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5/28/76

APPROVED

MAY 28 1976

THE WHITE HOUSE

ACTION

WASHINGTON

Last Day: May 28

May 27, 1976

Statement issued  
5/28

MEMORANDUM FOR

THE PRESIDENT

FROM:

JIM CANNON

SUBJECT:

S. 510 - Medical Device Amendments  
of 1976

Attached for your consideration is S. 510, sponsored by Senator Kennedy, which provides new authority to the Secretary of Health, Education and Welfare to assure the safety and effectiveness of medical devices. The enrolled bill is the first amendment to the Federal Food, Drug and Cosmetic Act of 1938 since 1938 dealing with medical devices and represents several years of work by the Executive Branch and the Congress to assure that modern medical devices are safe and effective.

A detailed discussion of the provisions of the bill is provided in OMB's enrolled bill report at Tab A.

OMB, Max Friedersdorf, Counsel's Office (Lazarus) and I recommend approval of the enrolled bill and the proposed signing statement. Approval from the Editorial Office has not been received and rather than hold the package any longer, it is being submitted for your consideration.

RECOMMENDATION

That you sign S. 510 at Tab B.

That you approve the signing statement at Tab C.

Approve

*JRC*

Disapprove

\_\_\_\_\_

To Archives  
5/28/76





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 pre-market 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 <u>actual</u>	<u>1977</u>	<u>1978</u>	<u>1979</u>
HEW current activity level projected	8.2	9.4	23.1	36.7
HEW proposed funding for S. 510 authorities	-- <u>8.2</u>	<u>13.6</u> <u>23.0</u>	<u>13.6</u> <u>36.7</u>	<u>13.4</u> <u>50.1</u>
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

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.

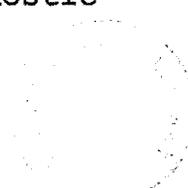
It is almost exactly 70 years since President Theodore Roosevelt signed the Pure Food and Drugs Act of 1906, the nation's first federal food and drug legislation designed to protect the American consumer against health threats arising from harmful substances and deceptive practices. Since then, there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

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.

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





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.

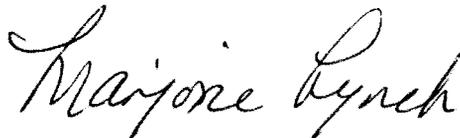


For the reasons given, we urge that the enrolled bill be approved.

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,



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.

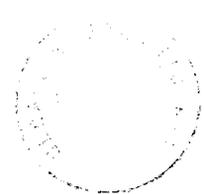
The Secretary would be authorized to change the classification of a device based upon new information and revoke any regulation or requirement in effect under new section 514 or 515 of the Act with respect to the device.

#### 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

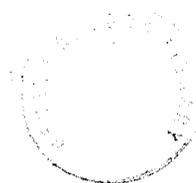
Section 6 of the enrolled bill would amend section 704(a) of the Act (relating to inspections of establishments in which foods, drugs, devices or cosmetics were manufactured, processed, packed or held for introduction into interstate commerce) to render provisions now applicable to establishments in 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**

	<u>1976</u>		<u>1977 Request</u>		<u>1977 with Supplemental</u>		<u>1978</u>		<u>1979</u>		<u>1980</u>		<u>1981</u>	
	<u>Pos.</u>	<u>\$000</u>	<u>Pos.</u>	<u>\$000</u>	<u>Pos.</u>	<u>\$000</u>	<u>Pos.</u>	<u>\$000</u>	<u>Pos.</u>	<u>\$000</u>	<u>Pos.</u>	<u>\$000</u>	<u>Pos.</u>	<u>\$000</u>
Classification	36	1,086	40	1,288	50	2,790	23	2,040	23	2,040	23	2,040	23	2,040
Pre Market Approval	---	---	4	134	84	2,394	194	5,897	209	6,968	209	7,073	209	7,073
Regulation	3	78	8	176	18	435	18	505	18	505	18	505	18	505
Registration	6	156	8	156	21	698	31	1,038	31	1,108	31	1,108	31 <sup>31</sup>	1,108
Records and Reports	4	104	4	104	16	611	19	789	24	932	29	1,103	29	1,140
Standards	33	1,310	44	1,881	94	2,435	84	4,938	119	6,471	144	7,803	144	7,978
Regulatory Operations	43	1,118	46	1,176	97	2,797	97	3,354	167	4,999	187	5,959	187	6,099
Research and Testing	16	782	16	963	31	1,812	51	3,609	71	4,908	91	6,018	91	6,158
Surveillance/Span. Invest.	43	1,118	43	1,118	54	1,543	54	1,620	64	1,855	69	2,843	69	2,078
Inspection	95	2,470	100	2,368	300	7,363	440	12,935	700	20,325	750	23,570	750	23,920
<b>TOTAL Program</b>	<b>281</b>	<b>8,222</b>	<b>311</b>	<b>9,564</b>	<b>729</b>	<b>23,080</b>	<b>1,013</b>	<b>36,735</b>	<b>1,428</b>	<b>50,131</b>	<b>1,553</b>	<b>57,224</b>	<b>1,553</b>	<b>58,099</b>



5/28/76

**Increases for Implementing  
Medical Device Legislation \***  
1977

	1977 Increases		Supplemental		1978 Increases		1979 Increases		1980 Increases		1981 Increases	
	Pos.	\$000	Pos.	\$000	Pos.	\$000	Pos.	\$000	Pos.	\$000	Pos.	\$000
Classification	4	202	10	1,502	-25	-750	--	--	--	--	--	--
Pre Market Approval	4	134	80	2,260	110	3,503	15	1,071	--	105	--	--
Regulation	5	98	10	259	--	70	--	--	--	--	--	--
Registration	--	--	15	542	10	340	--	70	--	--	--	--
Records and Reports	--	--	10	507	5	188	3	153	5	153	--	35
Standards	9	571	10	554	30	2,503	35	1,533	25	1,332	--	175
Regulatory Operations	3	30	51	1,621	--	357	70	1,645	20	960	--	140
Research and Testing	--	181	15	849	20	1,797	20	1,299	20	1,110	--	140
Surveillance/Spc. Invest.	--	--	11	425	--	77	18	235	5	188	--	35
Inspections	5	98	200	4,997	140	3,370	260	7,390	50	3,245	--	350
<b>TOTAL Program</b>	<b>30</b>	<b>1,342</b>	<b>412</b>	<b>13,516</b>	<b>290</b>	<b>13,655</b>	<b>415</b>	<b>13,306</b>	<b>125</b>	<b>7,093</b>	<b>--</b>	<b>875</b>

\* 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 as safe and effective as it could or should be.



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.

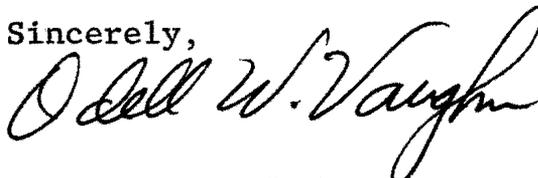
The Veterans Administration, in the administration of far-flung medical activities, is, of course, vitally interested in the protection of public health and safety. We applaud the purposes of this legislation and are particularly concerned with the need to protect the consumer of medical services from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



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,"

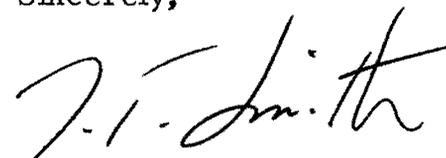
to be cited as the "Medical Device Amendments of 1976."

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,

  
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,



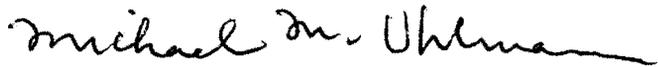
Drug and Cosmetic Act would be applicable, see 21 U.S.C. 331, 333.

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  
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,

A handwritten signature in cursive script, reading "Martin R. Hoffmann", is written over the typed name.

Martin R. Hoffmann  
Secretary of the Army



5125176  
9:50a.m.  
91

THE WHITE HOUSE

ACTION MEMORANDUM

WASHINGTON

LOG NO.:

Date: May 25

Time: 930am

FOR ACTION: Robert Hartmann

cc (for information):

FROM THE STAFF SECRETARY

DUE: Date: May 25

Time: 500pm

SUBJECT:

Revised signing statement for 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

This revised version by Spencer Johnson supercedes the signing statement sent to you on May 21. *which is attached*

*5/25 sent copy to Owen for researching gail  
Research copy att + attached.*



*Recd 5/28 11:00 AM  
71*



PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

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

James M. Cannon  
for the President

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.

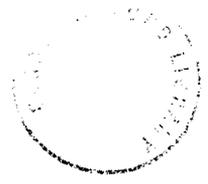
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While we as a nation were able to take justifiable pride in the laws providing for safety, honesty and efficacy in the foods and drugs we consume, it became increasingly clear that there remained a large, significant and growing gap in that security.

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 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.

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



SP

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.



Date: May 25

Time: 9:30am

FOR ACTION: Robert Hartmann

cc (for information):

*to Ryo 5/25 10:25 GAMS to DJB 5/25 2:26 GAMS*

FROM THE STAFF SECRETARY

DUE: Date: May 25

Time: 5:00pm

SUBJECT:

Revised signing statement for S. 510 -  
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ACTION REQUESTED:

For Necessary Action

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Draft Remarks

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THE WHITE HOUSE

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For Your Recommendations

Prepare Agenda and Brief

Draft Reply

For Your Comments

Draft Remarks

REMARKS:

Please return to Judy Johnston, Ground Floor West Wing  
This revised version by Spencer Johnson supercedes the  
signing statement sent to you on May 21.

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

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

---

K. R. COLE, JR.  
For the President



THE WHITE HOUSE

ACTION MEMORANDUM

WASHINGTON

LOG NO.:

Date: May 21

Time: 530pm

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

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

FROM THE STAFF SECRETARY

DUE: Date: May 24

Time: 400pm

SUBJECT:

S. 510-Medical Deviate Amendments of 1976

ACTION REQUESTED:

- |   |   |
|---|---|
| <input type="checkbox"/> For Necessary Action         | <input type="checkbox"/> For Your Recommendations |
| <input type="checkbox"/> Prepare Agenda and Brief     | <input type="checkbox"/> Draft Reply              |
| <input checked="" type="checkbox"/> For Your Comments | <input type="checkbox"/> Draft Remarks            |

REMARKS:

Please return to Judy Johnston, Ground Floor West Wing



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\_\_\_\_\_  
 K. R. COLE, JR.  
 For the President

THE WHITE HOUSE

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

For Your Comments

Draft Remarks

REMARKS:

Please return to Judy Johnston, Ground Floor West Wing

*5/22  
Recommended Approval  
[Signature]*

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

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



THE WHITE HOUSE

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

For Your Comments

Draft Remarks

REMARKS:

Please return to Judy Johnston, Ground Floor West Wing

No objection -- Ken Lazarus 5/24/76

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



John M. Gandy  
Staff Secretary

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

For Your Comments

Draft Remarks

REMARKS:

Please return to Judy Johnston, Ground Floor West Wing

*Concur - ~~h~~*  
*1) See reml 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

THE WHITE HOUSE

WASHINGTON

May 25, 1976

MEMORANDUM FOR: JIM CAVANAUGH  
FROM: MAX L. FRIEDERSDORF *m.l.f.*  
SUBJECT: S. 510 - Medical Device Amendments of 1976

The Office of Legislative Affairs concurs with the agencies that the subject bill be signed.

Attachments



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.