similar to H.R. 11124 in the Ninety-third Congress and has long endorsed the need for modernizing the authority of the Food and Drug Administration (FDA) over medical devices. We also presented testimony generally favorable to H.R. 5545 at hearings before the Subcommittee on July 28, 1975. Provided that it is amended to meet a few continuing concerns outlined in an analysis which we will shortly forward to your attention, the Department vigorously supports H.R. 11124 as a balanced response to this need.

If H.R. 11124 were enacted, FDA would use both existing resources and a substantial part of the $17 million requested increase for the Agency in the President's 1977 budget to implement a strengthened medical device regulation program.

A number of changes made in the Subcommittee simplified and thus improved administrative proceedings under the bill. We favor, among other changes, the amended investigational device provisions, the transitional provisions for projects formerly categorized as "drugs," the substitution of "questioning" for "cross-examination" at informal hearings, the provisions requiring FDA to make

public a detailed summary of safety and effectiveness information respecting certain devices, the exemption of class I, General Control devices, from the biennial inspection provision, and the understanding that the restricted device provisions apply both as to effectiveness as well as safety of a device.

In each of the areas where H.R. 11124 would strengthen FDA's current authority, the Agency has been operating under serious handicaps because of lack of legislative authority to enable the Agency to keep pace with the burgeoning growth in the introduction of complex new medical equipment for use on or in humans.

We understand that certain industry representatives are urging your Committee to use H.R. 11124 as a vehicle for amending the criminal liability provisions of the Federal Food, Drug, and Cosmetic Act with respect to all products subject to the Act, not just medical devices. This subject was never raised by any witness or member of the Subcommittee at hearings on the device legislation. This Department strongly opposes any amendment to the criminal liability provisions of the Act. Our position has been set forth in prior testimony and is summarized in the appended enclosure.

The present criminal liability provisions have been consistently upheld by the courts and most recently by the Supreme Court in United States v. Park, 421 U.S. 658 (1975). The present criminal liability standard is also supported by consumer and public interest organizations. We would even venture to question the unanimity within the various regulated industries as to whether the long established strict criminal liability standard should be amended. Finally, of course, there is some question as to whether an amendment to the criminal liability provisions respecting all products subject to the Act may be considered germane to medical device legislation.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

/s/Marjorie Lynch

Under Secretary

Enclosure

STRICT CRIMINAL LIABILITY

The provisions of the Federal Food, Drug, and Cosmetic Act that define criminal violations do not make knowledge or intent elements of the offense. Rather, 21 U.S.C. §331 prohibits the enumerated "acts and the causing thereof."

More than thirty years ago, in the Dotterweich case, the Supreme Court declared, "[this] legislation dispenses with the conventional requirement for criminal conduct--awareness of wrongdoing" and punishes individuals "though consciousness of wrongdoing be totally wanting." And since 1943 the Court has reaffirmed this interpretation on several occasions. Last year when a divided Court of Appeals for the Fourth Circuit rejected the standard it was quickly and unreservedly reversed by the Supreme Court in the Park case.

There is no constitutional prohibition against punishing persons who violate certain classes of laws (of which public health laws, including the Act, are a principal example) even though they acted in good faith or were ignorant of the facts which comprised the violation. The issue, therefore, is whether such a standard serves a legitimate public purpose. As Mr. Justice Frankfurter stated in Dotterweich:

> "Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting.
>
> Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity for informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless."

The same reasoning was more recently echoed by Chief Justice Burger in his opinion for the Court in the Park case.

FDA believes strongly that the strict liability standard is an indispensable adjunct to its efforts to enforce the Act. The dimensions of the agency's enforcement responsibilities are dramatized by a glance at the food industry as an example. There are approximately 60,000 food factories and warehouses in the United States and fewer than 1000 FDA inspectors (many of whom are assigned full-time to other duties). Inspections must, of necessity, be sporadic. It is clear therefore that the purity of the nation's food supply rests, in the first instance, in the hands of food producers and processors.

Since the civil remedies available to FDA (seizure and injunction actions) are essentially retrospective in effect, regulated firms can, and often do, simply sit back and wait for FDA to act. It is far cheaper to risk the loss of a few hundred or thousand dollars as a result of an occasional seizure or injunction than to regularly allocate the resources necessary to fully comply with the requirements of the Federal Food, Drug, and Cosmetic Act. The primary impetus to self-regulation is the fear that criminal prosecution may result from failure to take every precaution to ensure that violations--and their potentially harmful consequences to health--will not occur.

THE WHITE HOUSE

ACTION MEMORANDUM WASHINGTON LOG NO.:

Date: May 21 Time: 530pm

FOR ACTION: Spencer Johnson
David Lissy
Robert Hartmann (signing statement attached)
Max Friedersdorf
Ken Lazarus

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

FROM THE STAFF SECRETARY

DUE: Date: May 24 Time: 400pm

SUBJECT:

S. 510-Medical Device 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

Encur — ~~1~~
1) See rcmd changes in statement
2) Signing ceremony

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please

DRAFT MESSAGE FOR THE PRESIDENT

Today, I have the pleasure of signing into law the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act of 1938.

It is almost exactly 70 years since President Theodore Roosevelt signed the Pure Food and Drugs Act of 1906, the nation's first federal food and drug legislation designed to protect the American consumer against health threats arising from harmful substances and deceptive practices. Since then, there have been a number of actions to strengthen and update the structure of protection sought by President Roosevelt.

While we as a nation were able to take justifiable pride in the laws providing for safety, honesty and efficacy in the foods and drugs we consume, it became increasingly clear that there remained a large, significant and growing gap in that security.

Until today, the American consumer could not be sure that a medical device used by his physician, his hospital, or himself was as safe and effective as it could or should be.

In 1906, President Roosevelt had no need to ask for legislation concerning medical devices; for the devices used by physicians of his day were comparatively simple. They stood at the edge of medicine, helpful but not essential, and, therefore, posed no regulatory need.

By the 1960's, however, enormous advances in science

and technology moved medical devices from the edge close to the center of the stage. Today devices are routinely implanted in our bodies. They replace limbs, bones, tissues, even entire organs. They permit treatment of forms of illness that can be accomplished in no other way. They magnify and speed ten thousandfold the diagnostic power of the human eye and brain.

Medical and diagnostic devices have produced a therapeutic revolution, but in doing so, they have also become more complex and less easily understood by those who use them. When well designed, well made, and properly used they support and lengthen life. If poorly designed, poorly made, and improperly used they can threaten and impair it.

Despite the increasing importance of devices, the Food and Drug Administration has had inadequate authority to deal with them. FDA has had no reliable way of knowing how many devices there are, who is making them, who is selling them, what injuries they can cause, and when a manufacturer has found it necessary to remove them from the medical marketplace.

In addition, no device was required to be proven safe and effective prior to marketing, no matter how crucial it might be to the person using it, even if that use involved implantation in his body.

Recognizing these and other deficiences, the Administration ordered a study of the problem in 1969 and subsequently asked Congress to enact remedial legislation.

In its deliberations since that time, Congress benefited greatly from the cooperation voluntarily extended by the medical device industry who clearly saw the need for legislation that would protect the consumer as well as the manufacturer who refused to compromise with safety. Representatives of consumers and health professionals also played an important role.

The Medical Device Amendments of 1976 eliminate the deficiencies that accorded FDA "horse and buggy" authority to deal with "laser age" problems. It is important not only in what it will do to protect the consumer; it is also important as a symbol for the kind of regulation that I feel is most appropriate to government. It does not represent another expansion of government into affairs we might better manage ourselves. Instead, this is an example of government doing for the individual citizen what he or she cannot do unaided.

I welcome this legislation and commend the FDA who identified the need, cooperated in its development, and finally, will be entrusted with its enforcement.

This agency daily faces a most difficult task -- preventing threats to the public health in a way that is not onerous, but fully consonant with the principles of competitive economic development on which this nation was built. It is a task that requires determination, scientific skill, judgement and most of all, compassion for the hopes and needs of our fellow man. Dr. Alexander M. Schmidt, Commissioner of Food and Drugs, has effectively taken on the job of assuring that the hope and expectations of the consumer for life giving drugs and devices are not false promises.

I reaffirm my support for the fine work of the Food and Drug Administration and the job ahead.

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

MAY 21 1976

MEMORANDUM FOR THE PRESIDENT

Subject: Enrolled Bill S. 510 - Medical Device Amendments of 1976
Sponsor - Sen. Kennedy (D) Mass. and 8 others

Last Day for Action

May 28, 1976 - Friday

Purpose

Provides new authority to the Secretary of Health, Education, and Welfare to assure the safety and effectiveness of medical devices intended for human use.

Agency Recommendations

Office of Management and Budget	Approval
Department of Health, Education, and Welfare	Approval (Signing statement attached)
Veterans Administration	Approval
Department of Commerce	No objection
Department of Justice	No objection
Department of Defense	Defers to HEW

Discussion

S. 510 would amend the Federal Food, Drug and Cosmetic (FDC) Act of 1938 to provide the Food and Drug Administration (FDA) in the Department of Health, Education, and Welfare (HEW) with significant new authority to regulate the safety and effectiveness of medical devices. The enrolled bill is the first amendment to the FDC Act since 1938 dealing with medical devices and represents several years of work by the Executive branch and the Congress to develop acceptable legislation to assure that modern medical devices are safe and effective.

Background. FDA's current regulatory authority under the 1938 Act is limited to action after a medical device has been offered for introduction into interstate commerce and only when the device is deemed to be "adulterated" (i.e., unsterile) or "misbranded" (i.e., not properly labelled). Once a device has been determined to be in violation of the Act, the FDA is limited to seeking seizure of the device by court order, seeking an injunction against the violation, or recommending criminal prosecution.

The 1938 provisions were directed toward relatively simple devices, such as surgical instruments, prosthetic devices, and ultraviolet lights whose safety or proper functioning could generally readily be determined by experts. It was also directed at protecting the public against quack machines and other fraudulent devices. The major concern with devices at the time the 1938 Act was enacted was assuring truthful labeling.

Since then, rapid technological change in the medical device field has led to the introduction of many highly sophisticated modern devices, such as heart pace-makers, kidney dialysis units and artificial blood vessels and heart valves. These devices are so intricate and complex that skilled health professionals are unable to ascertain whether they are defective without careful and thorough testing. Even where devices are determined by FDA to be unsafe or of questionable effectiveness, lengthy court proceedings are usually required to remove such devices from the market.

In Congressional hearings on S. 510 and related bills, FDA testified that litigation in some cases lasted for five to seven years costing the Federal Government several millions of dollars. To avoid such extensive court battles, FDA has resorted to classifying certain products, e.g., soft contact lenses, pregnancy kits, and intrauterine contraceptive devices, as drugs if the intended reaction is chemical, or if the potential hazards of the product may be reduced through drug controls, since FDA exercises premarket clearance authority over drugs (but not devices) under the FDC Act. Moreover, according to HEW, many unsafe devices which cannot technically be found to be in violation of the adulteration or misbranding provisions of the FDC Act lie outside the range of FDA's regulatory authority. S. 510 would eliminate the need for lengthy court proceedings to remove unsafe or ineffective devices from the market.

The detailed provisions of the bill are explained in HEW's attached views letter and in the accompanying Congressional committee reports on the measure.

Classification of Devices. S. 510 would classify all medical devices intended for human use into three categories based upon the extent of control necessary to insure the efficacy and safety of each such device:

(1) general controls (Class I)--manufacturer registration, recordkeeping and reporting requirements, good manufacturing practice regulations, etc., would be established for devices for which such controls would be adequate to assure safety and efficacy;

(2) performance standards (Class II)--HEW would develop and issue performance standards for those devices for which general controls would be inadequate and for which performance standards can be devised; and

(3) premarket approval procedures (Class III)--manufacturers would be required to submit safety and efficacy data to HEW before marketing a device where insufficient information exists to assure that general controls and performance standards would provide reasonable assurance of the safety and effectiveness of devices, and where such devices are purported or represented for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury.

The bill would authorize the Secretary to ban devices intended for human use which presented substantial deception or an unreasonable and substantial risk of illness or injury.

S. 510 would regulate device marketing through the classification system, i.e., by authorizing HEW to classify devices in one of the three specified categories. Manufacturers would be permitted to file applications for the approval of devices in Classes I, II, or III, and the HEW Secretary would be empowered to either approve or deny the applications through the issuance of orders. Manufacturers and other applicants adversely affected by the HEW regulations or orders would be permitted to appeal such decisions to the appropriate United States Court of Appeals.

General Provisions. In addition to prescribing detailed procedures for the classification of devices and the judicial review of regulations and orders, S. 510 contains a number of general provisions dealing with the regulation and control of medical devices for human use. Briefly, the bill would:

-- provide an exception for certain "custom devices" and devices used in investigational use;

-- authorize HEW to issue good manufacturing practice requirements;

-- provide for the release of safety and effectiveness information to the public;

-- require advisory panels and committees to maintain transcripts of any proceedings;

-- authorize HEW to enter into contracts for research, testing and demonstrations of devices;

-- provide for Federal preemption of State and local requirements for medical devices;

-- require the registration and inspection (every two years) of manufacturers of Class II and Class III devices;

-- provide for the temporary administrative detention of devices in violation of the FDC Act;

-- authorize HEW to provide trade secrets and other confidential information to persons under contract with the Secretary;

-- establish a presumption of existence of connection with interstate commerce required to establish jurisdiction in legal actions to enforce the Act with respect to devices;

-- require HEW to establish an office to provide technical and other nonfinancial assistance to small manufacturers to assist them in complying with the Act.

Costs. As indicated above, HEW already undertakes some medical device regulatory activity. The following table shows current and HEW's proposed supplemental funding levels if you approve S. 510:

	Budget Authority (In $ millions)			
	1976 actual	1977	1978	1979
HEW current activity level projected	8.2	9.4	23.1	36.7
HEW proposed funding for S. 510 authorities	--	13.6	13.6	13.4
	8.2	23.0	36.7	50.1
Proposed position levels	281	723	1,013	1,428

We have not had an opportunity to review the HEW estimates and HEW Under Secretary Lynch states in the Department's letter:

> "I recognize that in earlier correspondence with the Congress we indicated that no funds beyond the President's Budget would be sought to implement this activity in fiscal year 1977. Nevertheless, I would like to retain the option of submitting a supplemental request for your consideration."

Recommendation

HEW fully supports enactment of S. 510. The Department notes that it has worked with the Congress for several years to perfect the legislation and that "In its present form, the bill embodies nearly all of the amendments suggested by the Department and combines the best features of the Senate and House-passed versions." HEW has prepared a draft signing statement for your consideration and recommends a signing ceremony.

* * * * * * * *

S. 510 is similar to medical device legislation submitted by the Executive branch to the 93rd and prior Congresses. It represents Administration proposals and is strongly supported by HEW, the medical device industry and the Congress--an unusual display of unanimity. Accordingly, we recommend that you approve S. 510 with a signing statement along the lines of the one proposed by HEW.

James M. Frey
Assistant Director for
Legislative Reference

Enclosures

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

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

MAY 20 1976

Dear Mr. Lynn:

This is in response to your request for a report on S. 510, an enrolled bill "To amend the Federal Food, Drug, and Cosmetic Act to provide for the safety and effectiveness of medical devices intended for human use, and for other purposes."

In short, the Department recommends enactment of this bill because it is a well balanced and meticulously formulated piece of legislation which properly addresses an important aspect of public health and safety protection, without unduly restricting an innovative and important health industry.

The enrolled bill is summarized in detail at Tab A. Briefly stated the bill would amend the Federal Food, Drug, and Cosmetic Act to provide the Secretary of Health, Education, and Welfare with a basis for a comprehensive program to protect the public from unsafe or ineffective medical devices. It would require premarket approval of certain medical devices, and permit promulgation of performance standards to assure safe and effective performance of others for which premarket approval is not needed. It would also provide new or strengthen existing authority to prescribe good manufacturing practice regulations; require registration of device manufacturers; authorize the Secretary to take remedial action against devices presenting an unreasonable risk of substantial harm to the public health; require maintenance of records and submission of reports; and authorize the Secretary to inspect records, processes, controls and facilities of establishments which manufacture restricted devices.

The bill presents a balanced regulatory framework incorporating the basic principle that the least regulation consistent with public health protection is the best. General controls (e.g., manufacturer registration, recordkeeping and reporting requirements, and good manufacturing practice regulations) are preferred to performance standards, and performance standards are preferred to premarket approval, where general controls, or general controls and standards, can provide reasonable assurance of device safety and effectiveness. This regulatory framework would assure, on the one hand, adequate protection to the public, including health professionals, from unsafe and ineffective medical devices, and, on the other, that advances in the state of the art of medical device technology would not be stifled by unnecessary regulatory restrictions.

The bill recognizes the need to minimize any potential economic impact on the medical device industry, especially the small manufacturers who have been responsible for the development of many new and innovative devices. It would provide the Secretary with the authority to exempt, consistent with the protection of public health, certain devices subject to general controls from the requirements of registration, recordkeeping and reporting, and good manufacturing practices, while requiring adherence to other regulatory requirements such as the prohibitions of misbranding and adulteration.

In each of the areas where S. 510 would strengthen our current authority we have been operating under a serious handicap. Legislative authority to keep pace with the ever increasing variety of complex new medical equipment being introduced for use on, or for implantation in, the body is long overdue.

The Department has fully supported enactment of S. 510, both in testimony and in reports, and has worked with the Congress for several years to perfect the legislation. In its present form, the bill embodies nearly all of the amendments suggested by the Department and combines the best features of the Senate and House-passed versions.

For the reasons given, we urge that the enrolled bill be approved.

The amendments are a fine tribute to the diligent and tireless efforts and cooperation of a number of highly publicly motivated individuals representing the Administration, Congress, consumers, health professionals, and industry. A ceremony for the signing of the medical device amendments by the President would be a most fitting recognition of the importance of this legislation.

We have enclosed at Tab B, for your information, preliminary cost estimates for the bill. The projection includes a 1977 supplemental. I recognize that in earlier correspondence with the Congress we indicated that no funds beyond the President's Budget would be sought to implement this activity in fiscal year 1977. Nevertheless, I would like to retain the option of submitting a supplemental request for your consideration. A draft signing statement may be found at Tab C.

Sincerely,

Marjorie Lynch

Under Secretary

Enclosures

SUMMARY OF THE PROVISIONS OF ENROLLED BILL S. 510

Classification of Medical Devices Intended for Human Use

Section 2 of the enrolled bill would amend the Federal Food, Drug and Cosmetic Act (hereinafter referred to as "the Act") by adding a new section 513, which would classify all medical devices intended for human use into three categories based upon the extent of control necessary to insure the safety and efficacy of each such device. The three categories are: (1) Class I, General Controls (e.g. manufacturer registration, recordkeeping and reporting requirements, and good manufacturing practice regulations) - devices for which controls other than standard-setting and premarket approval are sufficient to assure safety and effectiveness or for which insufficient information exists to determine that general controls are sufficient but which are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health and which do not present a potential unreasonable risk of illness or injury; (2) Class II, Performance Standards - devices for which general controls are insufficient to provide reasonable assurance of safety and effectiveness and for which there is sufficient information to establish a performance standard to provide such assurance; (3) Class III, Premarket Approval - devices for which insufficient information exists to assure that general controls and performance standards would provide reasonable assurance of safety and effectiveness and which are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury.

New section 513 of the Act would further require the establishment of expert panels to make classification recommendations to the Secretary of Health, Education, and Welfare (hereinafter referred to as "the Secretary"). These classification panels

would be organized according to the various fields of clinical medicine and fundamental sciences in which devices intended for human use would be used. After panel recommendations, the Secretary would provide an opportunity for comment, and, thereafter, classify devices by regulation.

The Secretary would be authorized to change the classification of a device based upon new information and revoke any regulation or requirement in effect under new section 514 or 515 of the Act with respect to the device.

Performance Standards

Section 2 of the enrolled bill would also amend the Act by adding a new section 514, which would authorize the Secretary to establish, by regulation, a performance standard for a class II device (including a device in class III, the reclassification of which into class II is effective upon the effective date of a performance standard for it). Such performance standards established for devices would provide reasonable assurance of safe and effective performance; and, where necessary, would include provisions respecting: (1) the construction, components, ingredients, and properties of the device and its compatibility with power systems; (2) the testing of the device; (3) demonstration that the device is in conformity with portions of the standards for which tests were required; (4) the measurement of the performance characteristics of the device; and (5) restrictions on the distribution of a device. Performance standards would, where appropriate, prescribe certain labeling for a device.

Premarket Approval

Section 2 of the enrolled bill would amend the Act by adding a new section 515, which would prescribe the authority and responsibilities of the Secretary with respect to premarket approval of devices classified in class III.

A device, which had not been introduced or delivered for introduction into interstate commerce before the date of enactment of this enrolled bill, and which had been classified in class III, would be able to be marketed only after an application for premarket approval had been approved. A class III device which had been introduced or delivered for introduction into interstate commerce before the date of enactment of this enrolled bill or was substantially equivalent to another device which had been so introduced or delivered for introduction into interstate commerce would have to follow the application procedure only after the Secretary had promulgated a regulation to require premarket approval pursuant to a notice and comment procedure set forth in this section.

Any person would be authorized to file an application for premarket approval for a class III device and the Secretary would be required to refer such application to the appropriate classification panel under new section 513 of the Act for study and for submission of a report and recommendation respecting approval of the application. Within 180 days from the receipt of the application, the Secretary would approve or deny approval of the application, unless the period were extended by agreement between the Secretary and the applicant in cases in which the device had been introduced or delivered for introduction into interstate commerce before enactment of the enrolled bill or was substantially similar to another device which had been so introduced or delivered and the continued availability of the device was necessary for the public health.

The Secretary, upon obtaining advice on scientific matters from a classification panel, after notice and opportunity for an informal hearing, could issue an order withdrawing approval of an application for premarket approval.

The enrolled bill would authorize an alternative procedure for gaining approval of an application for premarket approval of a class III device whereby, an appropriate product development protocol (PDP) was developed and approved by the Secretary. A product development protocol would be a procedure whereby the development of a product and the

development of data necessary to demonstrate safety and effectiveness would evolve simultaneously. Approval by the Secretary of a notice of completion of a product development protocol would be the equivalent of approval of an application for premarket approval.

Banned Devices

Section 2 of the enrolled bill would amend the Act by adding a new section 516, which would authorize the Secretary to ban a device intended for human use which presented substantial deception or an unreasonable and substantial risk of illness or injury.

Judicial Review

Section 2 of the enrolled bill would amend the Act by adding a new section 517, which would prescribe procedures for judicial review of regulations and orders specified in this section.

Notification and Other Remedies

Section 2 of the enrolled bill would amend the Act by adding a new section 518, which would authorize the Secretary, upon his determination that a device intended for human use presents an unreasonable risk of substantial harm to the public health, that notification is necessary to eliminate the unreasonable risk, and that no other more practicable means are available to eliminate such risk, to issue an order requiring notification of the risk to all health professionals who prescribe or use the device and to any other person (including a device user) who should properly receive such notification in order to eliminate the risk. If, after affording opportunity for an informal hearing, the Secretary determines that notification by itself would not be sufficient to eliminate the unreasonable risk of substantial harm, he could order the manufacturer, importer, or distributor of the device to submit a plan to repair, replace or refund the purchase price of the device.

However, compliance with an order would not relieve persons from liability under Federal or State law, although any value received by a plaintiff as a result of such order would be taken into account in awarding damages.

Records and Reports on Devices Intended for Human Use

Section 2 of the enrolled bill would amend the Act by adding a new section 519, which would require manufacturers, importers, and distributors of devices intended for human use to establish and maintain records, make reports and provide information required by regulations of the Secretary to assure that devices were not adulterated or misbranded and to otherwise assure their safety and effectiveness.

General Provisions Respecting Control of Devices Intended for Human Use

Section 2 of the enrolled bill would amend the Act by adding a new section 520, which would establish general provisions respecting control of devices intended for human use.

Custom Devices

The enrolled bill would allow "custom devices" to deviate from performance standards and requirements for premarket approval in order to comply with an order of an individual physician, dentist, or other specially qualified person if (1) the device was not generally available in finished form for purchase or dispensing upon prescription, and was not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and (2) the device (a) was either intended for use by an individual patient named in an order of a physician or dentist (or other specially qualified person so designated) or intended solely to meet the special needs of such physician, dentist, or other specially qualified person in the course of his practice, and (b) was not generally available to or generally used by other physicians, dentists, or other designated persons.

Restricted Devices

The enrolled bill would authorize the Secretary to restrict the sale, distribution, or use of a device if, because of its potentiality for harmful effect or as a result of the collateral measures necessary to its use, the Secretary determines that there can not otherwise be reasonable assurance

of its safety and effectiveness. The label of such a device, called a "restricted device" would have to bear such appropriate statements of restrictions as the Secretary may prescribe.

Good Manufacturing Practice Requirements

The enrolled bill would authorize the Secretary to prescribe regulations requiring that the methods used in, and the facilities and controls used for the manufacture, packing, storage, and installation of devices conform to good manufacturing practice in order to assure safety and effectiveness. Such regulations could be promulgated only after opportunity for oral hearing and only after the opportunity to submit recommendations with respect to such proposed regulations had been afforded to a nine-person advisory committee established by the Secretary. Persons subject to good manufacturing practice requirements would be able to petition for exemptions or variances from such requirements. A petition for an exemption for a device could be approved if the Secretary determined that compliance with the contested requirement was not necessary to assure that the device was safe, effective, and otherwise in compliance with the Act. Additionally, a petition for a variance for a device could be approved if the Secretary determined that the proposed methods, facilities, and controls to be used were sufficient to assure that the device was safe, effective, and otherwise in compliance with the Act.

Exemption for Devices for Investigational Use

The enrolled bill would authorize the Secretary to exempt a device from the requirements of the Act if it was intended for investigational use.

Release of Safety and Effectiveness Information

The enrolled bill would require the Secretary to promulgate regulations under which a detailed summary of information respecting the safety and effectiveness of a device would be made available to the public. Such information would be made public upon approval, denial of approval, or withdrawal

of approval of an application for premarket approval; or upon the revocation of an approved product development protocol (PDP), an order declaring a PDP completed or not completed, an order revoking the approval of a device approved under the PDP procedure, or an order approving, disapproving, or withdrawing approval of an application for exemption for investigational use of a device.

Proceedings of Advisory Panels and Committees

The enrolled bill would require each classification panel, each advisory committee established to review performance standards, and each advisory committee established to review the Secretary's action with respect to class III devices to make and maintain a transcript of any of its proceedings. Confidential information would be deleted.

Traceability Requirements

The enrolled bill would require that no regulation could impose requirements for the traceability of a type or class of device unless such requirements were necessary to assure the protection of the public health.

Research and Development

The enrolled bill would authorize the Secretary to enter into contracts for research, testing, and demonstrations respecting devices and would authorize the Secretary to obtain devices for such purposes without regard to sections 3648 and 3709 of the Revised Statutes (relating to advanced payment and procurement).

Transitional Provision for Devices Considered as New Drugs or Antibiotic Drugs

The enrolled bill would prescribe transitional provisions for devices in various stages of regulation which had been classified as new drugs or antibiotic drugs. Such devices would be classified in class III unless the Secretary had classified them into class I or class II pursuant to a petition filed by the manufacturer or importer of the device.

State and Local Requirements Respecting Devices Intended for Human Use

Section 2 of the enrolled bill would amend the Act by adding a new section 521, which would preempt State and local requirements for medical devices intended for human use that differed from or were in addition to requirements established by the Secretary, although the Secretary could exempt a requirement of a State or locality from the preemption provision were the requirement more stringent than the Federal requirement or were the requirement required by compelling local conditions and were a device which complied with the requirement not in violation of the Act.

Export of Devices

Section 3(f) of the bill would amend section 801(d) of the Act to prohibit the export of devices that did not comply with the provisions of the Act unless they accorded to the specifications of the foreign purchaser, were not in conflict with the laws of the importing country, were labeled on the outside of the shipping package as intended for export, and the health agency of the foreign country (or the Secretary if there were no such agency) would have to determine for devices which did not comply with any applicable performance standard, or premarket approval requirement, or which were exempt or banned that export was not contrary to public health.

Registration of Manufacturers of Drugs and Listing of Drugs

Section 4 of the enrolled bill would amend section 510 of the Act (relating to registration of manufacturers of drugs and listing of drugs) to make the provision applicable to device manufacturers and to require that every establishment registered under the provisions of section 510 which engaged in the manufacture, propagation, compounding, or processing of class II or class III devices be inspected at least once every two years pursuant to section 704 of the Act.

Official Names

Section 5 of the enrolled bill would amend section 502(e) of the Act (relating to the use of established names for drugs) and section 508 of the Act (which provides authority to designate official names for drugs) to make these sections applicable to devices.

Inspections Relating to Devices

Section 6 of the enrolled bill would amend section 704(a) of the Act (relating to inspections of establishments in which foods, drugs, devices or cosmetics were manufactured, processed, packed or held for introduction into interstate commerce) to render provisions now applicable to establishments in which prescription drugs are manufactured applicable to establishments in which restricted devices are manufactured, to render the provisions with respect to access to research data applicable to inspections with respect to restricted devices, and would add a new section 704(e) to assure access by officers or employees of the Secretary to records required to be maintained.

Administrative Restraint

Section 7 of the enrolled bill would amend section 304 of the Act (relating to seizure of products in violation of the Act) to add a new provision (section 304(g) authorizing temporary administrative detention of devices).

Confidential Information; Presumption of Interstate Commerce

Section 8 of the enrolled bill would add two new sections, 708 and 709 to the Act. New section 708 would authorize the Secretary to provide trade secrets and other confidential information to persons under contract with the Secretary and only require security precautions as a condition to receipt of such information. New section 709 would establish a presumption of existence of connection with interstate commerce required to establish jurisdiction in actions to enforce the Act with respect to devices.

Color Additives

Section 9 of the enrolled bill would amend section 706 of the Act (relating to color additives) to render a color additive in a device subject to the provisions of that section if the color additive came into contact with the body of man or other animals for a significant period of time, and would authorize the Secretary to designate by regulation the uses of color additives in or on devices which are subject to section 706.

Assistance for Small Device Manufacturers

Section 10 of the enrolled bill would require the Secretary to establish, within the Department of Health, Education, and Welfare, an office to provide technical and other non-financial assistance to small manufacturers of devices to assist them in complying with requirements of the Act.

In this regard, the Secretary, in order to expedite implementation of this section, will publish a notice in the Federal Register identifying an existing organizational entity within the Food and Drug Administration (FDA) to carry out the responsibilities of this section. This notice will provide the name, mailing address, and phone numbers of the FDA unit which manufacturers can contact to obtain information to assist them in complying with the requirements of this Act. This unit will be a part of the office of FDA that provides guidance to regulated industry in general. The unit will provide printed informational materials, respond to inquiries about statutory requirements, and conduct meetings, workshops, and symposia designed to acquaint manufacturers with their regulatory responsibilities under this legislation.

Medical Devices Program
Resource Requirements with
Medical Devices Legislation

	1976		1977 Request		1977 with Supplemental		1978		1979		1980		1981	
	Pos.	$000	Pos.	$000	Pos.	$000	Pos.	$000	Pos.	$000	Pos.	$000	Pos.	$000
Classification	36	1,036	40	1,288	50	2,790	25	2,040	25	2,040	25	2,040	25	2,040
Pre Market Approval	---	---	4	134	84	2,394	184	5,897	209	6,968	209	7,073	209	7,073
Regulation	3	78	8	176	18	433	18	505	18	505	18	505	18	505
Registration	6	156	6	156	21	698	31	1,038	31	1,108	31	1,108	31	1,108
Records and Reports	4	104	4	104	14	611	19	799	24	952	29	1,105	29	1,140
Standards	33	1,310	44	1,891	54	2,435	84	4,938	119	6,471	144	7,803	144	7,978
Regulatory Operations	43	1,118	45	1,176	97	2,797	97	3,334	167	4,939	187	5,959	187	6,089
Research and Testing	16	782	16	963	31	1,812	51	3,609	71	4,908	91	6,018	91	6,153
Surveillance/Spec. Invest.	43	1,118	43	1,118	54	1,543	54	1,620	64	1,853	69	2,063	69	2,078
Inspection	95	2,470	100	2,568	300	7,565	440	12,933	700	20,325	750	23,570	750	23,720
TOTAL Program	221	8,222	311	9,564	723	23,080	1,013	35,733	1,428	50,131	1,553	57,224	1,553	58,099

5/19/76

Increases for Implementing Medical Device Legislation *

	1977 Increase		Supplemental 1977		1978 Increase		1979 Increase		1980 Increase		1981 Increase	
	Pos.	$000	Pos.	$000	Pos.	$000	Pos.	$000	Pos.	$000	Pos.	$000
Classification	4	202	10	1,302	-25	-750	—	—	—	—	—	—
Pre Market Approval	4	134	80	2,260	110	3,503	13	1,071	—	105	—	—
Regulation	5	98	10	259	—	70	—	—	—	—	—	—
Registration	—	—	15	542	10	340	—	70	—	—	—	—
Records and Reports	—	—	10	507	5	188	5	153	5	153	—	35
Standards	9	571	10	554	30	2,503	35	1,533	25	1,332	—	175
Regulatory Operations	3	30	91	1,621	—	537	70	1,645	20	960	—	140
Research and Testing	—	181	15	849	20	1,797	20	1,299	20	1,110	—	140
Surveillance/Spec. Invest.	—	—	11	423	—	77	10	235	5	188	—	35
Inspections	5	98	200	4,997	140	5,370	260	7,390	50	3,245	—	350
TOTAL Program	30	1,342	412	13,516	290	13,635	413	13,396	125	7,093	—	875

* Excludes Buildings and Facilities considerations.

5/19/76

DRAFT MESSAGE FOR THE PRESIDENT

Today, I have the pleasure of signing into law the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act of 1938.

It is almost exactly 70 years since President Theodore Roosevelt signed the nation's first federal food and drug legislation designed to protect the American consumer against health threats arising from harmful substances and deceptive practices. In urging the passage of such legislation, he departed from his policy of speaking softly, instead saying about as plainly and as forcefully as it can be said, that: "Traffic in foodstuffs which have been debased or adulterated so as to injure health or to deceive purchasers should be forbidden."

Since the Pure Food and Drugs Act of 1906, there have been a number of actions to strengthen and update the structure of protection that President Roosevelt urged upon us.

While we as a nation were able to take justifiable pride in the laws providing for safety, honesty and efficacy in the foods and drugs we consume, it became increasingly clear that there remained a large, significant and growing gap in that protective wall.

Until today, the American consumer could not be sure that a medical device used by his physician, his hospital, or himself was

Theodore Roosevelt had no need to ask in 1906 for legislation concerning medical devices. For the devices used by physicians of his day were comparatively simple. There was not much that could go wrong with them. There were few ways they could be used incorrectly. They stood at the edge of medicine, helpful but not essential, and, therefore, posed no regulatory need.

By the 1960's, however, enormous advances in science and technology moved medical devices from the edge close to the center of the stage. Today devices are routinely implanted in our bodies. They replace limbs, bones, tissues, even entire organs. They permit treatment of forms of illness that can be reached in no other way. They magnify and speed ten thousandfold the diagnostic power of the human eye and brain.

Medical and diagnostic devices have produced what can only be called a therapeutic revolution. In doing so, they have also become more complex and less easily understood by those who use them. When well designed, well made, and properly used they support and lengthen life. If poorly designed, poorly made, and improperly used they can threaten and impair it.

Despite the increasing importance of devices, the Food and Drug Administration has had woefully inadequate authority to deal with them. FDA has had no reliable way of knowing how many devices there are, who is making them, who is selling them, what injuries they can cause, and when a manufacturer has found it necessary to remove them from the medical marketplace.

In addition, no device was required to be proven safe and effective prior to marketing, no matter how critical it might be to the person using it, and even if that use involved implantation in his body.

Recognizing these and other deficiencies, the Administration ordered a study of the problem in 1969 and subsequently asked Congress to enact remedial legislation.

In its deliberations since that time, Congress benefited greatly from the cooperation voluntarily extended by the medical device industry which clearly saw the need for legislation that would protect the consumer as well as the manufacturer who refused to compromise with safety. Representatives of consumers and health professionals also played an important role.

The Medical Device Amendments of 1976 eliminate the deficiencies that accorded FDA "horse and buggy" authority to deal with "laser age" problems. It is important not only in what it will do to protect the consumer; it is also important as a symbol for the kind of regulation that I feel is most appropriate to government. For this law, while it does expand the regulatory authority of an agency of the Federal government -- The Food and Drug Administration -- it does not -- as so much regulation has -- impinge our freedom or unduly restrict enterprise.

It does not represent another expansion of government into affairs we might better manage ourselves. Instead, this is an example of government doing for the individual citizen what he or she cannot do unaided.

It is not government expanding because the opportunity is there; it is government responding to a need by adding a vital protection to the public health.

It is not government that impairs the competitive nature of a dynamic new industry; this is government that strengthens our competitive posture in the world by insuring medical products of quality, safety and efficacy.

This is government action that does not further complicate the task of professionals affected by it, but rather frees them by permitting concentration on the patient rather than on the possible unreliability of the tools used to treat the patient.

Finally, this is government that is not preventing the full, productive exercise of the compassionate ingenuity that has fueled this society for 200 years: this is an example of government preventing threats to the public health in a way that is fully consonant with the principles of competitive economic development on which this nation was built.

These then are the reasons why I welcome this legislation and applaud all who devised, and those who will enforce, it. This legislation is a superlative example of the system working the way those who founded this nation 200 years ago expected it to work.

VETERANS ADMINISTRATION
OFFICE OF THE ADMINISTRATOR OF VETERANS AFFAIRS
WASHINGTON, D.C. 20420

May 20, 1976

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

Dear Mr. Lynn:

This will respond to the request of the Assistant Director for Legislative Reference for the views of the Veterans Administration on the enrolled enactment of S. 510, 94th Congress, "To amend the Federal Food, Drug, and Cosmetic Act to provide for the safety and effectiveness of medical devices intended for human use, and for other purposes."

The measure provides for classification of all medical devices intended for human use into one of three categories based on the extent of regulation necessary to assure safety and effectiveness.

The enrolled bill sets classifications ranging from a category of devices subject to general controls, to a second group that must meet performance standards, to a third classification under which devices are subject to premarket approval. That third class represents devices that cannot be set into the less rigorously regulated classes because insufficient information exists with which to determine the adequacy of general controls or standards to provide reasonable assurance of safety and effectiveness; also these are devices which are purported or represented to be for a use in supporting or sustaining life or for a use of substantial importance in preventing impairment of health or which present a potential unreasonable risk of illness or injury.

Under the legislation, panels composed of experts appointed by the Secretary of Health, Education, and Welfare

would submit recommendations regarding proper classification of "old," already introduced devices; thereafter the Secretary would promulgate a regulation classifying the devices. Newly introduced devices, not substantially equivalent to existing ones, would automatically fall within the third class until reclassified by the Secretary. In regard to the provisions governing the general requirement as to class III devices of applying for premarket approval, there is set a 180-day limit for action thereon by the Secretary.

With respect to the development and establishment of performance standards for so-called class II devices, the Secretary could accept offers by any person to develop such standards, could adopt an existing performance standard, or could authorize a Federal agency to develop such a standard. As to the Secretary's mandate to provide for periodic evaluation of these standards, we note the language of section 514(a)(5)(A) of the enrolled bill authorizing that official to "use personnel, facilities, and other technical support available in other Federal agencies." Persons adversely affected by a proposed standard could require its submission to an advisory committee of experts.

Among the many other significant provisions of the enrolled bill are measures requiring notification of patients subject to risks or hazards presented by devices; provision for restricting the sale, distribution, or use of devices; and authorization for establishment of requirements for good manufacturing practice.

The Veterans Administration, in the administration of far-flung medical activities, is, of course, vitally interested in the protection of public health and safety. We applaud the purposes of this legislation and are particularly concerned with the need to protect the consumer of medical services from unsafe and ineffective medical devices.

The number and diversity of devices used in diagnosis, monitoring and treatment of patients in modern clinical practice grows increasingly significant. Moreover, there has been an increase in the number of firms engaged in the manufacture and sale of these devices. Their products may vary substantially with regard to effectiveness of performance and margin of safety.

The VA has for many years regulated the quality, safety, and performance of prosthetic devices for amputees, and has established performance standards for these and other devices. We believe this program has been eminently successful and welcome an extension of its benefits to all medical devices.

The major features of the bill--classification, use of performance standards, good manufacturing practices, and reliance upon panels and advisory committees--have attained general acceptance after years of debate. The bill is a well conceived, thoroughly detailed document. We favor the provisions of the enrolled bill. Therefore, I recommend that the President approve S. 510.

Sincerely,

Odell W. Vaughn

Deputy Administrator - in the absence of

RICHARD L. ROUDEBUSH
Administrator

GENERAL COUNSEL OF THE
UNITED STATES DEPARTMENT OF COMMERCE
Washington, D.C. 20230

MAY 18 1976

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

Attention: Assistant Director for Legislative Reference

Dear Mr. Lynn:

This is in reply to your request for the views of this Department concerning S. 510, an enrolled enactment

> "To amend the Federal Food, Drug, and Cosmetic Act to provide for the safety and effectiveness of medical devices intended for human use, and for other purposes,"

to be cited as the "Medical Device Amendments of 1976."

The purpose of S. 510 is to provide new authority to the Secretary of Health, Education, and Welfare to assure the safety and effectiveness of medical devices intended for human use. It would require premarket approval of certain medical devices and authorize establishment of performance standards for others. Also, it would strengthen the authority of the Food and Drug Administration to take regulatory action against hazardous or deceptive medical devices, to prescribe good manufacturing practice regulations, to inspect records, to register device manufacturers, and to require maintenance of records and submission of reports concerning these products.

This Department would have no objection to approval by the President of S. 510.

Enactment of this legislation will not involve any increase in the budgetary requirements of this Department.

Sincerely,

J. T. Smith

General Counsel

Department of Justice
Washington, D.C. 20530

May 20, 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 S. 510 "To amend the Federal Food, Drug and Cosmetic Act to provide for the safety and effectiveness of medical devices intended for human use, and other purposes."

The enrolled bill, otherwise known as "The Medical Device Amendments of 1976," is the culmination of several years work by Congress, the Food and Drug Administration, other Executive Departments, industry and consumer groups. In short S. 510 establishes classifications for devices intended for human use, and sets out the standards for both safety and efficacy of medical devices. At present, there is no relevant federal law on the regulation of most devices except to the extent the government has been able to argue successfully that a particular item is a drug and thus within the present Food, Drug and Cosmetic Act.

Section 515 of the enrolled bill provides, with certain "grandfather" provisions (section 520(1)) that medical devices must prior to their introduction into interstate commerce receive premarket approval from the Food and Drug Administration. Devices not receiving approval would be banned by virtue of section 516 and the enforcement sanctions of the present Food,

Drug and Cosmetic Act would be applicable, see 21 U.S.C. 331, 333.

Judicial review would be available under section 517 to anyone seeking reversal of agency action regarding a medical device to which the person has an interest.

The enrolled bill appears to effectively solve many problems previously associated with medical devices, the safety and efficacy of which have been outside the scope of the Food and Drug Administration's responsibility.

The Department of Justice has no objection to Executive approval of this bill.

Sincerely,

Michael M. Uhlmann

Michael M. Uhlmann
Assistant Attorney General

DEPARTMENT OF THE ARMY
WASHINGTON, D.C. 20310

21 May 1976

Honorable James T. Lynn

Director, Office of Management and Budget

Dear Mr. Lynn:

The Secretary of Defense has delegated responsibility to the Department of the Army for reporting the views of the Department of Defense on enrolled enactment S.510, 94th Congress, "To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety and effectiveness of medical devices."

The Department of the Army on behalf of the Department of Defense supports the objectives of the enrolled enactment but defers to the views of the Department of Health, Education and Welfare as to its merits.

The purpose of the act is stated in its title.

Approval of the enactment may have a minor impact on that portion of the DOD budget used to fund medical programs; however, no funds have been included in the budget for this item.

This report has been coordinated within the Department of Defense in accordance with procedures prescribed by the Secretary of Defense.

Sincerely,

Martin R. Hoffmann

Martin R. Hoffmann
Secretary of the Army

THE WHITE HOUSE

WASHINGTON

May 21, 1976

MEMORANDUM FOR: JIM CAVANAUGH

FROM: SPENCE JOHNSON

SUBJECT: Schedule Proposal: S. 510, Medical Devices Act of 1976.

Attached is the schedule proposal per our conversation.

Since the President is not returning to the White House until Thursday, Bill Nicholson has indicated there may be some problem in getting this on his schedule. Therefore, it may require some extra push.

Thanks.

THE WHITE HOUSE

WASHINGTON

SCHEDULE PROPOSAL
DATE: May 21, 1976
FROM: Spencer Johnson
THRU: Jim Cannon
VIA: Bill Nicholson

MEETING: Signing Ceremony

DATE: Thursday, May 27, 1976

PURPOSE: To sign S. 510, Medical Devices Act of 1976.

FORMAT: Rose Garden or Cabinet Room
10 minutes
Participants: Secretary David Mathews and selected HEW staff; Members of Congress and selected committee staff; industry representatives.

SPEECH MATERIAL: Talking points to be provided by the Domestic Council.

PRESS COVERAGE: Full coverage; press and photo opportunity.

STAFF: Jim Cannon, Spencer Johnson.

RECOMMEND: Domestic Council, Department of HEW, OMB.

BACKGROUND: S. 510 amends the Food, Drug and Cosmetic Act of 1962 to permit the Secretary of HEW to protect the public from unsafe or ineffective medical devices. The tremendous medical technological explosion has resulted in unknown numbers of medical devices used in the practice of medicine for which there is no effective means to insure safety and effectiveness. The legislation, the first significant amendment to the Food, Drug and Cosmetic Act of 1962, grants the Food and Drug Administration the authority to respond to this vital need to protect the public health. The measure frees professionals to concentrate solely on the patient in providing high quality medical care, rather than concerning themselves with the possible unreliability of the tools at their disposal.

APPROVE_____ DISAPPROVE_____

THE WHITE HOUSE

WASHINGTON

SIGNING CEREMONY
MEDICAL DEVICE AMENDMENTS OF 1976
(Enrolled Bill S. 510)

Friday, May 28, 1976
12:00 p.m. (10 minutes)
The Oval Office

From: Jim Cannon

I. PURPOSE

To sign into law Enrolled Bill S. 510, Medical Device Amendments of 1976 which provides new authority to the Secretary of Health, Education, and Welfare to assure the safety and effectiveness of medical devices intended for human use.

II. BACKGROUND, PARTICIPANTS, PRESS PLAN

A. Background: S. 510 would amend the Federal Food, Drug and Cosmetic (FDC) Act of 1938 to provide the Food and Drug Administration (FDA) in the Department of Health, Education and Welfare (HEW) with significant new authority to regulate the safety and effectiveness of medical devices. The enrolled bill is the first amendment to the FDC Act since 1938 dealing with medical devices and represents several years of work by the Executive branch and the Congress to develop acceptable legislation to assure that modern medical devices are safe and effective.

B. Participants:

Secretary David Mathews
Dr. Theodore Cooper, Assistant Secretary of Health
Dr. Alexander Schmidt, Commissioner, FDA
Sylvester Jones, Intern for Secretary Mathews

C. Press Plan: No announcement. White House photo opportunity.

III. TALKING POINTS

1. I am pleased to sign into law the Medical Device Amendments of 1976 which will give the Secretary of Health, Education and Welfare new authority to assure safe and effective medical devices for America's medical system.

2. These amendments will give the Food and Drug Administration the ability to do for the individual citizen what he or she cannot do for themselves -- prevent the sale or use of unsafe or ineffective medical devices.

3. The FDA faces a most difficult task that requires determination, scientific skills, judgement, and most of all, compassion for the hopes and needs of our fellow man.

4. I commend the Congress, HEW, and the FDA for their fine work and cooperation.

FOR IMMEDIATE RELEASE MAY 28, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

STATEMENT BY THE PRESIDENT

Today, I have the pleasure of signing into law S. 510, the Medical Device Amendments of 1976 to the Federal Food Drug, and Cosmetic Act of 1938.

It is almost exactly 70 years since President Theodore Roosevelt signed the Pure Food and Drugs Act of 1906, the nation's first federal food and drug legislation designed to protect the American consumer against health threats arising from harmful substances and deceptive practices. Since then, there have been a number of actions to strengthen and update the structure of protection sought by President Roosevelt.

While we as a nation were able to take justifiable pride in the laws providing for safety, honesty and efficacy in the foods and drugs we consume, it became increasingly clear that there remained a large, significant and growing gap in that security.

Until today, the American consumer could not be sure that a medical device used by his physician, his hospital, or himself was as safe and effective as it could or should be.

In 1906, President Roosevelt had no need to ask for legislation concerning medical devices; for the devices used by physicians of his day were comparatively simple. They stood at the edge of medicine, helpful but not essential and, therefore, posed no regulatory need.

By the 1960's, however, enormous advances in science and technology moved medical devices from the edge close to the center of the stage. Today devices are routinely implanted in our bodies. They replace limbs, bones, tissues, even entire organs. They permit treatment of forms of illness that can be accomplished in no other way. They magnify and speed ten thousandfold the diagnostic power of the human eye and brain.

Medical and diagnostic devices have produced a therapeutic revolution, but in doing so, they have also become more complex and less easily understood by those who use them. When well designed, well made, and properly used they support and lengthen life. If poorly designed, poorly made, and improperly used they can threaten and impair it.

Despite the increasing importance of devices, the Food and Drug Administration has had inadequate authority to deal with them. FDA has had no reliable way of knowing how many devices there are, who is making them, who is selling them what risks to health and life they may present, and when a manufacturer has found it necessary to remove them from the medical marketplace.

more

In addition, no device was required to be proven safe and effective prior to marketing, no matter how crucial it might be to the person using it, even if that use involved implantation in his body.

Recognizing these and other deficiencies, the Administration ordered a study of the problem in 1969 and subsequently asked Congress to enact remedial legislation.

In its deliberations since that time, Congress benefited greatly from the cooperation voluntarily extended by the medical device industry who clearly saw the need for legislation that would protect the consumer as well as the manufacturer who refused to compromise with safety. Representatives of consumers and health professionals also played an important role.

The Medical Device Amendments of 1976 eliminate the deficiencies that accorded FDA "horse and buggy" authority to deal with "laser age" problems. It is important not only in what it will do to protect the consumer, it is also important as a symbol for the kind of regulation that I feel is most appropriate to government. It does not represent another expansion of government into affairs we might better manage ourselves. Instead, this is an example of government doing for the individual citizen what he or she cannot do unaided.

I welcome this legislation and commend the FDA who identified the need, cooperated in its development, and finally, will be entrusted with its enforcement.

This agency daily faces a most difficult task -- preventing threats to the public health in a way that is not onerous, but fully consonant with the principles of competitive economic development on which this nation was built. It is a task that requires determination, scientific skill, judgment and most of all, compassion for the hopes and needs of our fellow man. Dr. Alexander M. Schmidt, Commissioner of Food and Drugs, has effectively taken on the job of assuring that the hope and expectations of the consumer for life-giving drugs and devices are not false promises.

I reaffirm my support for the fine work of the Food and Drug Administration and the job ahead.

# # # #

FOR IMMEDIATE RELEASE MAY 28, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

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Despite the increasing importance of devices, the Food and Drug Administration has had inadequate authority to deal with them. FDA has had no reliable way of knowing how many devices there are, who is making them, who is selling them, what risks to health and life they may present, and when a manufacturer has found it necessary to remove them from the medical marketplace.

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I reaffirm my support for the fine work of the Food and Drug Administration and the job ahead.

# # # #

June 9, 1976

Dear Miss Glisson:

As you know, I signed S. 510, the Medical Device Amendments of 1976, on May 28. Because of your efforts on behalf of this legislation, I am pleased to send you a ceremonial pen to mark the bill becoming Public Law 94-295.

Sincerely,

Miss JoAnne Glisson
Research Assistant
Subcommittee on Health
and the Environment
Committee on Interstate
and Foreign Commerce
House of Representatives
Washington, D. C. 20515

cc: Spencer Johnson -FYI

GRF:MLF:JEB:VO:emu

June 9, 1976

Dear Mr. Greene:

As you know, I signed S. 510, the Medical Device Amendments of 1976, on May 28. Because of your efforts on behalf of this legislation, I am pleased to send you a ceremonial pen to mark the bill becoming Public Law 94-295.

Sincerely,

Mr. N. Thomas Greene
Associate Counsel
Committee on Interstate
and Foreign Commerce
House of Representatives
Washington, D. C. 20515

cc: Spencer Johnson - FYI

GRF:MLF:JEB:VO:emu

June 9, 1976

Dear Mr. Meade:

As you know, I signed S. 510, the Medical Device Amendments of 1976, on May 28. Because of your efforts on behalf of this legislation, I am pleased to send you a ceremonial pen to mark the bill becoming Public Law 94-295.

Sincerely,

Mr. David E. Meade
Assistant Counsel
Office of the Legislative Counsel
House of Representatives
Washington, D. C. 20515

cc: Spencer Johnson, FYI

GRF:MLF:JEB:VO:emu

June 9, 1976

Dear Mr. Lawton:

As you know, I signed S. 510, the Medical Device Amendments of 1976, on May 28. Because of your efforts on behalf of this legislation, I am pleased to send you a ceremonial pen to mark the bill becoming Public Law 94-295.

Sincerely,

Mr. Stephan Lawton
Counsel
Subcommittee on Health
and the Environment
Committee on Interstate
and Foreign Commerce
House of Representatives
Washington, D. C. 20515

cc: Spencer Johnson - FYI

GRF:MLF:JEB:VO:emu

June 9, 1976

Dear Dick:

As you know, I have signed S. 519, the Medical Device Amendments of 1976. Because of your special interest in this legislation, I am pleased to send you a ceremonial pen to mark the bill becoming Public Law 94-295 on May 28.

Sincerely,

The Honorable Richard S. Schweiker
United States Senate
Washington, D. C. 20510

cc: Spencer Johnson, FYI

GRF:MLF:JEB:VO:emu

June 9, 1976

Dear Ted:

As you know, I have signed S. 510, the Medical Device Amendments of 1976. Because of your special interest in this legislation, I am pleased to send you a ceremonial pen to mark the bill becoming Public Law 94-295 on May 28.

Sincerely,

The Honorable Edward M. Kennedy
United States Senate
Washington, D. C. 20510

cc: Spencer Johnson, FYI

GRF:MLF:JEB:VO:emu

June 9, 1976

Dear Tim:

As you know, I have signed S. 510, the Medical Device Amendments of 1976. Because of your special interest in this legislation, I am pleased to send you a ceremonial pen to mark the bill becoming Public Law 94-295 on May 28.

Sincerely,

The Honorable Tim Lee Carter
House of Representatives
Washington, D. C. 20515

cc: Spencer Johnson, FYI

GRF:MLF:JEB:VO:emu

June 9, 1976

Dear Paul:

As you know, I have signed S. 510, the Medical Device Amendments of 1976. Because of your special interest in this legislation, I am pleased to send you a ceremonial pen to mark the bill becoming Public Law 94-295 on May 28.

Sincerely,

The Honorable Paul G. Rogers
House of Representatives
Washington, D. C. 20515

cc: Spencer Johnson, FYI

GRF:MLF:JEB:VO:emu

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

June 23, 1976

Mr. Spencer C. Johnson
Associate Director for Health,
Social Security, and Welfare
The Domestic Council
Washington, D. C. 20501

Dear Mr. Johnson:

Thank you for sending me a copy of the photograph taken at the signing of the Medical Device Amendments of 1976 at the White House. Dr. Mathews was very accurate in saying that I am "delighted" to have a copy of the photograph with President Ford signing the Amendments.

I can assure you that it was a great pleasure to meet President Ford. It was an event that will always be remembered as a highlight of my summer in Washington, D. C. with the Department of Health, Education, and Welfare.

Sincerely,

Sylvester Jones
Student Assistant

cc: Secretary Mathews

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D. C. 20201

The Honorable Spencer C. Johnson
Associate Director
The Domestic Council
Washington, D.C. 20500

Dear Spence:

Thank you for sending me copies of the photograph taken at the signing of the Medical Device Amendments of 1976. Sylvester Jones is delighted to have a copy also.

Cordially,

Secretary

cc: Mr. Sylvester Jones

Spencer Johnson

June 25, 1976

Dear Bill:

This is in further reply to your May 27 letter to the President concerning the Medical Device Amendments and the possible affect of this legislation on ophthalmologists in your District.

I understand you have written a apparate letter on this matter to Commissioner Schmidt of the Food and Drug Administration, and that he is preparing a detailed reply which you should receive shortly. I hope the information he will furnish will be helpful to you. If you have additional questions, please let me know.

With kindest regards,

Sincerely,

Charles Leppert, Jr.
Deputy Assistant
to the President

The Honorable William M. Ketchum
House of Representatives
Washington, D.C. 20515

bcc: James Cannon (attn: Spencer Johnson) -- FYI

CL:HEW:DOM.COUNCIL:JEB:jem

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE SECRETARY

WASHINGTON, D.C. 20201

12 JUL 1976

TO: Spencer Johnson

FROM: Gene Haislip

SUBJECT: Recognition for Major Contribution to the Enactment of Medical Devices Legislation

Attached is a list of persons whose efforts were in large measure responsible for the passage of P.L. 94-295, a major piece of legislation establishing necessary controls over the marketing of medical devices. The list was prepared at my request by FDA with the instruction that only those persons who had played a leading role were to be included. I suggest that each of them receive a Presidential pen and suitable expression of appreciation for their contribution to the enactment of this law.

Gene

LIST OF INDIVIDUALS TO RECEIVE PENS USED IN SIGNING THE MEDICAL DEVICE BILL INTO LAW

Members of Congress

Jacob K. Javits, Ranking Minority Member
Committee on Labor and Public Welfare
United States Senate

Edward M. Kennedy, Chairman
Subcommittee on Health
Committee on Labor and Public Welfare
United States Senate

Paul G. Rogers, Chairman
Subcommittee on Health and the Environment
Committee on Interstate and Foreign Commerce
House of Representatives

Tim Lee Carter, Ranking Minority Member
Subcommittee on Health and the Environment
Committee on Interstate and Foreign Commerce
House of Representatives

Department of Health, Education, and Welfare

Theodore Cooper, M.D., Assistant Secretary for Health

Congressional Staff Members

Stephan E. Lawton, Counsel
Subcommittee on Health and the Environment
Committee on Interstate and Foreign Commerce
House of Representatives

H. Thomas Greene, Associate Counsel
Minority Staff
Committee on Interstate and Foreign Commerce
House of Representatives

Lawrence Horowitz, M.D.
Professional Staff Member
Subcommittee on Health
Committee on Labor and Public Welfare
United States Senate

Congressional Staff Members (Continued)

Jay Cutler, Minority Counsel
Subcommittee on Health
Committee on Labor and Public Welfare
United States Senate

Alan Fox, Staff Assistant
Subcommittee on Health
Committee on Labor and Public Welfare
United States Senate

Food and Drug Administration Staff Members

Richard A. Merrill, Chief Counsel

Linda Horton, Associate Chief Counsel for Medical Devices and Diagnostic Products

David H. Link, Director, Bureau of Medical Devices and Diagnostic Products

*One for the Food and Drug Administration

Medical devices

National Bureau of Standards

FEDERAL INFORMATION PROCESSING STANDARDS TASK GROUP 13 WORKLOAD DEFINITION AND BENCHMARKING

Meeting

Pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. I (Supp. IV, 1974), notice is hereby given that the Federal Information Processing Standards Task Group 13 (FIPS TG–13), "Workload Definition and Benchmarking," will hold a meeting from 10 a.m. to 4 p.m. on Wednesday, August 18, 1976 in Room B–255, Building 225, of the National Bureau of Standards at Gaithersburg, Maryland.

The purpose of this meeting is to review FIPS TG–13 accomplishments to date and to define future FIPS TG–13 task activities.

The public will be permitted to attend, to file written statements, and, to the extent that time permits, to present oral statements. Persons planning to attend should notify the Acting Executive Secretary, Mr. Arthur F. Chantker, Institute for Computer Sciences and Technology, National Bureau of Standards, Washington, D.C. 20234 (Phone—301–921–3485).

Dated: July 7, 1976.

ERNEST AMBLER,
Acting Director.

[FR Doc.76–20117 Filed 7–12–76;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Education

ADVISORY COUNCIL ON ENVIRONMENTAL EDUCATION

Meeting; Amendment

In FR Doc.76–18397 appearing at page 25922 in the FEDERAL REGISTER of June 23, 1976, the first paragraph is amended to include a meeting of the Proposal Evaluation Criteria work group to be held on July 20–21, 1976 from 9:00 a.m. to 5:30 p.m. in Room 2004, 400 Maryland Avenue, S.W., Washington, D.C. for the purpose of preparing a draft report on their findings.

Dated: July 9, 1976.

WALTER J. BOGAN, Jr.,
Director, Office of Environmental Education.

[FR Doc.76–20385 Filed 7–12–76;10:11 am]

Food and Drug Administration

ADVISORY COMMITTEE FOR MEDICAL DEVICES CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS

Request for Nominations for Members

The Food and Drug Administration (FDA) describes the current status of current good manufacturing practice regulations and invites the submission of nominations for membership to the Advisory Committee for Current Good Manufacturing Practice Regulations in accordance with the requirements of section 520(f) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360j); submissions by September 13, 1976.

Since December 1973, FDA has been involved in the development of current good manufacturing practice regulations for medical devices. A preliminary draft of a proposed current good manufacturing practice regulation was made available to the public by notice of availability published in the FEDERAL REGISTER of August 8, 1975 (40 FR 33482). A subsequent notice published in the FEDERAL REGISTER of October 9, 1975 (40 FR 47530)) announced four public meetings that were held across the country to give interested parties the opportunity to present data, information, and views concerning the draft current good manufacturing practice regulations. These meetings were held in November 1975 in cooperation with various district offices of FDA. Based upon the information derived from these meetings and numerous comments on the draft document, significant alterations have been made to the original draft.

On May 28, 1976, the Medical Device Amendments of 1976 (Pub. L. 94–295) were enacted into law, amending the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.). Section 520(f) of the act provides the agency with authority to develop and promulgate regulations requiring that methods used in, and the facilities and controls used for the manufacture, packing, storage, and installation of medical devices conform to current good manufacturing practice. These regulations are designed to assure that devices will be safe and effective and otherwise in compliance with the act.

Under section 520(f)(3) of the act, the Commissioner of Food and Drugs must establish an advisory committee for the purpose of advising and making recommendations on these regulations. Additionally, under this provision, the Commissioner is authorized to request recommendations from the advisory committee on any petitions submitted requesting exemptions or variances from good manufacturing practice requirements.

In the near future, the agency intends to publish in the FEDERAL REGISTER a proposed good manufacturing practice regulation for medical devices. The current good manufacturing practice advisory committee, when appointed, will review and comment on the proposed current good manufacturing practice regulations as well as on the comments received as a result of the proposal.

As required by section 520(f) of the act the advisory committee shall be composed of nine members selected from different interest groups as follows:

1. Three of the members shall be appointed from persons who are officers or employees of any State or local government or of the Federal Government;

2. Two of the members shall be appointed from persons who are representative of interests of the device manufacturing industry;

3. Two of the members shall be appointed from persons who are representative of the interests of physicians and other health professionals;

4. Two of the members shall be representative of the interests of the general public.

To be considered for appointment to this advisory committee, each nomination must be received on or before September 13, 1976 and must be accompanied by a curriculum vitae that includes the nominee's current employment, professional affiliations, and educational and experience background, if any, with respect to medical devices. Additionally, each nomination must affirmatively state that the nominee is aware of the nomination, is interested in participating in the mission of the current good manufacturing practice advisory committee, and indicate any areas of possible conflict of interest.

Nominations are solicited from consumer, industry, government, health professional organizations, and the public. It is recommended that representatives from each interest group develop a list of nominees acceptable to the constituent organizations making up a particular interest group. The Commissioner will appoint as members those nominees who are most representative of an interest group to serve on the advisory committee.

Interested persons are invited to submit names of nominees and accompanying information to:

Food and Drug Administration, Bureau of Medical Devices and Diagnostic Products, Division of Compliance (HFK–123), 8757 Georgia Ave., Silver Spring, MD 20910.

Dated: July 6, 1976.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.76–20134 Filed 7–12–76;8:45 am]

ADVISORY COMMITTEES

Notice of Meetings

Correction

In FR Doc. 76–17818 appearing in the issue of Friday, June 18, 1976, on page 24750, the fourth line in the second column should read "vice; hyperthermia device; mechanical cardiac resuscitator;".

Public Health Service

TEXAS

Intention to Redesignate Professional Standards Review Areas

Notice is hereby given that, pursuant to the order of the United States District Court in the case of *Texas Medical Association et al* v. *Weinberger* (U.S.D.C., W.D. of Texas, No. A–74–CA–108, January 9, 1976), and in the light of the withdrawal of the Government's appeal from that order, the Department of Health, Education, and Welfare (the Department) will undertake appropriate procedures to redesignate Professional Standards Review Organization (PSRO) areas in the State of Texas in accord with section 1152(a) of the Social Security Act (42 U.S.C. 1320(1) and 42 CFR 101.1 et seq.

The District Court Order set aside the nine PSRO areas designated in Texas under the Department's regulations (42 CFR 101.48) and remanded the case to the Secretary to perform his statutory function of designating appropriate PSRO areas in Texas, without "inhibiting external influences" from Congress. The United States filed a Notice of Appeal in this case to the United States Court of Appeals for the Fifth Circuit on March 9, 1976. After further consideration of the need to expedite the establishment of the Professional Standards Review program in Texas and, in light of the considerable delay that the completion of the appeal process would entail, the Secretary of Health, Education, and Welfare requested the Department of Justice not to pursue the Appeal and to withdraw the Notice of Appeal. The Department of Justice has agreed with this recommendation and has taken appropriate action to withdraw the appeal.

I.

The Department's decision should not be read as indicating approval of or agreement with either the factual or legal conclusions of the District Court. The Department continues to believe that the District Court's legal conclusion was clearly erroneous in ignoring the existing administrative record which contained the basis for the Secretary's decision (*Camp* v. *Pitts*, 411 U.S. 138, (1973)). Moreover, it is our view that the District Court's conclusion that "agency action is invalid if based, even in part, on pressures emanating from Congressional sources" is incorrect since Congressional input is entirely appropriate in the quasi-legislative function of rulemaking (see *Angel* v. *Butz*, 487 U.S. 967). Finally, the District Court's opinion fails to recognize the appropriate role of Congress in overseeing the "application, administration, and execution" of laws (2 U.S.C. 190(d)) and further fails to follow the single case which it cited as precedent, *D.C. Federation of Citizens* v. *Volpe*, 459 F. 2d 1231 (D.C. Cir. 1971). In that case the court plainly focused on irrelevant Congressional pressure as being an undue influence on administrative action (459 F. 2d at 1248), which is clearly distinguished from the Congressional attempts in this case to call attention to the legislative history of the statute involved, which the Courts have always considered highly relevant to the process of statutory construction.

The factual conclusion of the District Court that the Secretary and HEW Administrators were, in fact, influenced by the "financial leverage" of the Congressional sources of the alleged "pressure" is plainly wrong, since the "source" obviously had no power to control the appropriation of funds to HEW. The Department's decision to require local areas in Texas was based on the Department's guidelines for designation of areas, as published in regulations (42 CFR 101.2). This was demonstrated by the adherence of the Department to the guidelines in the designation of areas, not only in Texas, but in other States, as discussed in the preamble to the regulations (39 FR 10206, 3/18/74).

II.

The specific procedures which the Department will follow in redesignating PSRO areas in Texas pursuant to the judgment of the court will be set out in a notice to be published in the FEDERAL REGISTER in the near future. These procedures will enable the Secretary to take into consideration the criteria established under 42 CFR 101.2 and to comply with the District Court's suggestion that HEW develop and preserve a "full-scale administrative record to remove any doubts about the true basis of its forthcoming action."

The Department also plans to conduct an informal secret ballot poll of all doctors of medicine or osteopathy engaged in active practice in Texas to ascertain whether they favor the designation of Texas PSRO areas on a local or statewide basis. Physicians engaged in active practice in Texas will be advised further by the Department of the detailed procedures for the conduct of this poll. This poll will be purely advisory to the Secretary in connection with the process of redesignating areas and will not constitute the poll required under section 1152(g) of the Social Security Act (section 105 of Pub. L. 94-182).

Dated: July 8, 1976.

DAVID MATHEWS,
Secretary.

[FR Doc.76-20178 Filed 7-12-76;8:45 am]

Social Security Administration

REDELEGATIONS OF AUTHORITY

Various Certifications and To Cause the Department Seal To Be Affixed or Impressed

The Assistant Secretary for Administration and Mangement of the Department of Health, Education, and Welfare had redelegated to the Commissioner of Social Security (the Commissioner), with authority to further redelegate, authority to certify true copies of any books, records, papers or other documents on file within the Social Security Administration (SSA); to certify extracts from such material; to certify that true copies are true copies of the entire file; to certify the complete original record; to certify the nonexistence of records on file; and authority to cause the HEW Seal to be affixed to such certifications (34 FR 18049-50, dated November 7, 1969). The Commissioner was also authorized at such time to cause the HEW Seal to be affixed or impressed to agreements, awards, citations, diplomas, and similar documents. The redelegation by the Assistant Secretary of certification authorities did not rescind previous further redelegations of authority made by the Commissioner. The Commissioner previously further redelegated these authorities (except authority to certify that true copies are true copies of the entire file, and authority to certify the complete original record) to appropriate SSA positions, as set forth in 33 FR 2613-14, dated February 6, 1968; and 34 FR 13046-47, dated August 12, 1969. Subsequent to the Assistant Secretary's redelegation of November 7, 1969, the Commissioner made additional further redelegations to SSA positions, as set forth in 37 FR 10602-3, dated May 25, 1972; 38 FR 21681, dated August 10, 1973; and 40 FR 25616, dated June 17, 1975. These further redelegations did not include authority to certify the complete original record.

I. Notice is hereby given that the Commissioner has rescinded all prior further redelegations of the subject authorities to SSA positions.

II. Notice is also hereby given that the Commissioner has concurrently further redelegated the following authorities to the SSA positions specified below:

1. Authority to certify true copies of any books, records, papers or other documents on file;

2. Authority to certify extracts from material on file;

3. Authority to certify that true copies are true copies of the entire record on file;

4. Authority to certify the complete original record on file;

5. Authority to certify that particular records are not on file; and

6. Authority to cause the HEW Seal to be affixed or impressed to those certifications identified above.

Delegates	*Scope of authority*
1. Deputy Commissioner	1 and 2. SSA-wide.
2. Associate Commissioner for Management and Administration, and Deputy Associate Commissioner for Management and Administration.	
3. Associate commissioners and deputy associate commissioners; Director, Bureau of Health Insurance; Director and Deputy Director, Bureau of Hearings and Appeals; and the Director, Office of Advanced Systems.	3. Office or Bureauwide.
4. Those headquarters component head positions and deputy component head positions at the 1st organization level below the positions specified in items 2 and 3 above.	4. Componentwide.
5. Regional commissioners and deputy regional commissioners, Office of Program Operations.	5. Cases within the jurisdiction of regional components of the Office of Program Operations.

Delegates	*Scope of authority*
6. Assistant Bureau Director, Operations, and Deputy Assistant Bureau Director, Operations, Bureau of Data Processing, Office of Program Operations.	6. Cases within the jurisdiction of components reporting to the Assistant Bureau Director, Operations, Bureau of Data Processing, Office of Program Operations.
7. Director and Deputy Director, Division of Adjustment Operations; Director and Deputy Director, Division of Claims Operations; Director and Deputy Director, Division of Registration Operations; Director and Deputy Director, Division of Earnings Operations; and Director and Deputy Director, Division of Health Insurance Operations; Bureau of Data Processing, Office of Program Operations.	7. Divisionwide.
8. Assistant Bureau Director, Disability Operations, and Deputy Assistant Bureau Director, Disability Operations, Bureau of Disability Insurance, Office of Program Operations.	8. Cases within the jurisdiction of components reporting to the Assistant Bureau Director, Disability Operations, Bureau of Disability Insurance, Office of Program Operations.
9. Assistant Bureau Director, Systems and Methods, and Deputy Assistant Bureau Director, Systems and Methods, Bureau of Retirement and Survivors Insurance, Office of Program Operations.	9. Cases within the jurisdiction of components reporting to the Assistant Bureau Director, Systems and Methods, Bureau of Retirement and Survivors Insurance, Office of Program Operations.
10. Assistant Bureau Director, Technical Policy, and Deputy Assistant Bureau Director, Technical Policy, Bureau of Health Insurance.	10. Cases within the jurisdiction of components reporting to the Assistant Bureau Director, Technical Policy, Bureau of Health Insurance.
11. Chief, Civil Actions Branch, Division of Appeals Operations, Bureau of Hearings and Appeals.	11. Cases within the jurisdiction of the Civil Actions Branch, Division of Appeals Operations, Bureau of Hearings and Appeals.
12. Regional representatives and deputy regional representatives, Health Insurance.	12. Cases within the jurisdiction of regional offices of the Bureau of Health Insurance.
13. Regional chief administrative law judges, Bureau of Hearings and Appeals.	13. Cases within the jurisdiction of regional offices of the Bureau of Hearings and Appeals.
14. Directors, SSA program service centers, Bureau of Retirement and Survivors Insurance, Office of Program Operations.	14. Cases within the jurisdiction of SSA program service centers, Bureau of Retirement and Survivors Insurance, Office of Program Operations.
15. Program review officers, Office of Quality Assurance, Office of Management and Administration.	15. Cases within the jurisdiction of program review offices, Office of Management and Administration.
16. Directors and deputy directors, data operations centers, Bureau of Data Processing, Office of Program Operations.	16. Cases within the jurisdiction of data operations centers, Bureau of Data Processing, Office of Program Operations.

III. Notice is also hereby given that the Commissioner has rescinded all previous further redelegations to SSA positions of authority to cause the HEW Seal to be affixed or impressed to agreements; awards; citations; diplomas; or similar documents, and concurrently further redelegated such authority to the SSA positions specified below:

Delegates	*Scope of authority*
1. Deputy Commissioner	1 and 2. SSA-wide.
2. Associate Commissioner for Management and Administration, and Deputy Associate Commissioner for Management and Administration.	
3. Associate Commissioners and deputy associate commissioners; Director, Bureau of Health Insurance; Director and Deputy Director, Bureau of Hearings and Appeals; and the Director, Office of Advanced Systems.	3. Office or Bureauwide.
4. Those headquarters component head positions and deputy component head positions at the first organizational level below the positions specified in items 2 and 3 above.	4. Componentwide.
5. Regional commissioners and deputy regional commissioners, Office of Program Operations.	5. Cases within the jurisdiction of regional components of the Office of Program Operations.
6. Regional representatives and deputy regional representatives, Health Insurance.	6. Cases within the jurisdiction of regional offices of the Bureau of Health Insurance.

Delegates	*Scope of authority*
7. Regional chief administrative law judges, Bureau of Hearings and Appeals.	7. Cases within the jurisdiction of regional offices of the Bureau of Hearings and Appeals.
8. Directors, SSA program service centers, Bureau of Retirement and Survivors Insurance, Office of Program Operations.	8. Cases within the jurisdiction of SSA program service centers, Bureau of Retirement and Survivors Insurance, Office of Program Operations.
9. Program review officers, Office of Quality Assurance, Office of Management and Administration.	9. Cases within the jurisdiction of program review offices, Office of Management and Administration.
10. Directors and deputy directors, data operations centers, Bureau of Data Processing, Office of Program Operations.	10. Cases within the jurisdiction of data operations centers, Bureau of Data Processing, Office of Program Operations.

IV. Any actions heretofore taken by the incumbents of the positions specified in sections II and III above which, in effect, involve the exercise of authority further redelegated by this document, are hereby affirmed and ratified.

V. The rescissions and further redelegations specified in sections I through III above are effective July 13, 1976. The incumbents of those positions further redelegated the subject authorities may not themselves redelegate such authorities.

Dated: July 6, 1976.

J. B. CARDWELL,
Commissioner of Social Security.

[FR Doc.76-20131 Filed 7-12-76;8:45 am]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Assistant Secretary for Consumer Affairs and Regulatory Functions

[Docket No. N-76-564]

NATIONAL MOBILE HOME ADVISORY COUNCIL

Establishment

The National Mobile Home Construction and Safety Act of 1974 (Title VI of the Housing and Community Development Act of 1974) authorizes the Secretary of the Department of Housing and Urban Development to establish Federal construction and safety standards for mobile homes. It provides for the appointment by the Secretary of a National Mobile Home Advisory Council composed of 24 members. One-third of the membership of the Council is to be selected from each of the following categories: (a) Consumer organizations, community organizations, and recognized consumer leaders; (b) the mobile home industry and related groups including at least one representative of small business; and (c) government agencies including Federal, State and local governments. The National Mobile Home Advisory Council provides advice to the Secretary on the development of initial Federal Mobile Home Construction and Safety Standards and on changes in those standards.

Section 6(c) of the National Mobile Home Advisory Council Charter stipulates that of the initially appointed members, one-half shall be appointed for one year, and one-half for two years. The one and two year terms were evenly distributed among the three basic groups which make up the Council, so that four members of each group have one year terms and four members of each group have two year terms. The one year terms expired on April 30, 1976, and the initial two year terms expire on December 31, 1976. All future terms are for two years and expire on December 31 of the second year of the term.

Additionally, at this time, as a result of the resignation of two members and the deaths of two others, there are four vacancies on the Council. These four terms expire on December 31, 1976. The vacancies were for: one consumer representative, one industry representative and two government representatives. Appointments for the four vacant terms were made from those persons nominated in 1975.

Nominations for the 12 expiring terms were requested at 41 FR 3500 on January 23, 1976. In response to that request, 36 persons were nominated. Their qualifications as well as those persons previously nominated in 1975 and persons on the Council not serving until December 31, 1976, were evaluated and appointments made from that group.

In making its selections, the Department, in general, sought to achieve geographic balance in the Council and to weigh that balance according to the size of the mobile home industry and the number of mobile homes in use in each region of the country, and participation by persons who would present it with a broad spectrum of views.

Additionally, the Department decided that: due to the wide interest in the Federal mobile home standards program and the need to get the broadest input possible, no person would be permitted to serve consecutive terms; that for the same reasons persons associated with the financial or insurance communities who had no other interest in the program would not be appointed at this time. It was also decided that, since the Federal mobile home standards and enforcement programs contemplate participation to a substantial extent by the states, and since inter-governmental participation may be achieved by other means, representatives of Federal agencies would not be appointed to the Council.

Pursuant to the requirements of section 605 of Title VI of the Housing and Community Development Act of 1974 (P.L. 93-383) and the Federal Advisory Committee Act of 1972 (P.L. 92-463), I, Constance B. Newman, am appointing the following persons to serve terms on the National Mobile Home Advisory Council:

To complete terms expiring December 31, 1976.

GOVERNMENT OFFICIALS

William E. Dell, Assistant to the Director, Department of Labor nad Industries, Seattle, Washington.

Marion B. Robinson, Director, Division of Inspection Services, Columbia, South Carolina.

COMMUNITY AND CONSUMER REPRESENTATIVES

Herbert F. Hugo, President, Golden State Mobilhome Owners League, Garden Grove, California.

INDUSTRY

Bill Novak, President, Gallatin Homes Corporation, Belgrade, Montana.

To replace members whose terms expired April 30, 1976, and who will serve terms expiring December 31, 1977:

GOVERNMENT OFFICIALS

C. Sutton Mullen, Administrator, Industrialized Building Law, State Corporation Commission, Richmond, Virginia.

Kenneth E. Meiser, Public Advocate, Division of Public Interest Advocacy, Department of Public Advocate, Trenton, New Jersey.

Richard Bullock, Chief, Mobile Home Section, Department of Labor and Human Relations, Madison, Wisconsin.

Fred H. Jolly, Director, Division of Environmental Health Services, State Department of Health, Lincoln, Nebraska.

COMMUNITY AND CONSUMER REPRESENTATIVES

Margery Moore, Manpower Counselor, Orleans County Council of Social Agencies (OCCSA), Newport, Vermont.

William R. Palmer, Editor, Mobile Homeowner's Association of N.J., Inc., Newspaper, Birmingham, New Jersey.

Robert Myers, President, Michigan Mobile Home Owner's Association, Ypsilanti, Michigan.

Jane Conrad, American Mobile Home Association, Lakewood, Colorado.

INDUSTRY REPRESENTATIVES

Philip J. Braff, President, Braff Building Company, Madison, Ohio.

William Stewart, California Mobilehome Dealers Association, Sacramento, California.

Charles T. Ashford, Vice President, Corp. Purchasing and Engineering, Redman Industries, Dallas, Texas.

Daniel Siegel, President and Chairman of the Board, Siegel Mobile Home Group, Siegel Financial Services, Salt Lake City, Utah.

The following members were previously appointed and will continue to serve until December 31, 1976:

John L. Adams, President, Florida Coalition of Mobile Home Owners, Tampa, Florida.

Peter B. Maier, Director, Mobile Home Task Force, Center for Auto Safety, Washington, D.C.

Charles H. Mann, President, Federation of Mobile Home Owners, St. Petersburg, Florida.

Donald A. Barrow, Vice President, Skyline Corporation, Elkhart, Indiana.