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**Department of
Health, Education, and Welfare
Washington, D.C. 20201**

Ms. Needham

Date: July 28, 1975

The attached may be of interest to you.

Room 5448 North
330 Independence Avenue, S.W.
Telephone: (202) 245-7450

Dale Sopper
~~Frank E. Samuel, Jr.~~
Acting Deputy Assistant Secretary
for Legislation (Health)



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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

file
medical
devices
A.P. 5545

STATEMENT

BY

THEODORE COOPER, M.D.

ASSISTANT SECRETARY FOR HEALTH

BEFORE THE

SUBCOMMITTEE ON PUBLIC HEALTH AND ENVIRONMENT

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES



MONDAY, JULY 28, 1975

Mr. Chairman and Members of the Subcommittee:

We are pleased to appear before you this morning to discuss the need to assure the safety and effectiveness of medical devices and to present our views on H.R. 5545, the Medical Device Amendments of 1975.

The Federal Food, Drug, and Cosmetic Act, enacted in 1938 and subsequently amended, has provided this Department with authority to regulate drugs by requiring manufacturers to establish safety and effectiveness prior to marketing. The Department has lacked comparable authority for regulating medical devices.

As you are aware, the Department supported legislation similar to H.R. 5545 in the 93rd Congress. If amended to meet a number of objections outlined below, the Department would have no objection to the substance of H.R. 5545. If this legislation were to become law, the existing Bureau of Medical Devices and Diagnostic Products within the Food and Drug Administration would be charged with carrying out the responsibilities created by the bill's enactment. The Committee should understand that the Bureau would carry out a strengthened medical devices regulation program within FDA's resources during the current year.

INADEQUACIES OF CURRENT REGULATORY AUTHORITY

The regulatory authority of the Food and Drug Administration (FDA) over medical devices has not been changed since 1938 despite enormous progress in the scientific and technological disciplines related to modern sophisticated products. Since current Federal law imposes no duty upon medical device manufacturers to establish the safety and effectiveness of their products prior to marketing, FDA has experienced considerable difficulty in taking appropriate remedial action against dangerous or misleading devices.

Although FDA does have some authority to regulate medical devices, the Agency does not have clear authority to prescribe performance standards to which devices must conform to assure that they are safe and work properly. For example, there presently exist a number of device standards relating to performance, structural engineering, and materials composition which have been established by various medical and technical organizations. These standards may, if properly applied, help assure device safety and efficacy. FDA has encouraged development of voluntary standards and has also attempted to make full use of its present authority to develop certain requirements, such as those relating to portable oxygen units.

Where a product is found to be defective, and the manufacturer does not recall it, or make labeling corrections or repairs, FDA must resort to legal proceedings which are cumbersome, time consuming, and not always effective in removing products from the market.

Risks from medical devices can, however, also be addressed by a preventive approach including, wherever applicable, the establishment of general controls, such as current good manufacturing practices, and performance standards applicable to product classes in lieu of case-by-case actions. Where general controls and standards are not sufficient to assure safety and effectiveness, the manufacturer, not FDA, should bear the burden of proof concerning safety and effectiveness through applications for product approval prior to marketing.

HAZARDS OF MEDICAL DEVICES

Accurate statistics as to the number of deaths and injuries related to medical devices are not available. We believe, however, that the public is now being exposed to an undesirable level of risk.

1. In 1969, as Director of the National Heart and Lung Institute, I headed a study group established by the Department on the safety and efficacy of medical devices. As part of the study, we searched the scientific literature for accounts of injuries associated with medical devices. This study uncovered 10,000 injuries of which 731 had resulted in death.
2. An FDA death certificate search of ten States covering ten years (1962 to 1972) disclosed 858 deaths directly related to medical devices.

3. The Commission on Professional and Hospital Activities, an independent health group, projected an estimated 36,000 complications from medical devices in the year 1970.

4. The laboratory of the Downstate Medical Center, in Brooklyn, which established its own review laboratory for medical devices for use in that hospital, reported that fully 40 percent of the devices tested were defective after two years of testing.

5. Recent problems, ranging from tragic deaths to fraudulent marketing, have occurred with a number of different types of devices.

All of the following kinds of devices, which represent different levels of potential harm to the consumer, should be subject to careful regulation:

-- Devices which are used in life-threatening situations and which are ineffective or fail in use--for example, heart valves, cardiac pacemakers, vascular implants. We are aware that about 23,000 individual pacemakers have been involved in recalls since 1972. FDA is now involved in the "recalls" of about 256 pacemakers and 54 myocardial leads for use with pacemakers. Two children had died from problems associated with the leads.

-- Devices that are hazardous to patients and/or medical personnel due to defects in design or manufacture. For example, there have been cases of faulty monitoring devices in intensive-care units that have caused fatal electric

shock, and cases of defective anesthesia machines that caused explosions in operating rooms. Also in this category are EKG machines that give faulty readings and result in serious misdiagnosis.

- Devices in which the traditional risk-benefit assessment cannot now be made prior to marketing--and in which the risks outweigh the benefits--for example, certain IUD's. FDA has learned of 43 deaths and 315 septic abortions associated with IUD's. While these devices have been shown to be a relatively safe and reliable form of contraception, comparing favorably with oral contraceptives, the injury data clearly indicates the need to evaluate the potential hazards of all IUD's.
- Devices that are useless and can cause delay in diagnosis, and treatment of serious conditions, such as the old "quack" colored lights devices.
- Devices that are probably harmless but are useless and therefore economic frauds, such as "hot pants" for weight reduction.

STATUS OF PRESENT PROGRAM

As I mentioned, in 1969 this Department convened a study group to devise the most appropriate means of assuring the safety and reliability of medical devices. The Cooper Committee, as it became known, reported its findings in 1970 and its recommendations were the basis for the Department's bill to regulate medical devices and also for later versions developed by Congress. The report called for the classification of devices into three regulatory categories: (1) those devices subject

only to general regulatory controls; (2) those for which standards should be set and enforced to assure safety and effectiveness; and (3) those requiring premarket review.

The Committee also recommended ancillary provisions to fill existing gaps in the law. These provisions included:

- mandatory registration for establishments manufacturing devices;
- specific Federal authority to assure the use of good manufacturing practices;
- increased Federal inspection authority;
- a requirement that device manufacturers maintain records and make reports on clinical experience with devices; and
- procedures to require manufacturers or distributors of devices violative of Federal standards to repair or replace the devices or refund their purchase price.

These features are all part of H.R. 5545.

In response to the Committee Report, the Secretary asked the FDA to develop a system for the classification of medical devices into regulatory categories consistent with the proposed legislative plan and to undertake an inventory of these devices. This was to enable a smooth and orderly transition from regulatory controls appropriate to the 1930's to those consistent with the demands of the 1970's.

CLASSIFICATION OF DEVICES

Since the recommendations of the Cooper Committee, the FDA has completed an inventory of devices. The classification process was begun with the division of the inventory of devices into 14 separate categories generally based on medical specialties in the following areas: orthopedics; cardiovascular; dental; anesthesiology; obstetrical and gynecological; gastroenterology and urology; radiology; neurology; ear, nose, and throat; opthalmic; general and plastic surgery; physical medicine; diagnostic products; and general hospital and personal use. Considerable progress has been made in reviewing the devices in each of these 14 categories and, through the use of panels of experts, classifying them into one or more of the three regulatory control classes previously mentioned. It should be noted that in addition to its expert members, each classification panel has nonvoting representatives for both consumer interests and industry interests. These procedures were formalized by notice in the Federal Register of May 19, 1975 (40 FR 21848).

The first four panels to review and classify devices within their respective medical specialty areas have already completed a large measure of their work and are providing FDA with additional scientific support and direction. To date, over 3,000 devices have been classified by panels into the three basic regulatory control categories identified by the Cooper Committee.

OUTLINE OF PANELS' OPERATING PROCEDURES

It may be useful to describe the operations of the medical device review panels. These panels have three basic functions:

1. Most importantly, to classify the devices into proposed regulatory categories;
2. To identify the need for specific devices standards; and
3. To identify problems with specific devices.

Under the pending legislation, these panels would also assume the important task of reviewing applications for premarket approval.

Once a panel has classified all the devices in its specialty area, it considers specific device hazards and the requisite performance and safety standards which some devices require. For specific complex technical areas, the panels have sought advice from standard-setting professional, medical, and scientific organizations such as the Association for the Advancement of Medical Instrumentation (AAMI), in the development of pacemaker performance and electromagnetic compatibility standards and the American Society for Testing and Materials (ASTM) in the development of standards for surgeons' gloves and orthopedic implants. The International Organization for Standardization (IOS) and the International Electrotechnical Commission (IEC) have also been consulted.



VIEWS ON MEDICAL DEVICE LEGISLATION

As I have indicated, the Department has no objection to the substance of H.R. 5545, to provide a comprehensive new system to help protect the public from unsafe or ineffective medical devices. H.R. 5545 would provide for premarket approval of certain devices, and promulgation of such standards as are necessary to assure safe and effective performance.

The bill would also improve our authority concerning good manufacturing practice regulations, records inspection, registration of device manufacturers, maintenance of records and submission of reports, and remedial action concerning hazardously defective devices.

The fundamental principles of H.R. 5545 are similar to S. 510, a bill which was passed by the Senate earlier this year and which the Department did not object to in substance. We opposed the overly specific provision of S. 510 relating to clinical investigational phase of medical device development since that language would freeze into statutory form present Department policy. This may prevent necessary administrative updating to keep pace with biomedical technology, which may soon need to be done after the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research presents its findings. H.R. 5545, contains preferable language which would give the FDA broad authority to issue regulations to assure adequate protection of human subjects of device testing without restricting the requirements to what may today be considered necessary and appropriate.

We also opposed the premarket approval provisions of S. 510 as overly broad and ambiguous. We proposed alternative language which tightened up this category both by assigning to this category devices whose uses are of substantial importance and by explaining that general controls or standards are preferred to premarket approval. H.R. 5545 is similar to that proposed by the Department, but we still prefer the Department's proposed provisions. We are attaching a copy of our April 17 letter to Senator Scott in which this provision was proposed. This language will assure that devices that need premarket approval will get it, but without requiring approval of trivial products which pose no risk to the consumer.

Another way in which H.R. 5545 is an improvement over S. 510 is in the breadth of the recordkeeping and reporting authority provided in section 519. This authority will enable us to require submission of data relevant to classification, adulteration, or misbranding for all devices. It is similar to the authority in the Department's proposed Food Drug and Cosmetic Amendments of 1975 (H.R. 12847) in the last Congress. We do, however, believe that the records and reports provision in H.R. 5545 could be improved, as I will discuss in a few minutes.

We are also pleased that H.R. 5545 includes authority to temporarily detain devices suspected of violating the law. This was proposed in the Department bill (H.R. 12847) in the last Congress.

We believe that the Subcommittee has developed a clear and workable proposal which reflects the Cooper Committee report and synthesizes the views of medical practitioners, research scientists, engineers, consumer groups, industry, and Federal agencies.

We are confident that the Agency's efforts thus far to classify devices and establish standards have been wholly consistent with the bill, and we hope the legislative history reflects this. We believe it should be clearly understood that the FDA can build upon what has been done already and can develop and use flexible procedures consistent with Congressional intent.

Several features of H.R. 5545 cause us concern or could be improved or clarified.

1. The procedure for establishing a standard includes two initial steps that FDA believes can be collapsed into one. The bill should combine the notice for submission of comments concerning the establishment of a standard (proposed section 514(b)) with the notice inviting submission of offers concerning the proposed standards (proposed section 514(c)).

2. H.R. 5545 provides for an opportunity for review of a device standard by an independent advisory committee which shall not be a panel established for purposes of recommendations on classification and premarket approval. We believe this provision can be changed in a way that will allow FDA to make efficient use of its advisory committees while assuring that standards are not reviewed by individuals who may have prejudged an issue. We believe it is enough that the bill prohibit inclusion on an independent advisory committee of those individuals who have served on a classification panel which had considered the particular standard under review.

3. The FDA has experienced great delays in removing unsafe and ineffective drugs from the market. One problem with the current drug law is the requirement of opportunity for a formal, evidentiary hearing, as prescribed in 5 U.S.C. 554. H.R. 5545 would require the FDA to provide opportunity for this same type of formal hearing when the agency approves, denies, or withdraws approval of a device application or takes comparable action regarding a product development protocol. We believe that an informal hearing, as defined in the bill, will assure fairness to interested persons without hindering Agency activities.

4. We have related concerns about the banned device provisions of section 516. Based on our experience with drug removals, we would urge that all banning orders take effect upon publication and pending any further administrative proceedings, including any decision as to whether a hearing is to be held.

5. It is important that device manufacturers, importers, and distributors notify the Agency of all defects in medical devices. This has been a particular problem in our experience with pacemakers, where companies have not told the Agency that they have found defects in their products or that they have undertaken recalls. Under S. 510, there would be specific defect notification authority as a part of the "3-R" remedies--repair, replacement, or refund. However, this notification authority would be limited to product-related defects presenting a substantial risk to the public safety. Under H.R. 5545, there would be no specific defect reporting provision, but the general reporting provision of section 519 authorizes regulations requiring defect reporting in all appropriate cases. We favor the provisions of section 519 of H.R. 5545 which would authorize us to require defect notification in instances in which industry may not regard a degree of risk as "substantial," or where it is unclear whether the risk is due to the product itself or the lack of skill of users. However, we believe the Committee should make it clear that the deletion of the specific defect reporting provision is not meant to imply that FDA lacks authority to require device manufacturers, importers, and distributors to report device defects.

6. The records and reports provisions could be improved by deletion of the provision in proposed section 519(a)(1) 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 in view of current and proposed requirements that Federal agencies take into account the economic impact of their requirements. These provisions would merely lead to unproductive argument and possible litigation between FDA and industry as to what is burdensome but would not add any real safeguards to assure that burdensome requirements are not imposed. Also, the section 519(a)(5) restrictions upon reporting authority 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 need.

It should be noted that if FDA does not have adequate authority to obtain information on class I (general controls) devices, there will be an incentive to place these devices in class II (standards) or class III (premarket approval).

7. Researchers and teachers who directly import devices for their own use should be subject to recordkeeping and reporting requirements, which would require a change in proposed section 519(b)(2).

8. There is a need to allow marketing of custom devices which necessarily deviate from requirements which would otherwise be applicable to the device under the standard-setting or premarket approval provisions of the bill. However, it is essential that the custom device provisions not serve as a loophole that will allow the marketing of dangerous or deceptive products. The custom device provision of H.R. 5545 (section 520(b)) would not, as we read the bill, exempt any device from otherwise applicable regulations for investigational devices or banned 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 as a course of conduct on a number of 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 that many of the devices used by certain practitioners, for example, dentists, involve a certain degree of custom design for each patient, as a course of conduct, and this is not objectionable. Thus, a provision limiting use of custom devices as a course of conduct must be carefully drafted to prevent abuses, but not to prevent use of custom products where justified by medical need.

9. We understand the prescription device provisions of new section 520(e), and related provisions in sections 514 and 515, would authorize restrictions to assure effectiveness as well as safety. However, this understanding is based upon our knowledge of similar terms used in drug law and may be easily misunderstood by those who are not familiar with the history of those terms. To prevent misunderstanding, these provisions should be clarified, but it should be made clear that the Committee does not intend to imply any limitations on our authority concerning restrictions on use or distribution of drugs.

10. We believe it is unnecessary to require establishment of a separate advisory committee to advise FDA concerning good manufacturing practice regulations. Our 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. We also regard as unnecessary an explicit system for petitions for exemption or variance from good manufacturing practice regulations.

CONCLUSION

In summary, Mr. Chairman, we recognize the need for medical device legislation. Within the budget restrictions and current resource limitations which I alluded to earlier, this Department has no objections to the substance of H.R. 5545, with the changes outlined above.

Mr. Chairman and Members of the Subcommittee, this concludes my statement. My colleagues and I will be pleased to answer any questions you may have.



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

17 APR 1975

Honorable Hugh Scott
Minority Leader
United States Senate
Washington, D. C. 20510

Dear Hugh:

There is before the Senate, as reported by the Committee on Labor and Public Welfare, S. 510, the "Medical Device Amendments of 1975."

The reported bill is identical with S. 2368, which was passed by the Senate during the 93rd Congress, providing the Food and Drug Administration (FDA) with a number of new authorities relating to medical devices. S. 510 would enable the establishment of mandatory standards, require premarket scientific review in certain cases, and control investigational devices. It would also require manufacturers to register, maintain records, make reports, notify FDA of defective products, and comply with good manufacturing practice regulations.

We have certain objections to the reported bill, as discussed below.

One of the principal issues of medical device legislation concerns what types of devices should be subject to scientific review.

S. 510 provides that devices that are life-sustaining or life-supporting must be classified as requiring premarket scientific review even if standards or an exemption would be adequate. We believe this provision is too broad and that the following alternative language would be preferable to the first sentence of proposed section 514(a)(1) of the Act.

SEC. 514. (a)(1) The Secretary may declare that a device (or type or class of device) for which scientific review has been determined to be appropriate pursuant to section 511(d) shall be subject to scientific review under this section with respect to any particular use or intended use thereof, if, after consultation with the appropriate panel or panels specified in subsection (b), and finds that (A) insufficient information exists (i) to assure effectiveness or (ii) to assure that exposure to such devices will not cause unreasonable risk of illness or injury and (B) scientific review may assure effectiveness or may reduce or eliminate such unreasonable risk and (C) no more practicable means to assure effectiveness or to reduce or eliminate the unreasonable risk are appropriate and (D) the device purports or is represented to be for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health.***

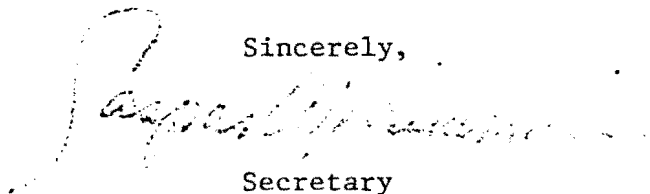
Conforming amendments would be needed in proposed section 511 of the Act regarding criteria for classification of medical devices, including deletion of the last sentence in proposed section 511(c)(1)(B).

The Department also opposes the provision in the bill concerning protection of human subjects in device legislation. The excessive specificity of this language would freeze into law the current requirements of Department policy, and thereby interfere with its further administrative updating to keep pace with developments in biomedical technology.

As you are aware, the Department supported legislation similar to S. 510 in the 93rd Congress. If amended to meet the objections outlined above, the Department would have no objections to the substance of S. 510. If S. 510 were to become law, FDA's existing Bureau of Medical Devices and Diagnostic Products would be charged with carrying out the responsibilities created by the bill's enactment. The Senate should understand that, because of budget restrictions, the Bureau would begin to implement a strengthened medical devices regulation program within FDA's current resources. No additional sums would be necessary in the current year. In future years funds for this program will continue to be provided by adjustments in existing programs rather than by any increase in the FDA's budget.

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,

A handwritten signature in dark ink, appearing to read "J. Edgar Hoover", is written over the typed name "Secretary".

Secretary



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The fundamental principles of H.R. 5545 are similar to S. 510, a bill which was passed by the Senate earlier this year and which the Department did not object to in substance. We opposed the overly specific provision of S. 510 relating to clinical investigational phase of medical device development since that language would freeze into statutory form present Department policy. This may prevent necessary administrative updating to keep pace with biomedical technology, which may soon need to be done after the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research presents its findings. H.R. 5545, contains preferable language which would give the FDA broad authority to issue regulations to assure adequate protection of human subjects of device testing without restricting the requirements to what may today be considered necessary and appropriate.

We also opposed the premarket approval provisions of S. 510 as overly broad and ambiguous. We proposed alternative language which tightened up this category both by assigning to this category devices whose uses are of substantial importance and by explaining that general controls or standards are preferred to premarket approval. H.R. 5545 is similar to that proposed by the Department, but we still prefer the Department's proposed provisions. We are attaching a copy of our April 17 letter to Senator Scott in which this provision was proposed. This language will assure that devices that need premarket approval will get it, but without requiring approval of trivial products which pose no risk to the consumer.

Another way in which H.R. 5545 is an improvement over S. 510 is in the breadth of the recordkeeping and reporting authority provided in section 519. This authority will enable us to require submission of data relevant to classification, adulteration, or misbranding for all devices. It is similar to the authority in the Department's proposed Food Drug and Cosmetic Amendments of 1975 (H.R. 12847) in the last Congress. We do, however, believe that the records and reports provision in H.R. 5545 could be improved, as I will discuss in a few minutes.

We are also pleased that H.R. 5545 includes authority to temporarily detain devices suspected of violating the law. This was proposed in the Department bill (H.R. 12847) in the last Congress.

We believe that the Subcommittee has developed a clear and workable proposal which reflects the Cooper Committee report and synthesizes the views of medical practitioners, research scientists, engineers, consumer groups, industry, and Federal agencies.

We are confident that the Agency's efforts thus far to classify devices and establish standards have been wholly consistent with the bill, and we hope the legislative history reflects this. We believe it should be clearly understood that the FDA can build upon what has been done already and can develop and use flexible procedures consistent with Congressional intent.

Several features of H.R. 5545 cause us concern or could be improved or clarified.

1. The procedure for establishing a standard includes two initial steps that FDA believes can be collapsed into one. The bill should combine the notice for submission of comments concerning the establishment of a standard (proposed section 514(b)) with the notice inviting submission of offers concerning the proposed standards (proposed section 514(c)).

2. H.R. 5545 provides for an opportunity for review of a device standard by an independent advisory committee which shall not be a panel established for purposes of recommendations on classification and premarket approval. We believe this provision can be changed in a way that will allow FDA to make efficient use of its advisory committees while assuring that standards are not reviewed by individuals who may have prejudged an issue. We believe it is enough that the bill prohibit inclusion on an independent advisory committee of those individuals who have served on a classification panel which had considered the particular standard under review.

3. The FDA has experienced great delays in removing unsafe and ineffective drugs from the market. One problem with the current drug law is the requirement of opportunity for a formal, evidentiary hearing, as prescribed in 5 U.S.C. 554. H.R. 5545 would require the FDA to provide opportunity for this same type of formal hearing when the agency approves, denies, or withdraws approval of a device application or takes comparable action regarding a product development protocol. We believe that an informal hearing, as defined in the bill, will assure fairness to interested persons without hindering Agency activities.

4. We have related concerns about the banned device provisions of section 516. Based on our experience with drug removals, we would urge that all banning orders take effect upon publication and pending any further administrative proceedings, including any decision as to whether a hearing is to be held.

5. It is important that device manufacturers, importers, and distributors notify the Agency of all defects in medical devices. This has been a particular problem in our experience with pacemakers, where companies have not told the Agency that they have found defects in their products or that they have undertaken recalls. Under S. 510, there would be specific defect notification authority as a part of the "3-R" remedies--repair, replacement, or refund. However, this notification authority would be limited to product-related defects presenting a substantial risk to the public safety. Under H.R. 5545, there would be no specific defect reporting provision, but the general reporting provision of section 519 authorizes regulations requiring defect reporting in all appropriate cases. We favor the provisions of section 519 of H.R. 5545 which would authorize us to require defect notification in instances in which industry may not regard a degree of risk as "substantial," or where it is unclear whether the risk is due to the product itself or the lack of skill of users. However, we believe the Committee should make it clear that the deletion of the specific defect reporting provision is not meant to imply that FDA lacks authority to require device manufacturers, importers, and distributors to report device defects.

6. The records and reports provisions could be improved by deletion of the provision in proposed section 519(a)(1) 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 in view of current and proposed requirements that Federal agencies take into account the economic impact of their requirements. These provisions would merely lead to unproductive argument and possible litigation between FDA and industry as to what is burdensome but would not add any real safeguards to assure that burdensome requirements are not imposed. Also, the section 519(a)(5) restrictions upon reporting authority 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 need.

It should be noted that if FDA does not have adequate authority to obtain information on class I (general controls) devices, there will be an incentive to place these devices in class II (standards) or class III (premarket approval).

7. Researchers and teachers who directly import devices for their own use should be subject to recordkeeping and reporting requirements, which would require a change in proposed section 519(b)(2).

8. There is a need to allow marketing of custom devices which necessarily deviate from requirements which would otherwise be applicable to the device under the standard-setting or premarket approval provisions of the bill. However, it is essential that the custom device provisions not serve as a loophole that will allow the marketing of dangerous or deceptive products. The custom device provision of H.R. 5545 (section 520(b)) would not, as we read the bill, exempt any device from otherwise applicable regulations for investigational devices or banned 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 as a course of conduct on a number of 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 that many of the devices used by certain practitioners, for example, dentists, involve a certain degree of custom design for each patient, as a course of conduct, and this is not objectionable. Thus, a provision limiting use of custom devices as a course of conduct must be carefully drafted to prevent abuses, but not to prevent use of custom products where justified by medical need.

9. We understand the prescription device provisions of new section 520(e), and related provisions in sections 514 and 515, would authorize restrictions to assure effectiveness as well as safety. However, this understanding is based upon our knowledge of similar terms used in drug law and may be easily misunderstood by those who are not familiar with the history of those terms. To prevent misunderstanding, these provisions should be clarified, but it should be made clear that the Committee does not intend to imply any limitations on our authority concerning restrictions on use or distribution of drugs.

10. We believe it is unnecessary to require establishment of a separate advisory committee to advise FDA concerning good manufacturing practice regulations. Our 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. We also regard as unnecessary an explicit system for petitions for exemption or variance from good manufacturing practice regulations.

CONCLUSION

In summary, Mr. Chairman, we recognize the need for medical device legislation. Within the budget restrictions and current resource limitations which I alluded to earlier, this Department has no objections to the substance of H.R. 5545, with the changes outlined above.

Mr. Chairman and Members of the Subcommittee, this concludes my statement. My colleagues and I will be pleased to answer any questions you may have.



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

17 APR 1975

Honorable Hugh Scott
Minority Leader
United States Senate
Washington, D. C. 20510

Dear Hugh:

There is before the Senate, as reported by the Committee on Labor and Public Welfare, S. 510, the "Medical Device Amendments of 1975."

The reported bill is identical with S. 2368, which was passed by the Senate during the 93rd Congress, providing the Food and Drug Administration (FDA) with a number of new authorities relating to medical devices. S. 510 would enable the establishment of mandatory standards, require premarket scientific review in certain cases, and control investigational devices. It would also require manufacturers to register, maintain records, make reports, notify FDA of defective products, and comply with good manufacturing practice regulations.

We have certain objections to the reported bill, as discussed below.

One of the principal issues of medical device legislation concerns what types of devices should be subject to scientific review.

S. 510 provides that devices that are life-sustaining or life-supporting must be classified as requiring premarket scientific review even if standards or an exemption would be adequate. We believe this provision is too broad and that the following alternative language would be preferable to the first sentence of proposed section 514(a)(1) of the Act.

SEC. 514. (a)(1) The Secretary may declare that a device (or type or class of device) for which scientific review has been determined to be appropriate pursuant to section 511(d) shall be subject to scientific review under this section with respect to any particular use or intended use thereof, if, after consultation with the appropriate panel or panels specified in subsection (b), and finds that (A) insufficient information exists (i) to assure effectiveness or (ii) to assure that exposure to such devices will not cause unreasonable risk of illness or injury and (B) scientific review may assure effectiveness or may reduce or eliminate such unreasonable risk and (C) no more practicable means to assure effectiveness or to reduce or eliminate the unreasonable risk are appropriate and (D) the device purports or is represented to be for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health.***

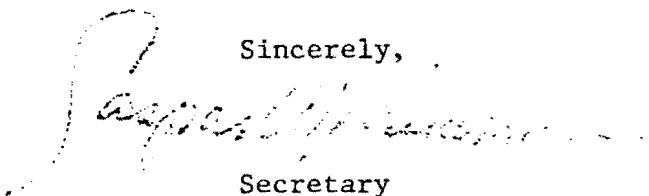
Conforming amendments would be needed in proposed section 511 of the Act regarding criteria for classification of medical devices, including deletion of the last sentence in proposed section 511(c)(1)(B).

The Department also opposes the provision in the bill concerning protection of human subjects in device legislation. The excessive specificity of this language would freeze into law the current requirements of Department policy, and thereby interfere with its further administrative updating to keep pace with developments in biomedical technology.

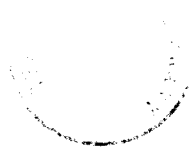
As you are aware, the Department supported legislation similar to S. 510 in the 93rd Congress. If amended to meet the objections outlined above, the Department would have no objections to the substance of S. 510. If S. 510 were to become law, FDA's existing Bureau of Medical Devices and Diagnostic Products would be charged with carrying out the responsibilities created by the bill's enactment. The Senate should understand that, because of budget restrictions, the Bureau would begin to implement a strengthened medical devices regulation program within FDA's current resources. No additional sums would be necessary in the current year. In future years funds for this program will continue to be provided by adjustments in existing programs rather than by any increase in the FDA's budget.

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,



Secretary



file

THE WHITE HOUSE
WASHINGTON

April 4, 1975

MEMO TO : PAM NEEDHAM
FROM : JIM CANNON *[Signature]*
SUBJECT : *Medical Device
Legislation

The attached is forwarded
for

 X Your handling

 FYI

 Other

Attachment *Memo from Secretary
Weinberger

THE WHITE HOUSE
WASHINGTON

4-4-75

TO: Warren Gendricks

For Your Information _____

For Appropriate Handling ✓

RDZ
Robert D. Linder



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

MEMORANDUM FOR THE PRESIDENT

April 3, 1975

FROM : CASPAR W. WEINBERGER

SUBJECT: Medical Device Legislation

OMB has advised us of your decision not to re-propose to the Congress legislation which the Administration previously sponsored if such legislation would cost additional resources not specifically included in your 1976 budget, even though it may be mentioned in the budget. One legislative proposal which is in this category and which I wish to bring to your attention involves authority to regulate medical devices. The circumstances surrounding this piece of legislation are such that you may wish us to support it even though it may be viewed by some as an exception to your general rule. Actually, I do not believe it requires an exception to that rule; it can and should be a no-cost proposal this year, and therefore need not be "caught in the net" of that rule.

The legislation would provide the Food and Drug Administration with needed authority to establish mandatory standards for medical devices, require premarket scientific review in certain cases, and control investigational devices. We have sought sensible legislation in this field in order to preclude such problems as defective pacemakers, implanted heart valves, kidney dialysis machines, and potentially dangerous intrauterine devices. Because of the critical nature of these devices even a very small error rate results in significant human tragedy, and so this new legislation is clearly in the "humanitarian" category.

The problem in not supporting medical device legislation this year is greater than just the fact that the Administration has supported this legislation in the past two Congresses. Prior to your decision the Food and Drug Commissioner, in testimony this year before the Congress, has used our medical device legislation and its prospective transmission to the Congress as a basis for heading off other undesirable legislation. He offered such testimony in good faith, believing that legislation would soon be transmitted based on our past support. It is reasonably clear that the Congress will pass some legislation on medical devices this session no matter what we say. But failure of the Administration to take a positive position on this legislation would place the Department in an awkward position at best.

Because I both understand and agree with your strong position to hold down Federal expenditures, I think we cannot proceed with this proposal in a "business as usual" fashion. We could, however, take the position that we favor enactment of this legislation this year with the understanding that implementation in FY 1976 would be conducted within resources already budgeted for the Food and Drug Administration. Given the circumstances in this case, I would prefer to proceed in this fashion if you agree.

I have attached at Tab A a copy of my draft letter to Senator Scott on the pending medical devices bill. The letter favors enactment this year but indicates an intention to implement within available resources in 1976. The letter to Senator Scott does state, correctly, that additional resources will be required in Fiscal 1977.

Recommendation

I recommend that you endorse our support of a medical devices bill but at no additional FY 1976 cost.

Decision

Support medical devices bill but
at no additional FY 1976 cost

Do not support medical devices bill

Attachment

Tab A

Honorable Hugh Scott
Minority Leader
United States Senate
Washington, D. C. 20510

Dear Hugh:

There is before the Senate, as reported by the Committee on Labor and Public Welfare, S. 510, the "Medical Device Amendments of 1975."

The reported bill is identical with S. 2368, which was passed by the Senate during the 93rd Congress, providing the Food and Drug Administration (FDA) with a number of new authorities relating to medical devices. S. 510 would enable the establishment of mandatory standards, require premarket scientific review in certain cases, and control investigational devices. It would also require manufacturers to register, maintain records, make reports, notify FDA of defective products, and comply with good manufacturing practice regulations.

We have certain objections to the reported bill, as discussed below.

One of the principal issues of medical device legislation concerns what types of devices should be subject to scientific review.

S. 510 provides that devices that are life-sustaining or life-supporting must be classified as requiring premarket scientific review even if standards or an exemption would be adequate. We believe this provision is too broad and that the following alternative language would be preferable to the first sentence of proposed section 514(a)(1) of the Act.

SEC. 514. (a)(1) The Secretary may declare that a device (or type or class of device) for which scientific review has been determined to be appropriate pursuant to section 511(d) shall be subject to scientific review under this section with respect to any particular use or intended use thereof, if, after consultation with the appropriate panel or panels specified in subsection (b), he finds that (A) insufficient information exists (i) to assure effectiveness or (ii) to assure that exposure to such devices will not cause unreasonable risk of illness or injury and (B) scientific review may assure effectiveness or may reduce or eliminate such unreasonable risk and (C) no more practicable means to assure effectiveness or to reduce or eliminate the unreasonable risk are appropriate and (D) the device purports or is represented to be for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health.***

Conforming amendments would be needed in proposed section 511 of the Act regarding criteria for classification of medical devices, including

deletion of the last sentence in proposed section 511(c)(1)(B).

The Department also opposes the provision in the bill concerning protection of human subjects in device investigations. The excessive specificity of this language would freeze into law the current requirements of Department policy, and thereby interfere with its further administrative updating to keep pace with developments in biomedical technology.

As you are aware, the Department supported legislation similar to S. 510 in the 93rd Congress. If amended to meet the objections outlined above, the Department also supports enactment of S. 510. FDA's existing Bureau of Medical Devices and Diagnostic Products would be charged with carrying out the responsibilities created by the bill's enactment. Because of the President's decision not to initiate new spending programs this year, the Bureau would begin to implement a strengthened medical devices regulation program within FDA's current resources. Additional resources necessary to implement enacted legislation would be requested in the President's Budget for FY 1977.

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,

Secretary

recd. 4/16/75

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Minority Leader
United States Senate
Washington, D. C. 20510

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*This version cleared by
Fischer + O'Neil -
transmitted to Thirsk
4/16/75 9:00 A.M.
on machine.*

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next
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outlined above, the Department ~~also supports enactment of S. 510.~~

Am. I would call your attention to the President's
~~FDA's existing Bureau of Medical Devices and Diagnostic Products would~~

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~~be charged with carrying out the responsibilities created by the~~

year which would require increased Federal spending
~~bill's enactment. Because of the President's decision not to initiate~~

over the amount to be included in his budget. Specifically
~~new spending programs this year, the Bureau would begin to implement~~

the President said in his State of the Union address 55%
~~a strengthened medical devices regulation program within FDA's~~

"no new spending programs can be
~~current resources. Additional resources necessary to implement~~

initiated this year, except for emergency."
~~enacted legislation would be requested in the President's Budget~~

I have also concluded that
~~for FY 1977.~~

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,

Secretary

Don Hirsch
HEW
Rm. 5109
245-7760

INSERT A

As you are aware, the Department supported legislation similar to S. 510 in the 93rd Congress. If amended to meet the objections outlined above, the Department would have no objection to the substance of S. 510. However, I must call your attention to the President's policy urging that no new programs be enacted this year which would require increased Federal spending over the amounts recommended in his budget. Specifically, the President said in his State of the Union address:

"I have [also] concluded that no new spending programs can be initiated this year, except those for energy."



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

MEMORANDUM FOR THE PRESIDENT

April 3, 1975

FROM : CASPAR W. WEINBERGER *CW Weinberger*
SUBJECT: Medical Device Legislation

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at no additional FY 1976 cost

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Attachment



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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,

Secretary



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

APR 10 1975

MEMORANDUM FOR THE PRESIDENT

FROM : Caspar W. Weinberger

SUBJECT: Medical Device Legislation

RL
You may have noted in the newspapers of April 8, 1975 (attachment), the articles referring to those heart pacemaker deficiencies which resulted in the death of 8 patients. It is possible that another 18 deaths will be attributed to deficiencies in these devices.

Heart pacemakers are devices which electrically stimulate the heart and cause it to beat at prescribed rates and regularity. Certain forms of heart disease result in failure of the normal mechanism which causes the heart to beat. The implantation of a pacemaker may make the difference between life and death. When properly functioning, the pacemaker application can result in restoration of the patient to a productive life.

In order to prevent the implantation of faulty pacemakers, we need the authority to review the devices before they are sold to physicians. It is this type of problem which has been the basis of my interest in the new medical device legislation. I have called your attention to the legislation in my memorandum to you dated April 3, 1975 (attachment). It occurred to me that this specific example may help clarify my reason for asking you to endorse our support of a medical devices bill at no additional FY 1976 cost.

Balt. Sun

April 8, 1975, p. 7

26 deaths associated with defective pacemakers, U.S. says

Washington (AP)—Defective cardiac pacemakers have been associated with at least 26 deaths of heart patients over the last three years, the secretary of Health, Education and Welfare said yesterday.

Eight of the deaths were attributed to the failure of implanted pacemakers. Secretary Caspar W. Weinberger said, and 18 other deaths gleaned from company files are under investigation.

Secretary Weinberger's 11-page letter was hand-delivered to Senator Abraham Ribicoff (D., Conn.), chairman of the Senate Government Operations Committee, who had asked for administration comment on a recent General Accounting Office report.

Congressional auditors were critical of the Food and Drug Administration's handling of the recall of about 23,000 pacemakers by General Electric, Biotronik, Cordis and Vitatron since 1972.

Until now, the FDA, which regulates medical devices, including pacemakers, has placed the toll at fewer than 10 deaths. An estimated 125,000 Americans have surgically implanted pacemakers to regulate their heart beat.

Secretary Weinberger said all the device failures were due to "improper design, material or component selection, or processing" and not, as Senator Ribicoff charged, to the agency's rejection of a 1969 Navy standard for hermetically sealing electronic components.

"FDA at this time does not believe imposition of a standard simply to require the hermetic sealing of all implanted pacemakers is necessary or wise," his letter said. "Moreover, it could introduce other problems which would adversely affect the present utility of pacemakers."

Secretary Weinberger said it often is difficult to determine whether a pacemaker failure resulted in death or injury. He said pacemaker patients range from infants with congenital defects to elderly persons suffering from arteriosclerosis, "all whose hearts are defective and whose deaths often are not unexpected."

He provided Senator Ribicoff with the following list of pacemaker deaths and injuries:

- General Electric recall of 574 units in early 1972, four

deaths associated with accelerated pulse rate and three others of questionable cause.

- GE recall of 1,241 units between June 1974 and February 1975, two deaths associated with accelerated pacing.

- Biotronik recall of 255 pacemakers in February and October 1974, one death and 27 injuries associated with inflammation and dead tissue allegedly caused by leaking batteries.

- Cordis recall of 4,500 demand-type pacemakers in October 1973 and February 1975, still under investigation with no report on deaths or injuries.

- Cordis recall of 11,050 asynchronous pacemakers in July 1973, one death associated with high pacing. The FDA said it is still investigating 12 deaths "associated with high-pacing-rate pacemakers as determined from an examination of records obtained from the firm."

- Vitatron recall of 556 pacemakers in June and October 1974 and March 1975, four injuries involving high pacing and loss of output.

Secretary Weinberger said the FDA will propose good

manufacturing-practice regulations this year to govern the quality of materials, parts and processing of pacemakers, to reduce defects. In addition, he said the National Bureau of Standards has developed new test and evaluation methods.

Responding to Senator Ribicoff's suggestion that the Navy standard should have been adopted, the secretary said manufacturers have been hermetically sealing semi-conductor devices since the early 1960's. The entire unit cannot be sealed, however, because mercury batteries produce hydrogen gas which must be released, he said.

Wall Street Jour.

April 8, 1975, p. 16

Defective Pacemakers Involved in 26 Deaths, HEW Secretary Says

WASHINGTON (AP)—Defective cardiac pacemakers have been associated with at least 26 deaths of heart patients in the past three years, the Secretary of Health, Education and Welfare said.

Eight of the deaths were directly attributed to implanted pacemaker failures, Secretary Caspar Weinberger said, and 18 other deaths are under investigation.

Mr. Weinberger's 11-page letter was hand delivered to Sen. Abraham Ribicoff (D., Conn.), chairman of the Senate Government Operations Committee, who asked for administration comment on a recent General Accounting Office report.

Congressional auditors were critical of the Food and Drug Administration's handling of the recall of about 23,000 pacemakers by General Electric Co., Cordis Corp., Miami, Fla.; Biotronik Corp., West Germany, and Vitatron Medical Inc., the Netherlands.

Until now, the FDA, which regulates medical devices, including pacemakers, has placed the toll at fewer than 10 deaths. An estimated 125,000 Americans have surgically implanted pacemakers to regulate their heart beat.

Mr. Weinberger said all the device failures were due to "improper" design, material or part selection, or processing, rather than, as Sen. Ribicoff has charged, to the agency's rejection of a 1969 Navy standard for hermetically sealing electronic parts.

"FDA at this time doesn't believe imposition of a standard simply to require the hermetic sealing of all implanted pacemakers is necessary or wise," Mr. Weinberger's letter said. "Moreover, it could introduce other problems which would adversely affect the present utility of pacemakers."

Mr. Weinberger said it often is difficult to determine whether a pacemaker failure resulted in death or injury. He said pacemaker patients range from infants with congenital defects to elderly persons suffering from arteriosclerosis, "all whose hearts are defective and whose deaths often aren't unexpected."

Mr. Weinberger said the FDA will propose good-manufacturing-practice regulations this year to govern the quality of materials, parts and processing of pacemakers. In addition, he said that the National Bureau of Standards has developed new test and evaluation methods.

Responding to Sen. Ribicoff's suggestion that the Navy standard should have been adopted, the Secretary said manufacturers have been hermetically sealing semiconductor devices since the early 1960s. The entire unit can't be sealed, however, because mercury batteries produce hydrogen gas that must be released, he said.

Wall Street Jour.

April 8, 1975, p. 1

Defective cardiac pacemakers have directly contributed to eight deaths of heart patients in the past three years and 18 other deaths are under investigation, Health, Education and Welfare Secretary Weinberger told a congressional committee looking into the matter.



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

April 3, 1975

MEMORANDUM FOR THE PRESIDENT

FROM : CASPAR W. WEINBERGER *5/10/75*

SUBJECT: Medical Device Legislation

OMB has advised us of your decision not to re-propose to the Congress legislation which the Administration previously sponsored if such legislation would cost additional resources not specifically included in your 1976 budget, even though it may be mentioned in the budget. One legislative proposal which is in this category and which I wish to bring to your attention involves authority to regulate medical devices. The circumstances surrounding this piece of legislation are such that you may wish us to support it even though it may be viewed by some as an exception to your general rule. Actually, I do not believe it requires an exception to that rule; it can and should be a no-cost proposal this year, and therefore need not be "caught in the net" of that rule.

The legislation would provide the Food and Drug Administration with needed authority to establish mandatory standards for medical devices, require premarket scientific review in certain cases, and control investigational devices. We have sought sensible legislation in this field in order to preclude such problems as defective pacemakers, implanted heart valves, kidney dialysis machines, and potentially dangerous intrauterine devices. Because of the critical nature of these devices even a very small error rate results in significant human tragedy, and so this new legislation is clearly in the "humanitarian" category.

The problem in not supporting medical device legislation this year is greater than just the fact that the Administration has supported this legislation in the past two Congresses. Prior to your decision the Food and Drug Commissioner, in testimony this year before the Congress, has used our medical device legislation and its prospective transmission to the Congress as a basis for heading off other undesirable legislation. He offered such testimony in good faith, believing that legislation would soon be transmitted based on our past support. It is reasonably clear that the Congress will pass some legislation on medical devices this session no matter what we say. But failure of the Administration to take a positive position on this legislation would place the Department in an awkward position at best.

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Because I both understand and agree with your strong position to hold down Federal expenditures, I think we cannot proceed with this proposal in a "business as usual" fashion. We could, however, take the position that we favor enactment of this legislation this year with the understanding that implementation in FY 1976 would be conducted within resources already budgeted for the Food and Drug Administration. Given the circumstances in this case, I would prefer to proceed in this fashion if you agree.

I have attached at Tab A a copy of my draft letter to Senator Scott on the pending medical devices bill. The letter favors enactment this year but indicates an intention to implement within available resources in 1976. The letter to Senator Scott does state, correctly, that additional resources will be required in Fiscal 1977.

Recommendation

I recommend that you endorse our support of a medical devices bill but at no additional FY 1976 cost.

Decision

Support medical devices bill but
at no additional FY 1976 cost

Do not support medical devices bill

Attachment

cc: Dr. Cooper - H
Samuel/Sopper - L
Dr. Altman - P

P:WAMorrill/mrj 4-2-75
REVISED:CWWeinberger/mrj 4-3-75

FILE
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

Honorable Hugh Scott
Minority Leader
United States Senate
Washington, D. C. 20510

Dear Hugh:

There is before the Senate, as reported by the Committee on Labor and Public Welfare, S. 510, the "Medical Device Amendments of 1975."

The reported bill is identical with S. 2368, which was passed by the Senate during the 93rd Congress, providing the Food and Drug Administration (FDA) with a number of new authorities relating to medical devices. S. 510 would enable the establishment of mandatory standards, require premarket scientific review in certain cases, and control investigational devices. It would also require manufacturers to register, maintain records, make reports, notify FDA of defective products, and comply with good manufacturing practice regulations.

We have certain objections to the reported bill, as discussed below.

One of the principal issues of medical device legislation concerns what types of devices should be subject to scientific review.

S. 510 provides that devices that are life-sustaining or life-supporting must be classified as requiring premarket scientific review even if standards or an exemption would be adequate. We believe this provision is too broad and that the following alternative language would be preferable to the first sentence of proposed section 514(a)(1) of the Act.

SEC. 514. (a)(1) The Secretary may declare that a device (or type or class of device) for which scientific review has been determined to be appropriate pursuant to section 511(d) shall be subject to scientific review under this section with respect to any particular use or intended use thereof, if, after consultation with the appropriate panel or panels specified in subsection (b), he finds that (A) insufficient information exists (i) to assure effectiveness or (ii) to assure that exposure to such devices will not cause unreasonable risk of illness or injury and (B) scientific review may assure effectiveness or may reduce or eliminate such unreasonable risk and (C) no more practicable means to assure effectiveness or to reduce or eliminate the unreasonable risk are appropriate and (D) the device purports or is represented to be for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health.***

Conforming amendments would be needed in proposed section 511 of the Act regarding criteria for classification of medical devices, including

deletion of the last sentence in proposed section 511(c)(1)(B).

The Department also opposes the provision in the bill concerning protection of human subjects in device investigations. The excessive specificity of this language would freeze into law the current requirements of Department policy, and thereby interfere with its further administrative updating to keep pace with developments in biomedical technology.

As you are aware, the Department supported legislation similar to S. 510 in the 93rd Congress. If amended to meet the objections outlined above, the Department also supports enactment of S. 510. FDA's existing Bureau of Medical Devices and Diagnostic Products would be charged with carrying out the responsibilities created by the bill's enactment. Because of the President's decision not to initiate new spending programs this year, the Bureau would begin to implement a strengthened medical devices regulation program within FDA's current resources. Additional resources necessary to implement enacted legislation would be requested in the President's Budget for FY 1977.

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,

Secretary