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

March 22, 1976

OFFICE OF THE
GENERAL COUNSEL

TO : Holders of HEW Institutional Patent Agreements

SUBJECT: Information Item No. 40

Attached is the March 9, 1976 Congressional Record covering the passage of H. R. 11124 by the House. In brief, the bill requires pre-marketing clearance by Food and Drug Administration of certain categories of medical devices. There is some argument over the test to be applied in determining what categories of devices will be subject to pre-market clearance. In that regard see the paragraph "Pre-market Approval" on page H 1724.

It would appear that the bill, if finally enacted, will impact on university and non-profit institutions in a number of ways. At the very least, acquiring patent protection on medical devices generated at your institutions will be of greater importance, if commercial utilization is to be accomplished. This follows from the fact that greater amounts of private risk capital will be necessary to finance clinical testing and may be available only if patent protection is afforded to the developer.

Further, I would presume that some of the resources for conducting clinical trials on medical devices will be found at your institutions. This will no doubt increase the number of problems arising from collaborative projects with industry. In this regard see at least section 520 (g) "Exemption for devices for investigational use" on page H 1754 which sets out what research investigators may need to do in order to clinically test medical devices.

Since the Senate passed a similar bill S.510, on April 17, 1975, I presume both bills are ready for conference in order to resolve differences.

It is my understanding the university and non-profit sector have had little input in the development of this bill. Accordingly, you may wish to discuss it with officials at your institution who may be interested.

After you have read this proposed regulation, I thought the attached article "Closet Capitalist Confesses" might aid in balancing things out.

Sincerely yours,

Norman J. Latker
Patent Counsel

Enclosures
cc: Mr. Steinbach, ACE
Mr. Keyes, AAMC
Mr. Eden, DOC

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SPECIAL

INTEREST ITEM

MEDICAL DEVICE AMENDMENTS OF 1976

Mr. ROGERS. Mr. Speaker, I move that the House resolve itself into the Committee of the Whole House on the State of the Union for the consideration of the bill (H.R. 11124) 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 SPEAKER pro tempore. The question is on the motion offered by the gentleman from Florida.

The motion was agreed to.

IN THE COMMITTEE OF THE WHOLE

Accordingly the House resolved itself into the Committee of the Whole House on the State of the Union for the consideration of the bill (H.R. 11124), with Ms. JORDAN in the chair.

The Clerk read the title of the bill.

By unanimous consent, the first reading of the bill was dispensed with.

The CHAIRMAN. Under the rule, the gentleman from Florida (Mr. ROGERS) will be recognized for 30 minutes, and the gentleman from Kentucky (Mr. CARTER) will be recognized for 30 minutes.

The Chair recognizes the gentleman from Florida (Mr. ROGERS).

Mr. ROGERS. Madam Chairman, I yield such time as he may consume to the distinguished chairman of the full committee, the gentleman from West Virginia (Mr. STAGGERS).

(Mr. STAGGERS asked and was given permission to revise and extend his remarks.)

Mr. STAGGERS. Madam Chairman, I commend the gentleman from Florida (Mr. ROGERS) and the committee for bringing out this bill. It is one that is needed now. I think it is a well-balanced bill. I am for it because it came out of our committee, the subcommittee, I believe unanimously, and it came out of the full committee by a unanimous voice vote.

Madam Chairman, I say it is a bill that is needed to be passed now for the protection of the citizens of this country.

Mr. ROGERS. I thank the chairman for his remarks.

Madam Chairman, I yield myself such time as I may consume.

(Mr. ROGERS asked and was given permission to revise and extend his remarks.)

Mr. ROGERS. Madam Chairman, I am pleased to present to this body, H.R. 11124, the Medical Device Amendments of 1976. This measure is the product of months of careful subcommittee deliberations and has been scrutinized as closely as any legislation with which I have been involved. As a result, all members of the Subcommittee on Health and the Environment are cosponsors of H.R. 11124.

Madam Chairman, no one can seriously question the need for revision of the existing authority of the Food and Drug Administration to regulate medical devices. In 1938, when the FDA was given authority to seek seizure, injunction, or criminal prosecution with respect to "adulterated" or "misbranded" devices, devices were relatively simple in purpose and design. The principal concerns at that time were with respect to truthful labeling and the removal of fraudulent devices from the market. Over the ensuing 38 years, thousands of medical devices have entered the market, due principally to the postwar boom in biomedical technology. While the majority of these devices have demonstrated few health problems, and in fact have improved the lives of millions of our citizens, some sophisticated and important devices have presented significant health hazards. A committee chaired by Dr. Theodore Cooper, now HEW's Assistant Secretary for Health, issued a report in 1970 indicating that in the 10 years prior to 1969 devices caused 10,000 serious injuries and over 750 deaths. An intrauterine device marketed in the early 1970's was linked to 16 deaths and 25 miscarriages. Significant defects in cardiac pacemakers have resulted in 34 voluntary recalls, involving 23,000 units.

Madam Chairman, it is widely recognized by government, by industry, by health professionals and by consumers that archaic legislation keyed to removing "adulterated" and "misbranded" devices from the market is no longer acceptable to the American public. What is needed is legislation authorizing premarket clearance and standards for devices, when necessary. Strict controls on investigations of devices must be assured, lest the American public be exposed to inappropriately tested devices. Authority to ban hazardous or deceptive devices, to require that devices be manufactured under conditions that assure safety and effectiveness, to restrict the sale or distribution of devices, to insure that the public and health professionals are notified of risks presented by devices, is crucial if the public is to be protected from unsafe and ineffective medical devices and if health professionals are to have confidence in devices they use or prescribe. Persons who have purchased devices presenting substantial harm should be insured that such devices are repaired or replaced or that the purchase price will be refunded.

This is exactly what H.R. 11124 will do.

Madam Chairman, let me briefly outline the major provisions of the proposed legislation.

First, the bill requires the Food and Drug Administration to classify all devices into regulatory categories based on the types of controls necessary to insure the safety and efficacy of devices. The categories are:

Class I, general controls;

Class II, performance standards; and

Class III, premarket approval.

Classification of a device into class I—general controls—means that it shall be subject to the existing and new general controls relating to adulteration, misbranding, banning, reporting, registration, restrictions on sale and distribution, and requirements for good manufacturing practices, except that FDA can exempt devices from some general controls.

If classified into class II—performance standards—a device shall be required to meet an applicable standard on such date as is prescribed by FDA, but not before 1 year after the date on which the standard is established. The major general controls will continue to apply to the device unless superseded by the standard.

If classified into class III—premarket approval—and it is a new device, the device may not be marketed until it meets premarket approval requirements. If it is a device which is on the market before the date of enactment a regulation must first be promulgated to require premarket approval and then the device has until the later of 30 months after its classification or 90 days after the promulgation of the regulation to obtain approval.

Second, the bill requires establishment of expert panels to assist the FDA in classifying devices and requires that these panels submit recommendations

for classification of marketed devices within 1 year of enactment.

Third, there are special provisions for implantable devices. The bill requires that panels recommend that devices intended to be implanted in the human body which are on the market prior to the date of enactment of the bill—or which are substantially equivalent to such devices—be classified into class III—subject to premarket approval—unless they determine that such classification is not necessary to provide reasonable assurance of safety and effectiveness. It also requires that implantable devices not on the market prior to the date of enactment—and not substantially equivalent to devices on the market before such date—undergo premarket approval before they may enter the market.

Fourth, the bill prescribes procedures whereby qualified groups may develop proposed standards or submit existing standards to be utilized by FDA in promulgating performance standards applicable to class II devices.

Fifth, the FDA is authorized to exempt a device from the requirements of the bill if the device is intended solely for investigational use and if the proponent of the device submits a plan demonstrating that the testing of the device will be supervised by an institutional review committee, insures appropriate patient consent, and maintains certain records and reports.

Sixth, the bill authorizes proponents of devices classified into class III to submit product development protocols in lieu of applications for premarket approval. This exception authorizes a procedure whereby the development of a product and the development of data necessary to secure premarket approval are, in effect, merged. The PDP exception requires submission of a protocol for testing, and approval of the protocol by FDA. Upon a finding by FDA that the protocol has been completed, the device is considered as having an approved application for premarket approval.

Seventh, the bill authorizes FDA to ban a device which presents a substantial deception or substantial risk of illness or injury; to require notification and repair, replacement or refund in appropriate circumstances in connection with medical devices; and to require maintenance of records and reports by manufacturers and distributors of medical devices. It authorizes FDA inspection of such records and reports, and authorizes FDA to prescribe good manufacturing practices for device manufacturers.

Eighth, the bill authorizes "custom devices"—devices specially ordered for patients or intended for use solely by an individual physician or other specially qualified person—to deviate from performance standards and requirements for premarket approval.

Madam Chairman, H.R. 11124 has the support of the administration, industry, and consumer groups. It deserves the support of every Member of this body, and I urge its passage.

Ms. ABZUG. Madam Chairman, will the gentleman yield?

Mr. ROGERS. I yield to the gentlewoman from New York.

(Ms. ABZUG asked and was given permission to revise and extend her remarks.)

Ms. ABZUG. Madam Chairman, I would like to commend the distinguished chairman of the Health and Environment Subcommittee and the entire committee for the excellent job done on this bill, and particularly for your responsiveness to the health needs of women. As is noted in your committee report, we have already had one bad experience due to unregulated marketing of IUD's. The Dalkon Shield was on the market for several years before its use was linked to several deaths and miscarriages, and a variety of other medical complications for its users. Approximately 5 million American women use intrauterine devices for the purpose of contraception and it is essential that only safe and effective models be sold. Your report states that—

> The committee expects that these provisions will have the effect of requiring that * * * intrauterine devices as well as other types of devices which have been associated with incidents of significant illness or injury, be classified into class III.

Would you please elaborate on the specific protections included in this bill for users of intrauterine devices?

Mr. ROGERS. Madam Chairman, I would be pleased to do so. As the gentlewoman from New York points out, testimony received during hearings on this legislation documented clearly the need for strong regulation of intrauterine devices. The bill includes provisions which will insure that devices which are to be implanted in the human body, such as the IUD, will receive the most stringent scrutiny. Included in the bill are provisions which have the effect of establishing a presumption that implantable devices on the market prior to the bill's enactment be classified into class III and required to demonstrate safety and effectiveness through premarket testing. Any decision by the Secretary not to classify such devices into class III must be accompanied by a statement of the reasons for the decision. Of course, organizations concerned with the special health needs of women and other interested parties would have opportunity for comment before a decision not to require any presently marketed implantable device, such as an IUD, to undergo premarket testing.

In addition, all implantable devices not on the market before the date of enactment—and not substantially equivalent to marketed devices—must be classified into class III and thus undergo premarket testing which demonstrates safety and effectiveness prior to entering the market.

Thus, under the legislation, most if not all models of the IUD will undergo premarket testing. This certainly would be the intention of the committee.

Mr. HANNAFORD. Madam Chairman, will the gentleman yield?

Mr. ROGERS. I yield to the gentleman from California.

(Mr. HANNAFORD asked and was given permission to revise and extend his remarks.)

Mr. HANNAFORD. Madam Chairman, we have needed laws to regulate medical devices for some time, not only to protect patients, but also to protect the manufacturers and physician prescribers of these devices. Previous to enactment of this bill, there has been no expression of Congressional intent as to how the FDA should deal with medical devices. H.R. 11124 will rectify this situation. At least the manufacturers and physicians will know what to expect from the FDA.

My concern over the lack of legislation in this area was aroused by hundreds of letters from constituents who had benefited from an implant device called the intraocular lens used in cataract surgery. This device has been on the market for a number of years, and over 30,000 implants have been made. The FDA is presently considering proposals to classify the intraocular lens a new drug so that they can remove it from the market for testing. My constituents were concerned that removal of the lens from the market would prevent others from receiving its benefits. Passage of H.R. 11124 would prevent this from happening, allowing the manufacturers of implants already in use to present evidence of the safety and efficacy of the device, and production standards which they would follow before the device is removed from the market.

We all agree that legislation is needed to regulate the production and use of medical devices, particularly those which are implanted in the human body. I have become increasingly concerned over the phenomenon of law by regulation during my term in Congress. We have been elected to enact the laws which govern this country, and we must make every effort to reassert our authority. H.R. 11124 is a clear expression of congressional intent in the area of regulating medical devices, permitting the FDA to implement the law, not write it. I urge my colleagues to support this bill.

Mr. ROGERS. Madam Chairman, I thank the gentleman from California (Mr. HANNAFORD) for his interest and for his concern which he had expressed previously to the committee. The committee bill does help in these matters the gentleman has addressed.

Madam Chairman, I reserve the balance of my time.

Mr. CARTER. Madam Chairman, I yield 10 minutes to the gentleman from Texas (Mr. COLLINS).

(Mr. COLLINS of Texas asked and was given permission to revise and extend his remarks.)

Mr. COLLINS of Texas. Madam Chairman, this bill has several good things going for it. I think the best thing about it is the Members who have sponsored it. The gentleman from Florida (Mr. ROGERS) has been most fair in our deliberations. He comes from the wonderful State of Florida where health is abundant and where people live forever.

I would like to thank my good friend, the gentleman from Kentucky (Mr. CARTER), who is our medical authority on the committee. He has always been most generous and most openminded on all legislation. Both these gentlemen favor this bill. So, I realize its merits.

My opposition to the bill is based on the fact that America today has all the regulations and all the redtape that it needs on its sore back. We are talking here about adding more regulations about medicine. I do not know much about medicine, but for 25 years I was in the life insurance business. We were keenly interested in who died because we had to pay the death claims.

Madam Chairman, I want to point out that there were very few people who ever died from medical devices. There was just a rare case here and there of a death resulting from medical devices. Let me tell the Members what they did die from. They died from heart trouble. Heart is the major cause of death.

If we keep on up here in Washington with the same kind of fool legislation that we turn out here everyday, day in and day out, we are going to develop heart trouble in all of America. From coast to coast every manager who is trying to make a living today has to sit back and fill out form after form after form. When he gets through filling them out, there is some bureaucrat in Washington who is going to tell him that he did not fill it out right.

There are many men in little businesses who do not even know about these regulations, and the bureaucrats are going to make them shut down the whole works. That kind of small businessman is probably going to go broke. How would Thomas Edison ever invented anything if he had been spending all his time filling out reports.

I guess it sums it up by saying that it is just one further burden on the already overburdened medical profession and the medical suppliers.

I want to remind my colleagues that the United States has the greatest medical system in the world, and we are going to seriously jeopardize this system's efficiency if we increase the amount of time that we require members of the medical profession to spend on these redundant and burdensome Federal requirements.

We know what happened in 1975. The medical profession was just loaded up to its ears with malpractice suits; and now we propose, in 1976, to give them the medical devices bill to further overburden their sore, sore backs.

I would like to call everyone's attention to the survey that was made last year on Federal bureauracy. The Citicorp surveyed the American public, and they found that 90.6 percent of the American people feel that there is already too much Government redtape. Therefore, what we are talking about here is more Government redtape in every shape and form.

In this medical devices bill they took 155 pages of small print to explain it. I am glad that they did because this report highlights just a few of the problems of the confusing language of this bill.

This big printed document is 116 pages, 11-inch pages, in which the bill goes into great detail to specify the law. Section after section promulgate thousands of pages of required reports.

If I could, I would like to just give an example of what is covered under this bill under section 502 (C). It is called, "Misbranded Drugs and Devices."

I will quote this:

If any word, statement, or other information required by or under authority of this act to appear on the label or labelling is not prominently placed thereon with such conspicuousness as compared with other words, statements, designs, or devices in the labelling and in such terms as to render the label to be readily understood by their personal use . . .

That is just one example of how confused a person could be as to what goes onto a label.

Mr. ROGERS. Madam Chairman, will the gentleman yield?

Mr. COLLINS of Texas. I yield to the gentleman from Florida.

Mr. ROGERS. Madam Chairman, I thank the gentleman for yielding.

I understand his concern. I might say that the section he has just read is present law and has been in the law since 1938.

What we have done is write a bill specific enough so that we just do not turn over to a bureaucracy and allow them to write whatever and however they want.

We have been very specific and careful in developing this legislation, and I think the gentleman will find that the committee has done a good job.

Mr. COLLINS of Texas. I appreciate that. I did not understand that that was detailed in the present law.

I would like to ask, What do we do in this bill, in these 116 pages; what do we do to clarify that section, because it is a very confusing section?

Mr. ROGERS. What we have done throughout the bill is detail the exact procedure that all interested parties—FDA, industry, and consumers—must follow. We do not turn over broad authority to the Food and Drug Administration and let them write regulations any way they want to.

We have been specific because we believe the Congress should write the law specifically. The committee does not intend to allow regulatory agencies to do anything they want to.

Mr. COLLINS of Texas. Can the gentleman tell me specifically, with respect to that particular section, how they are going to spell out any particular device, and how we are going to let them know what size is the right size?

Mr. ROGERS. This has already been accomplished through regulations, because the provision is in existing law, as the gentleman knows.

Mr. COLLINS of Texas. I did not find it in this bill. I can see where these businessmen are going to be confused in so many ways.

The term "devices" itself is confusing. It is defined as any "instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or to affect the structure of any function of the body of man or other animals."

That to me sounds very confusing. Is that simple language in the eyes of a bureaucrat?

Mr. ROGERS. If the gentleman will permit, and will yield further, the definition is set forth in such detail in order to insure that there be no question as to the distinction between devices and drugs. Presently, IDA is treating several device products as drugs and requiring such products to go through premarket clearance. The courts have upheld this procedure. Actually, this definition will clarify the distinction between drugs and devices and authorize the FDA to apply appropriate regulatory safeguards, only as necessary to protect the public.

Mr. COLLINS of Texas. Would the gentleman from Florida not say that classification of devices pretty well includes everything, or well nigh everything in creation?

Mr. ROGERS. We assume all medical devices will fall within the definition. But the gentleman will recall that the bill would establish three categories of regulation. A device classified into class I would be subject only to so-called general controls. Devices classified into class II would be subject to standards, and class III devices would be required to undergo premarket clearance. The gentleman will be pleased to know that the bill is structured so that the least amount of control necessary to assure reasonable safety and effectiveness will be made applicable to a device.

Mr. COLLINS of Texas. Madam Chairman, I would ask the gentleman from Florida how widely impacted this problem of medical devices is in America? How many people, for instance, does the gentleman think have died because the present law was not adequate?

Mr. ROGERS. The Cooper committee reported some 750 deaths and 10,000 injuries during a 10-year period. We have had severe problems, as the gentleman knows, with interuterine devices which have caused significant numbers of septic abortions, injuries, and deaths.

We also have experienced problems with heart pacemakers. Thousands have had to be recalled. We think the American public deserves to have the best possible devices that can be made and that health professionals can be confident of the devices they use.

Mr. COLLINS of Texas. We are talking about deaths of people.

Mr. ROGERS. And injuries.

Mr. COLLINS of Texas. And injuries. Let us talk about deaths and injuries. I was always impressed with the DWI cases that caused so many fatal accidents. I would say that for every single person who dies from a medical device, there will be about 100 who will die from a DWI situation, yet I know nothing of Federal legislation to reduce DWI's. Why do we not do something about the main cause of accidents. Instead, there is very little said on that matter. I think we should go into the subject of drunk drivers.

Mr. ROGERS. If the gentleman will yield further, I think the gentleman knows that the DWI problem is really a State issue, and I know of no State where it is not again, the law to drive while intoxicated. Yet we also have attempted to do something about the problem of alcoholism which I agree is one of the most serious problems we have in this country. In 1970, the Congress addressed the

problem of alcoholism by enacting the Hughes Act which, among other things, provides support for treatment and prevention programs. In fact, the Subcommittee on Health and Environment is presently marking up a revision and extension of the original Hughes Act which I am sure the gentleman from Texas will support in full committee.

Mr. COLLINS of Texas. I will be proud to support the gentleman's bill on DWI control. I might add on this subject of DWI, that I am as a rule a supporter of States rights, but based on the experience in England with the subject of DWI's, they were tremendously successful in facing this problem and continued to reduce DWI accidents until they began to ease back on enforcement.

The CHAIRMAN. The time of the gentleman has expired.

Mr. CARTER. Madam Chairman, I yield myself such time as I may consume.

(Mr. CARTER asked and was given permission to revise and extend his remarks.)

Mr. CARTER. Madam Chairman, I rise in support of H.R. 11124, the Medical Device Amendments of 1976.

The bill amends the Federal Food, Drug, and Cosmetic Act to afford the Secretary of Health, Education, and Welfare the long overdue authority to regulate medical devices.

Every member of the Subcommittee on Health and Environment is a cosponsor of this legislation.

Our subcommittee held lengthly hearings and gave this bill careful consideration. As a result, a number of constructive changes have been incorporated into the legislation in response to consumer, industry, scientific, medical, and administration concerns.

In particular, I would like to direct my colleagues' attention to several of the bill's provisions.

First, the subcommittee was aware of the need to continue to encourage scientific investigation and to assure product innovation.

To that end, I introduced an amendment with Mr. ROGERS to provide certain regulatory exemptions for devices for investigational uses.

This provision authorizes FDA to exempt devices intended solely for investigational use—from the bill's requirements—if the sponsor of the device submits a plan demonstrating that the testing of the device will be supervised by an institutional review committee.

He must also provide assurance of appropriate patient consent, and recordkeeping procedures.

This provision allows the flexibility which we feel is necessary in this important area of scientific research.

A second concern was the potential economic burden of a regulatory bill on the medical devices industry—and in particular—its impact on small business.

Several provisions have been included in the bill with this concern in mind.

One is an alternative procedure for premarket approval of devices—called "product development protocol."

This procedure allows the development of a product to evolve simultaneously with the development of data necessary to demonstrate safety and effectiveness.

Another provision establishes an office wthin the Department of Health, Education, and Welfare to provide technical assistance to small manufacturers of medical devices to assist them in complying with the requirements of the act.

The subcommittee was also aware of the special needs and circumstances surrounding provision of custom devices. These are items which are specially ordered for patients, or intended for use solely by an individual physician, or specially qualified person.

In light of this concern, the bill authorizes "custom devices" to deviate from performance standards and requirements for premarket clearance.

These and other provisions reflect the subcommittee's intent to develop a bill which would protect the public's safety—and yet not impose unduly burdensome requirements on the medical device industry.

We have all witnessed the revolution in biomedical technology which has contributed to the extremely rapid growth of the medical device industry in the past two decades.

Indeed, this growth has been critical for the development of many lifesaving and life-sustaining devices.

I am confident that this legislation will provide for continued progress in the medical device field—and at the same time—will provide the responsible regulatory authority over medical devices which is needed to protect the public's health and safety.

Madam Chairman, the following is a background statement concerning the need for the legislation and a summary of the legislation:

BACKGROUND

Medical devices were first regulated by the Federal Food, Drug, and Cosmetic Act of 1938, which defined devices to include both quack machines, and legitimate objects such as surgical instruments, prosthetic devices, and contraceptives. The 1938 Act, as amended, enables FDA to require that medical devices are manufactured under sanitary conditions, appropriately labeled, and not recommended for any use which could endanger health. The FDA has no authority to require manufacturers to demonstrate the safety and efficacy of medical devices before marketing them; they may only act after a device has been sold commercially.

Initially FDA's concern was with truthful labeling and the removal of fraudulent devices from the market. New medical research produced a great number of sophisticated and important medical devices, such as heart pacemakers, kidney dialysis units, and artificial heart valves. The complex nature of such devices, combined with the critical medical situations in which the devices are used, has caused increased concern over their potential for harm.

In the search to broaden medical knowledge new experimental approaches have been used before adequate premarket clinical or animal testing—in some instances, without patient consent. In the 10 years prior to 1969, devices caused 10,000 serious injuries and over 750 deaths. In early regulatory actions FDA was able to establish the hazardous nature of devices through expert testimony, but now they must test those suspected of being unsafe. One fraudulent and hazardous device marketed in 1949 could not be removed from the market until 1970, at a cost of $500 million to FDA. Two court decisions in the late 1960's, however, established that products which are not clearly devices or drugs (such as sutures) may be considered drugs and thus subject to FDA pre-market clearance. This prompted FDA to develop a clearer distinction between drug and device, classifying a product as a drug if its intended action is chemical, or based on complex technology which would be less hazardous under new drug controls.

In 1970 a Special Committee on Medical Devices reviewed the need for additional medical device legislation and recommended that HEW be given the authority to set standards for certain devices and require premarket clearance for others. They also recommended a peer review system to oversee device development.

Legislative history

Several bills regulating devices were introduced in both the House and Senate during the 93rd Congress, and on February 1, 1974, the Senate passed the Medical Device Amendments of 1973 which was not considered by the House. On April 17, 1975 the Senate again passed a medical devices bill S. 510, which contained virtually the same provisions as the 1974 bill. HEW was required to set up panels of scientific experts to review and classify medical devices into 3 classes: 1) those needing no regulation, 2) those who must meet standards set by outside groups to agencies selected by HEW, and 3) those requiring pre-market approval by panels of scientific experts.

PROVISIONS

Under H.R. 11124, articles are considered medical devices rather than drugs if they are not dependent upon chemical action and are not metabolized to accomplish their purpose. HEW is authorized to determine the safety and effectiveness of devices when used as recommended, weighing health benefits against, possible harm. FDA will be responsible for implementing the bill, which establishes 3 categories for medical devices, and provides for their classification.

Class I—General controls

Devices placed in class I shall be those for which existing controls on labeling and sanitation and the new general controls established by the bill are enough to assure safety and effectiveness. Where incomplete information exists to certify that general controls are sufficient, devices may be considered class I if they do not present potential risk.

Class II—Performance standards

Devices in class II are those for which general controls are inadequate and for which enough information exists to establish a performance standard. HEW will set a date for meeting a standard, and general controls shall continue to apply to class II devices, unless specifically superseded.

Performance standards may consist of design and labeling requirements as well as clinical demonstration of performance. Public and private organizations (including FDA) shall be required to submit proposed standards or offers to develop them to HEW. HEW may either accept a standard or develop one, and may refer proposals to expert advisory committees (panels composed of scientists and nonvoting representatives of both consumers and device manufacturers) for review. After a period for public comment, HEW may issue a regulation on the standard, which shall not take effect until 1 year after publication unless the protection of public health mandates an earlier date.

Class III—Premarket approval

Medical devices shall be placed in class III if insufficient information exists to assure that general controls or performance standards would certify their safety and effectiveness and if they are important medically or pose substantial risk. All products presently regulated as drugs will be placed in class III, as well as all new devices (not substantially equivalent to those on the mar-

ket) and most devices designed to be implanted.

Class III devices will be subject to premarket approval by HEW-appointed technical panels of experts. Approval requires the filing of an application with HEW including: 1) reports on the device's safety and effectiveness; 2) a description of design and manufacturing process; 3) reference to a performance standard applicable to the device if placed in class II; and 4) a sample of the device if possible. Applications are referred to an appropriate classification panel for study and judgment. HEW must aprove or disapprove the application within 180 days of receipt (unless extended by mutual agreement), and may condition an approval subject to restrictions on the device's sale or distribution.

Product Development Protocol (PDP)—The bill, recognizing the frequent modification of devices during development, allows the merging of the investigation of a device with the gathering of information needed for premarket approval. A PDP must contain descriptions of the: 1) device to be developed; 2) tests to be conducted on the device; and 3) expected results. PDP's shall be referred to classification panels for recommendations, with approval or disapproval by HEW taking place within 120 days after receipt. Approval of the PDP shall not constitute device approval, only the initial step. When the device is fully developed, a notice of PDP completion must be filed which should include results of the required tests. Within 90 days of submission HEW must either approve the device or, after conducting an informal hearing, declare the PDP not completed. An approved PDP may be revoked after a hearing if new information indicates risk.

Classification of devices

HEW shall establish panels of experts to recommend device classification. The panels shall be organized according to medical specialty (dentistry, urology, radiology, etc.), and each panel of experts must include 2 nonvoting members representing consumer interests and device manufacturers.

Panel Operation—HEW shall refer devices to the appropriate panel and the panel shall provide interested parties the opportunity for comment. Data considered by the panel shall be held confidential, and if a class III designation is made, shall continue to be confidential. After review the panel will submit the recommended classification to HEW, including: 1) rationale; 2) the data used; and 3) the possible health risks of the device. Classification panels shall report within 1 year of being funded regarding all devices on the market before the bill's enactment.

Panel recommendations of devices for class I shall include recommendations for possible waiver of recordkeeping and reporting, or any other of the general controls. Devices which are usually implanted in the body, and have been sold commercially before enactment (or are similar to marketed devices) shall be recommended by the panel as class III unless they determine this unnecessary. All devices not marketed before enactment shall be considered in class III unless: 1) they are similar to previously marketed class I or II devices, or 2) HEW reclassifies them in response to a petition by the manufacturer.

Classification—HEW shall publish the panel's recommendations in the Federal Register and shall provide for comment by interested parties. After review, they shall issue a regulation, including: 1) if the device is in class I, which general requirements shall not apply; and 2) if the device was eligible for class III but not so classified a statement of explanation.

Reclassification—HEW, upon receiving new information about a device, may change its classification and revoke any regulation regarding performance standards or premarket approval. Reclassification may be on HEW's own initiative or following petition by an interested party, and HEW may request a recommendation regarding a change from the panel initially reviewing the device.

General controls

The bill establishes a number of general controls applicable to all medical devices, regardless of classification.

Registration—Device manufacturers must register with HEW a list of all devices manufactured. HEW may develop a uniform system for device identification, and the present drug registration exemption for pharmacies, practitioners and researchers is extended for devices.

Banned Devices—HEW is given authority to ban any device after consulting the appropriate panel and conducting an informal hearing with the manufacturer and other interested parties, if the device presents an unreasonable health hazard. Labeling changes may be recommended instead of a ban, but HEW may immediately remove any device from the market if it presents a substantial direct danger to health.

Notification of Risks—When a device on the market is determined hazardous, HEW may require notification to people prescribing or using the device, or to manufacturers, distributors or retailers. Notifications may be sent by HEW, the manufacturer, the distributor, or the retailer, depending on the circumstances.

Records and Reports—HEW may require all parties involved in the marketing of devices to keep records and make reports to assure that devices meet the requirements of the bill. Reports and records are not to be burdensome, with HEW to balance health protection needs with the cost of providing the information.

Good Manufacturing Practices—HEW may issue regulations requiring that the production of devices conform to certain manufacturing practices. A 9-member advisory committee is established to develop requirements for good manufacturing practices which may be waived by HEW under certain circumstances.

Other provisions

Exemptions—HEW may exempt a device from the bill's requirements if: 1) it is intended solely for investigational use; and 2) reports on the technical supervision are submitted when the device is to be tested on humans. Patient consent must be obtained when devices are tested on humans, unless life-threatening conditions preclude this requirement. Custom devices may also be exempted from performance standards or premarket approval if a qualified person certifies that the device is intended for use only by a named individual.

State and Local Requirements—The bill preempts State and local medical device requirements, unless they are more stringent than those of HEW.

Exports—Devices not complying with the bill's provisions may be exported if: 1) they meet the laws of the importing country; 2) are labeled for export; and 3) the health agency of the importing country certifies the device's safety. This provision also covers the export of new drugs.

Judicial Review—Persons adversely affected by medical device regulations and orders issued by HEW may petition the appropriate US Court of Appeals for relief. All HEW records on the matter shall be released to the Court, including the proceedings of advisory committees or informal hearings.

Small Manufacturers—In addition to the provisions allowing the exemption of class I devices from various general controls, the bill requires HEW to establish an identifiable office to assist small manufacturers with regulation compliance.

COSTS

No authiorizations are included in H.R. 11124, although it is expected that the administration will request future appropriations. In FY 75, FDA's medical device program was appropriated $6.7 million, and the committee estimates the new requirements of the bill will bring total costs to approximately $15 million.

Madam Chairman, I also insert for the RECORD the following material from HEW Under Secretary Margaret Lynch concerning H.R. 11124:

ANALYSIS OF H.R. 11124

1. CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE

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

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

2. PERFORMANCE STANDARDS

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

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

In our testimony, we also expressed concern that the section providing for review of a device standard by an independent advisory committee should be amended. Under proposed section 514(g)(5)(B), as well as under proposed section 515(g)(2)(B), the Agency cannot use the panels (who advise on classification and premarket approval) as the independent advisory committee used for administrative review of proposed standards and of premarket approval decisions. We urged that section 514(g)(5)(B) be amended to allow FDA to merely disqualify those panel members who may have prejudged an issue from service on an independent review advisory committee. The Subcommittee staff has assured us that provisions in section 514(g)(5)(B) are intended merely to prohibit the use of the entire classification panel that had considered a device as the independent advisory committee for review of a device standard or premarket approval decision and that the provisions do not bar use of individual members of a panel as members of the independent advisory committee. We agree with this interpretation and, if it is correct, agree that the bill need not be amended.

3. PREMARKET APPROVAL

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

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

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

4. BANNED DEVICES

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

5. RECORDS AND REPORTS

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

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

6. CUSTOM DEVICES

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

7. RESTRICTED DEVICES

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

8. GOOD MANUFACTURING PRACTICE ADVISORY COMMITTEE

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

9. PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES

We question the advisability of the amendment adopted by the Subcommittee, new subsection 520(i), that advisory panels and committees maintain transcripts of their proceedings. It is FDA's policy to allow its committees to decide for themselves whether they wish to have transcripts or tapes made of their meetings as an aid to preparation of minutes, as set forth in proposed section 2.313 of Title 21, *Code of Federal Regulations* in FDA's proposed procedural regulations (*Federal Register* of September 3, 1975, 40 FR 40748). This policy has been maintained to protect the free interchange of ideas by these advisors. This concept that internal communications of Government employees may be exempted from public disclosure so as to promote full and frank discussion is set forth in the Freedom of Information Act as incorporated into the Federal Advisory Committee Act. We believe it consistent with this policy that maintenance of transcripts be optional rather than mandatory. We therefore recommend that this provision be deleted.

10. HEW OFFICE TO PROVIDE TECHNICAL ASSISTANCE TO SMALL MANUFACTURERS OF MEDICAL DEVICES

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

FEBRUARY 5, 1976.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

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

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

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

A number of changes made in the Subcommittee simplified and thus improved administrative proceedings under the bill. We favor, among other changes, the amended investigational device provisions, the transitional provisions for projects formerly categorized as "drugs," the substitution of "questioning" for "cross-examination" at informal hearings, the provisions requiring FDA to make public a detailed summary of safety and effectiveness information respecting certain devices, the exemption of class I, General Control devices, from the biennial inspection provision, and the understanding that the restricted device provisions apply both as to effectiveness as well as safety of a device.

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

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

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

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

Sincerely,

MARJORIE LYNCH,
Under Secretary.

STRICT CRIMINAL LIABILITY

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

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

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

"Hardship there doubtless may be under a statute which thus penalizes the transaction through consciousness of wrongdoing be totally wanting.

"Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity for informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless."

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

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

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

Madam Chairman, I reserve the balance of my time.

Mr. PREYER. Madam Chairman, will the gentleman yield?

Mr. ROGERS. Madam Chairman, I yield to the distinguished member of the subcommittee, the gentleman from North Carolina.

Mr. PREYER. Madam Chairman, I should like to ask the gentleman from Florida one question about this bill. I agree with the gentleman from Kentucky (Mr. CARTER), and the chairman, the gentleman from Florida (Mr. ROGERS), that this bill is necessary and that we need to do something in this area. One concern I have—and I am sure this is not unique in my district—is that I have a very small medical device manufacturer in my district which was established by a creative genius who operates that plant. I would hate to discourage creative geniuses all around the country from doing a good job in developing new medical devices.

The question I would like to ask the chairman is this: Does this bill contain sufficient protection for the small manufacturers of medical devices?

Mr. ROGERS. The reply to the gentleman's question is "Yes." As a matter of fact, the committee spent a great deal of time in drafting provisions designed to afford the small manufacturer necessary protection from overregulation.

Mr. CARTER. Madam Chairman, will the gentleman yield?

Mr. ROGERS. I will be glad to yield to the distinguished ranking member, who, I might say, has done a magnificent job on this legislation.

Mr. CARTER. I thank the gentleman for yielding.

This legislation sets up a special office within the Department of Health, Education, and Welfare to take care of small businesses. It will provide technical and other nonfinancial assistance to small manufacturers of devices. I hope that they will continue to develop useful medical devices.

Mr. ROGERS. I might also add to that that it is made clear in the bill that the Secretary is to require the least regulation necessary in order to assure safety and effectiveness. It also exempts custom devices—often made by small manufacturers—from requirements for performance standards and premarket approval.

Moreover, as the gentleman knows, provisions authorizing the exemption of class I devices from certain provisions of the bill, limiting traceability and record-keeping and reporting requirements, and authorizing the use of product development protocols all are intended in part to encourage the continued viability of smaller device manufacturers. So I think we have been especially careful to protect the interests of the small manufacturer who has contributed so much in this field.

Mr. PREYER. I thank the gentleman.

Mr. CARTER. Madam Chairman, I have no further request for time.

Mr. ROGERS. Madam Chairman, I yield 5 minutes to the gentleman from New Jersey (Mr. MAGUIRE), who is on the committee, who takes such a vital interest in and has had a considerable part to do with this legislation.

(Mr. MAGUIRE asked and was given permission to revise and extend his remarks.)

Mr. MAGUIRE. Madam Chairman, I thank the gentleman from Florida, the chairman of the committee, for yielding time to me.

Madam Chairman, first I would like to commend my colleague from Florida, Chairman PAUL ROGERS, for his outstanding leadership in developing this needed legislation. Without his tireless efforts this proposal would not have been possible.

There is a sore need to provide legislative authority for reasonable regulation of medical devices. The fact is that the Government's authority to regulate medical devices today is comparable to its authority to regulate drugs in 1906. Chairman ROGERS has characterized the existing authority of the Food and Drug Administration to regulate medical devices as "archaic and unclear." There is wide agreement on this assessment throughout the medical community. Unambiguous authority is necessary in order to assure safe and effective medical devices for the user.

The situation today is that the public is not receiving the protection from the dangers of certain medical devices. The number and complexity of medical devices on the market is increasing at an astounding rate. Medical devices include everything from surgical instruments and heart pacemakers to anesthesiology equipment and X-ray equipment to tooth fillings and tongue depressors. There are at least 1,000 medical device manufacturers producing about 12,000 different kinds of medical devices. It is a multi-billion dollar industry enjoying one of the fastest growth rates in the health industry. The lack of regulation of medical devices may account for countless deaths and injuries from medical devices which may otherwise have been avoided through adequate premarket testing, manufacturing standards, and other requirements.

A 1969 study undertaken by the Department of Health, Education, and Welfare estimated that 10,000 injuries attributable to medical devices occurred in a 6-year period; 731 of these injuries were fatal. Many authorities believe that this may be a conservative estimate. The devices with which the greatest incidence of injury and death have been associated are those which are implanted into the human body and which are used in life-threatening or life-sustaining situations. FDA is aware of about 23,000 individual heart pacemakers which have been recalled because of defects; 89 deaths and 186 injuries are known to be associated with pacemakers; 512 deaths and 300 injuries are known to be associated with heart valves; 8,000 injuries and several deaths are known to be associated with intrauterine devices.

The list goes on, but the numbers are deceptive because they only indicate the deaths and injuries which are known to be associated with certain devices. Without doubt there are countless number of deaths and injuries associated with devices for which no records exist. It is extremely difficult to clinically determine when, in fact, a death or injury was brought on by a defective device. It is difficult to determine, for instance, whether a fatal heart attack was brought on by an undetected defect in a heart pacemaker. It is clear that tremendous care must be taken to preclude such tragedies. Legislative authority must be provided to require premarket testing of such devices as pacemakers, intrauterine devices, and other implanted devices. Authority must also be provided for banning devices which present a substantial danger to the user. In addition the FDA must be able to develop adequate standards for manufacturing practices as well as developing general controls and recordkeeping, labeling, and performance requirements.

I believe that H.R. 11124 provides a minimum of legislative authority to FDA to insure the safety and effectiveness of medical devices. There are many who feel that the legislation does not go far enough. Nonetheless, I believe that this legislation provides many strong measures to protect the consumers of medical devices.

While there is considerable evidence to indicate that premarket approval should be required for all implanted devices, H.R. 11124 unambiguously directs the FDA to require premarket approval of all new implanted devices which are not substantially equivalent to implantable devices of the same type now on the market. Additionally FDA would be required to place devices in a premarket approval category if they are intended for a use which is of substantial importance in supporting, sustaining or preventing impairment of human life or health, or present a potential unreasonable risk of illness or injury. Furthermore, FDA would have the authority to require premarket approval for devices for which there is an insufficient information to provide reasonable assurance of the safety and effectiveness of the device. The committee anticipates that FDA will construe its authority broadly particularly in the case of implantable devices.

While I would have preferred language which would have required all implantable devices to undergo premarket approval, I believe that the approach in H.R. 11124 represents a reasonable compromise and certainly incorporates several improvements over earlier versions of the legislation.

Another important aspect of the bill deals with the mechanism for establishing standards for devices. Under an earlier version of the bill FDA could not develop its own standards if there were outside experts who offered and were qualified to develop a particular standard. There was considerable question whether this mechanism might have invited abuse in which interested outside parties with a proprietary interest in the standard for the device would be involved in the development of those standards. H.R. 11124, however, provides authority to FDA to exclude those who offer to develop a standard if there is a potential conflict of interest. Additionaly, H.R. 11124 gives FDA the option to develop the standard itself or to allow outside experts to develop them. This flexibility is essential in order to preclude undue pressures on the agency in establishing standards which will provide for the manufacture of safe and effective devices.

Many of my colleagues are familiar with the fact that FDA has had considerable difficulty in banning the distribution of unsafe substances. This difficulty is due to court interpretations of FDA authority which require an extreme burden of proof for the agency in proving that a particular substance is dangerous. While the bill does not address this issue for drugs and food additives, it does provide a reasonable standard for the banning of medical devices. Under the bill FDA may ban a device if it presents an "unreasonable, direct, and substantial danger to the health of individuals." It also provides authority for the FDA to act quickly against certain devices which pose an immediate threat.

We are all familiar with the fact that too much of the activities of Government are conducted behind closed doors. Important decisions are made without public knowledge or scrutiny. In the area of regulation of medical devices it is essential, of course, to protect legitimate trade secrets. However, it is equally essential to ensure that information concerning the most important decisions made by FDA and its advisory panels is made known to the public. For this reason, H.R. 11124 requires the advisory panels on medical devices to maintain transcripts of its proceedings which would be available to the public except for trade secrets. Furthermore the bill requires the release of safety and effectiveness information in the form of summaries so that the scientific and medical community as well as the general public can determine whether a particular regulatory action was justified.

The greatest care must be taken to insure that there is public confidence in this system, that the users of medical devices may feel assured that their devices are safe and effective, and that all may feel that the regulatory process was fair and equitable. This bill respects legitimate trade secrets, but it also provides for the release of information respecting the regulatory process and the data upon which the regulators make their decisions. This is also essential so that Congress may adequately perform its oversight responsibilities to evaluate the operation of the law.

Finally, the bill provides assistance for small manufacturers of devices to enable them to better cope with the complexity of the regulation which will result from this law. Too often Congress enacts needed legislation without paying heed to the particular problems of small businesses which are not equipped to deal with the Washington bureaucracy and its agents throughout the country. For this reason the committee adopted an amendment to the bill which provides for the establishment of an identifiable office in FDA to give technical assistance to small manufacturers of medical devices and to assist them in complying with the requirements of the act.

I would urge my colleagues to approve this needed legislation. Chairman ROGERS and his committee have taken great care in developing this bill which would provide the minimum legislative authority required so that FDA may develop measures to provide for safe and effective devices. We must act upon this measure quickly to prevent future tragedies of death and injury from unsafe devices.

Mrs. SULLIVAN. Madam Chairman, I strongly support H.R. 11124, to close one of the worse loopholes in the Food, Drug, and Cosmetic Act of 1938 by requiring medical and other therapeutic devices to be proved safe and effective before they are placed on the market, and I congratulate Chairman PAUL G. ROGERS and members of the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce for the subcommittee's unanimous endorsement of a strong bill.

A GOOD BILL—BUT 14 YEARS LATE

I regret, however, that it has taken 14 years since the Committee on Interstate and Foreign Commerce first held hearings on this issue in June, 1962, to bring a bill before the House. All of the arguments now being made for the need for legislation to protect the public from unsafe or ineffective medical and therapeutic devices were made before the Committee in 1962 by the then Secretary of Health, Education, and Welfare, Senator ABRAHAM RIBICOFF; by the then Commissioner of Food and Drugs, the late George Larrick and his assistants; and by me as the author of an omnibus bill, H.R. 1235, to close all of the loopholes in the 1938 act.

Unfortunately, 1962 was the last time the committee held hearings on the omnibus bill, H.R. 1235, although I have reintroduced substantially the same bill by the same number in every Congress since then. The committee in 1962 selected only a few things out of my bill and reported out legislation dealing only with the safety and efficacy of drugs. This action came only after the disclo-

sures of the tragedy in Europe of thousands of babies being born with missing arms, legs, feet, or hands, or with other deformities, because their mothers had been given a supposedly harmless tranquilizing drug known as thalidomide. Thanks to the courage and, in fact, the heroism of Dr. Frances O. Kelsey of the Food and Drug Administration, that drug had been stalled from going on sale in the United States; the Kefauver-Harris Act of 1962 in effect retroactively gave her and other FDA pharmacologists legal support for her previous action in blocking thalidomide and provided authority to FDA to require adequate premarket testing of all new drugs to prove both safety and effectiveness.

OTHER GLARING DEFICIENCIES IN FOOD, DRUG AND COSMETIC ACT OF 1938

Now, 14 years later, we are moving to close another big gap in the consumer protections of the Food, Drug and Cosmetic Act of 1938, dealing with medical type devices. But, as a mere reading of only the title of H.R. 1235 would disclose, the 1938 act is still full of other serious loopholes. For instance, cosmetics are still freely marketed without adequate testing for safety; there is no legal requirement for ingredient labeling of cosmetics; carcinogenic coloring ingredients may still be legally added to meat animal feeds—in fact, this loophole was added to the law in 1962 for no rational reason at all; soap is still exempt from any regulation under the Food, Drug, and Cosmetic Act; many untested and possibly dangerous chemicals in use in food prior to the passage of the Food Additives Act of 1958 are still covered by that act's "grandfather" clause; antibiotics administered to meat animals are not subject to batch-by-batch certification; drugs other than antibiotics used on humans and which are just as unstable in manufacture, are not subject to required batch-by-batch certification; there is no requirement for testing of new drugs for mutagenic or teratogenic effects similar to the "Delaney clause" requirements on cancer-testing ingredients in food or coloring matter.

It has been my contention for 15 years, since introducing the first version of H.R. 1235 in January, 1961, that it is far more effective and just as practical to consider and act on one bill which closes all of the loopholes in the 1938 act as it is to take up these issues one at a time over a period of many years. The fact that it has taken 14 years since the first hearings in 1962 to bring a medical device safety bill before the House is evidence of the validity of my argument before the committee in 1962 and on numerous occasions since then, that the piecemeal approach to strengthening the Food, Drug and Cosmetic Act is taking far too long.

ELIMINATING USELESS GADGETS AS WELL AS DANGEROUS DEVICES

When do we get to the serious problem of untested, and unsafe or allergy-causing, cosmetics? Must another 14 years go by? How many men, women, and children will be injured by untested cosmetics in the meantime?

While I congratulate the subcommittee and the parent committee for their effective work on H.R. 11124—I think the bill reflects a great deal of hard work—and while I know the Rogers subcommittee has had a tremendously heavy legislative agenda, I sincerely hope that it can find time to pursue all of the other issues covered in H.R. 1235 affecting the power of the Food and Drug Administration to protect America's consumers.

In the meantime, as one of the first Members of Congress to introduce legislation dealing with the safety and effectiveness of therapeutic devices, beginning 15 years ago, I am very grateful that we now have a bill before us which goes as far as H.R. 11124 goes in saving lives from defective or unsafe medical equipment while also eliminating harmless but useless mechanical devices and gadgets sold to the public on false claims of curing disease or improving one's health.

I am sure most of us are more concerned about the devices which injure, maim, or kill people than we are about those ineffective gadgets which merely cheat the consumer, but the bill properly covers the latter as well as the former and establishes machinery for weeding out devices which are either dangerous or ineffective.

Under the present law, since 1938, the dangerous devices can be removed from the market only after there is clear proof that they are causing harm; the useless gadgets cannot be controlled at all as long as they do no harm and as long as no misleading claims are made for them. The harmless gadgets nevertheless do harm the ill by encouraging them to put their faith in devices which cannot help them, thus delaying the seeking of proper medical care.

THE PACEMAKERS WHICH FAILED

Madam Chairman, in the field of devices used by the medical profession, the best illustration—although only one of many which could be cited—for the imperative need for the kind of legislation which the House is considering today is the incredible story of what happened in one of the biggest and most reputable companies in the field, General Electric, during 3 months in 1971 when 508 pacemakers were made containing a new type of circuit board which had apparently not been properly tested for chemical or metallurgical changes in the human body.

According to information I obtained from FDA shortly thereafter, the Food and Drug Administration not only did not know that General Electric had changed its pacemaker circuit boards, it did not learn of the failure of these devices and their recall by GE until "after the fact," through news media reports on the recalls beginning April 7 and 8, 1972. Yet GE had begun recalling some of the suspect units nearly 3 months earlier, on January 24, 1972, following complaints it had received the previous November and early December about malfunctioning units.

Here was an instance of a leading American corporation making a life-saving device for surgical implantation in the human body which was changed in materials and specifications without any notification either to the FDA or the medical profession, and then not even bothering to alert the FDA to the fact that hundreds of these products in use were probably defective.

STATEMENT BEFORE ROGERS SUBCOMMITTEE

Madam Chairman, the pacemaker malfunctions constitute one of the dramatic illustrations of the urgent need for this legislation, but there are many, many other incidents which could be cited. The committee report accompanying the bill clearly describes the scope of the problem, and the hearings of 1962, 1973, and 1975 contain voluminous evidence to support pretesting of all potentially dangerous devices and requiring evidence of efficacy.

Under unanimous consent granted in the House, I include as part of my remarks my statement to the Rogers subcommittee on this legislation on July 28, 1975, on the opening day of the hearings, as follows:

STATEMENT OF HON. LEONOR K. SULLIVAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSOURI

Mrs. SULLIVAN. Chairman Rogers and members of the subcommittee, I commend the Subcommittee on Health and Environment for holding these comprehensive hearings on the subject of therapeutic devices, which have been inadequately regulated under the Food, Drug, and Cosmetic Act ever since that law was passed in 1938. Improvement of the statute is urgently necessary and 37 years overdue—not only as it relates to medical devices but to many other areas of regulation, including cosmetics.

As the members of this subcommittee may know, I have been introducing since 1961 an omnibus bill—which has carried the same number, H.R. 1235, in every Congress beginning with the 87th Congress down to the present one—to rewrite the Food, Drug, and Cosmetic Act of 1938. This bill proposes to eliminate a wide variety of loopholes which were either written deliberately into the 1938 act or which have come to light since then as a result of court decisions or technological advances. Among the proposals contained in H.R. 1235 from the very beginning has been one to require pretesting for safety and efficacy of all therapeutic devices before being sold, and to permit prompt removal from the market of any which are now on sale which cannot meet satisfactory standards of safety and effectiveness.

The present law on medical devices, like the present law on cosmetics, allows any manufacturer to make and distribute any product it wants to, and places the burden of proof on the Food and Drug Administration to establish that the product is unsafe. There is no requirement that the devices be effective. As a result, countless products which should never have been allowed to go on sale have injured or killed consumers before the FDA even knew of their existence and the dangers they presented, and a great many harmless but useless devices have been marketed which defrauded the public of millions of dollars.

THE PACEMAKERS WHICH FAILED

The details of necessary corrective legislation for medical devices and other therapeutic devices have been the subject of debate in House and Senate committees for many years without any final action being taken. But in the meantime, we have experienced one tragedy after another as un-

tested equipment and devices used on human patients turned out to be improperly made or poorly designed or made of materials not able to withstand the demands made upon them, particularly when implanted in the body.

I checked several years ago into a pacemaker recall episode and found that one of the firms which manufactured and marketed this device had changed materials used in its pacemaker without notifying FDA or the medical profession. The wiring of the device failed in the body and all of the pacemakers made by the firm after a particular date had to be replaced. As I recall, there were several deaths from malfunctioning pacemakers included in the recall. The thing which amazed me about this incident was not that a leading American corporation making a life-saving device for implantation in the human body was free to market an untested product—as of course it can do under the law—but that it did not even think to notify FDA or the medical profession that it had changed specifications and materials in a product which had heretofore been used successfully. No one apparently was alerted to the fact that the product was no longer the same as the one the company had previously marketed.

CORRESPONDENCE WITH FDA

I would like to include with my statement my exchange of correspondence with the Food and Drug Administration on the pacemaker recall and on a number of other subjects dealing with recalls, as follows:

CONGRESS OF THE UNITED STATES,
HOUSE OF REPRESENTATIVES,
Washington, D.C. April 26, 1972.

DR. CHARLES C. EDWARDS,
Commissioner, Food and Drug Administration, Rockville, Md.

DEAR DR. EDWARDS: A number of questions occur to me after noting the listings in FDA's weekly recall report for April 13–19, 1972.

First of all, do these incidents reflect actions taken by FDA in ordering or requesting recalls, or actions by the individual firms involved in moving to recall their products on their own initiative and then notifying FDA of the facts? All of the recall actions are listed as "voluntary" and most of the listings show that the recall actions were initiated at various times between January 27 and April 1, yet they appear in the report as recall actions taken between April 13 and April 19. Hence, I would appreciate clarification of the procedures followed.

2. In the case of drugs and foods covered by recalls, am I correct that your inspectors have access to complaint files of the manufacturers but you do not have such access to the complaint files of manufacturers of devices or cosmetics?

3. In the case of the Standby Cardiac Pacemakers, were there any deaths attributed to the malfunction of the device? When was FDA first notified of the problem? Were all of the devices manufactured during the period between June 6 and September 8 traceable—or can they be traced—to the individuals who received implants? How many of the 487 which were implanted have been replaced? How serious is the operation necessary to make or replace an implant? Has the circuit board component used after September 8 been tested to establish its safety or reliability? Had the changes in specifications for the circuit board component used during the period June 6 to September 8 ever been tested for possible metallurgical and/or chemical changes such as later occurred in use? If any such pre-testing was done, was it equivalent to the kind of testing FDA would be likely to require under the terms of H.R. 1235's section on devices?

4. In the case of the water filled teether beads, found to be contaminated with bacteria, have any deaths or serious illnesses been attributed to them? When was the last time, prior to this incident, that the plant manufacturing or packaging the teether beads had been inspected by FDA for sanitation and what was found at that time?

5. Similarly, when was the last time Trylon Products Corporation's plant making the two cosmetics products which are listed in the April 13–April 19 recall list as having been "heavily contaminated with psuedomonas alcaligenes" had been inspected by FDA, and what were the findings? What illnesses could flow from psuedomonas alcaligenes, and have there been any cases of such illness from these recalled products? What steps have been taken by FDA to reduce bacterial contamination of cosmetics? Do you lack any necessary or desirable powers in this respect which H.R. 1235 would provide—that is, dealing with bacterial contamination?

6. I remember seeing a news article that GE had recalled certain of its pacemakers, but I do not remember seeing any public report on any of the other recalls listed in the April 13–19 report. Does FDA decide under what circumstances a public announcement should be made by the individual manufacturer or distributor or is that left to the individual firm to determine? If FDA decides, what are the criteria which are followed in deciding whether a public announcement should be made by the manufacturer and when? Under what circumstances does FDA itself issue a public warning, other than through the listings in the weekly recall report which, in the case of the April 13–19 report, summarizes recall actions generally taken weeks or months prior to that report?

Sincerely yours,
LEONOR K. SULLIVAN,
Mrs. John B. Sullivan,
Member of Congress.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, PUBLIC HEALTH SERVICE, FOOD AND DRUG ADMINISTRATION,
Rockville, Md., May 18, 1972.

Hon. LEONOR K. SULLIVAN,
House of Representatives,
Washington, D.C.

DEAR MRS. SULLIVAN: This is in further reply to your April 26 letter concerning recalls.

The answers to your questions in the order posed in your letter are as follows:

1. All recalls contained in the weekly recall report for April 13–19, 1972 were voluntary. The designation of a voluntary recall means that the individual firms involved recalled their products on their own initiative either prior to bringing it to the attention of FDA or after the problem was brought to the firm's attention by FDA. An FDA initiated recall is one in which removal action is undertaken after the Office of the Commissioner has notified the firm and requested such action.

Recalls ordinarily appear on the weekly recall list within two weeks after the recall is initiated. The January and February recalls were delayed in being published due to technical difficulties. Although late, we thought it better that they be published.

2. The Federal Food, Drug, and Cosmetic Act gives authority to FDA to gain access to complaint files for prescription drugs, whether or not they involve recalled products. The Act does not, however, require the manufacturer to give our inspectors access to complaint files for nonprescription drugs, foods, and cosmetics.

3. We are continuing our investigation into the matter involving the "Standby Cardiac Pacemaker," manufactured by the General Electric Comany. The General Electric Company has informed us that at least six persons in whom the suspect units were implanted have died. However, we do not know how many deaths, if any, can be directly attributed to the pacemakers.

FDA personnel (Office of Medical Devices staff members) learned of the recall "after the fact" through news media reports. The General Electric firm had prepared a press statement which was to be verbally transmitted to anyone inquiring about the recall. This information was carried over the radio on the evening of April 7, 1972, and in the newspapers on April 8, 1972. We subsequently confirmed that the firm had instituted recall of a limited number of suspect units on January 24, 1972 following complaints of malfuctioning units it had received in "late November-early December." This recall was limited to units manufactured during a nine-day period in June 1971.

On April 1, 1972, the firm, on the basis of additional information, extended the recall to units manufactured during a three-month period (June 6 to September 8, 1971).

General Electric has informed us that 508 units were distributed worldwide. Of these, 367 were distributed in the United States and Canada. All of the United States and Canadian units have been disimplanted or replaced, scheduled for removal and replacement, or otherwise accounted for, with the exception of three units. The patients cannot be located in these three instances. We are continuing the monitoring of the recall including those exported abroad.

The disimplantation-reimplantation operation is reported by General Electric to involve "minor" surgery of 25 to 30 minutes duration under a local anesthetic. In most cases, the procedure requires a one to two day hospital stay.

We do not know, at this time, the extent to which the circuit boards used in the suspect units were tested to establish safety and reliability or for metallurgical and/or chemical changes such as later occurred in use. In any event, any metallurgical and/or chemical changes that may have occurred and which may be the cause of the malfunctioning were not detected beforehand.

An answer to your last question in this paragraph would require conjecture and speculation based on unknown factors and incomplete information as discussed above. While we hope that all such failures could be prevented or detected prior to use of a device by or on a patient, we recognize that the complexity of many problems would make it virtually impossible to achieve this in every case However, the Administration's bill, S. 3028, which is similar to your medical device preclearance proposal, would reduce significantly the possibilities of post-market malfunctioning.

4. To our knowledge, no death or serious injuries have been attributed to the water teether beads made by Nippy Manufacturing Company (also known as P. L. Industries, Inc.). The firm was last inspected on Dememberr 9, 1971, and no sanitation problem was found at that time.

5. The most recent inspection of Trylon Products Corporation, prior to the discovery of the contaminated bath oils, was conducted on August 9, 1967. The only insanitary condition observed during this inspection was that the firm was not properly cleaning its plant equipment.

Pseudomonas alcaligenes is not considered to be an overt pathogen to man, but it can be an active secondary invader and cause respiratory diseases and urinary tact infections. No illnesses resulting from the use of the recalled bath oils have been reported.

Although we have no basis for insisting on the sterility of cosmetics, we take steps to eliminate pathogenic bacterial contamination in cosmetics through periodical inspections of facilities and products, analysis of samples, educational activities, and legal proceedings.

We presently have the necessary powers under the Federal Food, Drug, and Cosmetic Act to act against products that are contaminated with harmful bacteria. Such products would be adulterated and would be subject to action under Section 601 of the Act.

6. Removals from the market of products that present threats to the health or safety of the consumer are classified as a Class I recall. In addition to being placed on the recall list, Class I recalls are made the subject of a public warning issued by FDA. For recalls other than Class I, a press release may be issued by FDA when it is in the public interest to alert institutions, professional or industry groups, or other affected persons. A manufacturer or distributor responsible for a recall may, on his own initiative, issue a press release. The firm responsible for the recall does not dictate to FDA, whether or not a public warning or press release will be issued. We are enclosing a copy of our policy statement that will explain in general our recall procedures.

We hope this information will be helpful to you. If you have any further questions, please let us know.

Sincerely yours,

GERALD F. MEYER,
Director, Office of Legislative Services.

LAST HEARING ON H.R. 1235 IN 1962

As long ago as 1962, when the Committee on Interstate and Foreign Commerce held hearings on all of the issues contained in my bill, H.R. 1235—the first and last hearings by the committee on omnibus legislation to rewrite the entire Food, Drug, and Cosmetic Act—it was clear that the law as it relates to medical devices was woefully inadequate. It was equally clear at that time that the Food, Drug, and Cosmetic Act of 1938 was full of other shortcomings and loopholes—only a few of which have been corrected since that time. The remaining ones are all spelled out in H.R. 1235 as introduced in this Congress, and I would appreciate having the title of that bill printed in your hearing record as part of my statement as a "laundry list" of things remaining to be done to bring the 1938 act up to date with current needs and realities.

I strongly endorse effective legislation to regulate therapeutic devices across the board. The provisions of H.R. 1235 in this respect are particularly strong, and I urge that you consider them.

In acting on medical devices separately, however, the subcommittee should also, I believe, be looking very hard at the other areas of consumer deficiencies in the Food, Drug, and Cosmetic Act as dealt with in H.R. 1235, the title of which is as follows:

[H.R. 1235, 94th Cong., 1st sess.]

A bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act, so as to amend certain labeling provisions of the food, drug and cosmetic chapters to assure adequate information for consumers, including cautionary labeling of articles where needed to prevent accidental injury; expand the coverage of the "Delaney Clause" to apply to mutagenic and tetratogenic agents; eliminate the "Grandfather's Clause" for pre-1958 chemical additives used in food; require nutritional labeling of foods; require labeling of all ingredients in foods, listed in order of predominance, including sepcific coloring and preservative ingredients; prohibit worthless ingredients in special dietary foods; authorize the establishment of standards for medical devices; require medical devices to be shown safe and efficacious before they are marketed commercially; require all antibiotics to be certified; provide for the certification of certain other drugs; require records and reports bearing on drug safety; limit the distribution of sample drugs; require cosmetics to be shown safe before they are marketed commercially; clarify and strengthen existing inspection authority; make additional provisions of the Act applicable to carriers; provide for administrative subpenas; provide for strengthening and facilitating mutual cooperation and assistance, including training of personnel, in the administration of that Act and of related State and local laws; prohibit the use of carcinogenic color additives in animal feeds; safeguard the health of children by banning sweetened or flavored aspirin from commerce; authorize a system of coding for prescription drugs; establish a United States Drug Compendium; and for other purposes.

(By Mrs. Sullivan)

January 14, 1975.

Referred to the Committee on Interstate and Foreign Commerce.

Mr. FOUNTAIN. Madam Chairman, I rise in support of the bill, H.R. 11124, the medical device amendments.

I want to commend the Committee on Interstate and Foreign Commerce, and especially the chairman of the Health and Environment Subcommittee, the gentleman from Florida (Mr. ROGERS), for their diligent work in bringing this important bill to the House floor.

In 1972 the Intergovernmental Relations and Human Resources Subcommittee, which I chair, conducted an investigation of FDA's regulation of medical devices, with particular attention devoted to the safety of the intrauterine contraceptive devices. We held 5 days of oversight hearings which convinced the subcommittee of the need for a strong and effective medical device law. The present device law, enacted in 1938, has remained essentially unchanged despite the vast changes that have taken place in the number, complexity, and importance of therapeutic devices. It is obvious that the scale of research and development in this field has far outpaced the authority and capacity of FDA to regulate these devices under present law.

The subcommittee's 1972 investigation brought to light serious weaknesses in the present law and its enforcement, and stimulated congressional efforts to correct those deficiencies with modern legislation. Although H.R. 11124 does not go as far as I have proposed in requiring the premarket clearance of devices that are implanted into the human body, on the whole it is a good bill that will provide needed protection for the American people. I strongly recommend its enactment.

Mr. WAXMAN. Madam Chairman, the bill before us today, the Medical Device Amendments of 1975, is a landmark piece of legislation. For the first time, it brings under Federal regulation an industry on which all our citizens depend for the delivery of quality health care.

From a legislative perspective, the need for this bill is abundantly clear. Currently, Federal law contains no requirement that medical devices which reach the market be established as safe and effective. A device manufacturer does not have to register with the Government, is free to produce and market devices, and need not make a showing regarding the products' reliability. Additionally, there is not now a requirement that the place of manufacture be inspected to guard against adulteration, or that records and papers bearing on the device's history be kept.

In the absence of affirmative congressional action, the Food and Drug Administration has sought to regulate the industry by stretching the provisions of the Food and Drug Act to include some medical devices, notably those implanted in the body, under its provisions. The Supreme Court has conceded that, although this backdoor method of regulation is very questionable from a standpoint of public policy, it is—unless and until the Congress acts—essential for the protection of the public health.

The passage of this legislation will lay all these questions—the right of the Federal Government to regulate the industry, and the requirements upon industry if it is to meet its responsibilities under the law—to rest.

In human terms, there are even more compelling reasons for the adoption of this bill. There are well over 10,000 types of medical devices currently on the market, manufactured by an industry which last year grossed over $6 billion and which is growing—as the demands on our health care system are growing—at a rate approaching 10 percent per year.

Although there is no question that the overwhelming number of devices on the market are safe, testimony before our subcommittee documented that in the absence of standards of safety and effectiveness, the public is exposed in many instances to an unacceptably high level of risk. For example:

A 1969 HEW study discovered 10,000 injuries from medical devices, and over 700 deaths, over a 10-year period.

A 10-year FDA death-certificate search found over 850 deaths tied directly to medical devices.

An independent health group, the Commission on Professional and Hospital Activities, estimated that in 1970 there were 36,000 complications arising from the use of medical devices.

With certain types of devices, particularly those implanted in the body, the need for effective regulation is even more dramatic:

Although intraocular lenses have proved greatly beneficial to many people as an alternative to glasses after cataract surgery, there are continuing and disturbing reports that use of these lenses has resulted for many patients, in the contraction of glaucoma, corneal disease, inflammation, and infection.

For the eight million women who use intrauterine devices, there are many, many unanswered questions about how they work, and why, or why one variant is considered "better" than another. In the absence of certainty, rates of injury have been shocking. The FDA reported that over a 10-year period, 39 IUD-related deaths and 239 septic abortions had occurred. Other complications including uterine perforations—which require major surgery—and pelvic infections—which may cause sterility and ovarian cysts—have surfaced.

Although pacemakers have revolutionized cardiology, there is ample cause for concern over their use. Over 23,000 pacemakers have been recalled since 1972. And 1,300 have had to be removed by emergency surgery. Nearly 30 deaths due to ineffective or failed pacemakers have been recorded. The major problem associated with them has been the leakage of body fluids into the instrument.

In all these instances, the promise that these devices hold for better health care and more rational family planning has been deeply tarnished by recrurring failures, defects, injury, and death. The public has placed its faith and trust in an industry which has consistently guaranteed the highest quality from its products. The protection of the public health deserves no less than the regulatory system which is proposed in the legislation before us.

As originally introduced, the medical device amendments embodied the regulatory structure first proposed by the Cooper Commission: classification of all devices into three categories, depending on their potential for harm or abuse; procedures for the development of performance standards; requirements for premarket approval; guidelines for the use of investigational devices; and the use of outside panels of experts to advise the Secretary at various crucial stages of regulation.

In all these areas, I felt it important that this new legislation be as sensitive as possible to protecting the consumer from dangerous and ineffective products—that when there were grey areas, the regulatory system would err on the side of caution. To this end, I believed it critically important that this bill include, as a minimum, the following provisions:

First, that the burden for establishing a device's safety and effectiveness be placed squarely on the manufacturer;

Second, that the public should have every possible assurance, if not absolute certainty, that any device on the market is safe and effective when used properly;

Third, that there should be available to the public, and consumer groups, comprehensive information regarding a device's safety and effectiveness, including reports of any adverse health effects which emerged during the testing of the device;

Fourth, that those devices most intimately connected with human health, notably implants, undergo premarket clearance;

Fifth, that authority be granted to immediately ban any device which presents a substantial endangerment to health;

Sixth, that the performance standards which are developed not be consensus standards—representing what most manufacturers agree to, rather than what consumer safety requires—instead of true safety standards;

Seventh, that outside advisory committees, when utilized, conscientiously and thoroughly address the issues before them, evaluating all the evidence before reaching their opinions.

All of these standards, Mr. Chairman, have been written into this bill.

There were four other amendments which I sponsored which are also a part of this legislation. First, it is required that if a device is found to be defective or presents a risk to health, the physician who prescribed the device is to notify his patient of the dangers and discuss corrective action. I believe a patient has a right to know when a threat to his or her health exists.

Second, each investigator who is experimenting with a device on a human subject must obtain informed consent for participation in the research. The shocking revelations that patients, particularly inmates, have been abused because they did not know the medical implications of the research experiments they volunteered for has documented the need for such an amendment. The requirement for informed consent is waived only in life-threatening situations in which there is insufficient time to obtain the concurrence of the patient or his representative.

Third, the States are authorized, with the Secretary's approval, to establish standards for medical devices which are more stringent than the Federal standards contained in this legislation. California has been a leader in this area. In 1970, the State legislature adopted the Sherman Food, Drug, and Cosmetic Law. It requires the premarket approval of a "new" medical device, including intrauterine devices. The amendment I introduced to this bill will permit California's progressive program to continue in effect in that State.

Finally, FDA is authorized to develop performance standards for medical devices when it has the in-house capability to do so. This amendment does not preclude industry from simultaneously developing a standard, but allows FDA to utilize its own resources and expertise when appropriate. I very much hope that by providing an alternative to relying on industry for the development of performance standards for its products, this amendment will encourage standards which reflect the highest possible levels of safety and efficacy.

Mr. FITHIAN. Madam Chairman, I rise in support of H.R. 11124, the Medical Device Amendments of 1976. Although I am not entirely satisfied with all facets of this bill, it is the result of commendable and extensive work by Mr. ROGERS and his subcommittee, as well as the full Interstate and Foreign Commerce Committee.

In the Second District of Indiana, which I have the privilege to represent, nearly 75 percent of the Nation's production of orthopedic devices is located. I have had an opportunity to visit and inspect these industrial facilities, and I have talked extensively with industrial officials and workers at the plant.

These individuals have expressed to me on several occasions their fear of increasing Federal redtape interfering with the functioning of their enterprise. I share that fear and I remain committed to removing Government interference from the operation of American business.

However, we all recognize the need for a reasonable degree of regulation to protect the life and health of the consumer. My concern with legislation in this area stems from a feeling that unless this bill is passed today, the medical device industry will suffer from regulations which do not reflect congressional intent and which might be promulgated without the due consideration given this issue by my esteemed colleagues who serve on the Interstate and Foreign Commerce Committee.

Earlier today my staff contacted the major manufacturers of orthopedic devices, and they indicated their support for this completed bill. I note, additionally, that the bill is supported by the Pharmaceutical Manufacturers Association and the administration, and that the American Medical Association has voiced no objection to the bill. I believe that it successfully avoids overregulation which could stifle advances in medical device technology.

Accordingly, I urge my colleagues to join me in support of H.R. 11124 today.

Mr. BINGHAM. Madam Chairman, on October 16, 1973, I introduced a bill, H.R. 10916, to amend the Federal Food, Drug, and Cosmetic Act, requiring the public dissemination of information related to seizures and recalls made under the Act. This bill would have directed the Secretary of HEW not to withhold information regarding products recalled by the FDA as deadly or dangerous. The bill had referred to the House Committee on Interstate and Foreign Commerce, but no action was taken on it.

I am, therefore, pleased that the bill before us today, the Medical Device Amendments of 1976 does contain provisions which address this issue. The bill, H.R. 11124, generally amends the Federal Food, Drug, and Cosmetic Act to include classification and regulation of medical devices.

Section 519(a) stipulates that the Secretary of HEW may issue an order, should he determine that a medical device intended for human use presents an unreasonable risk of substantial harm to the public health, to assure that adequate notification is provided to all the persons involved. Included among those receiving the notification would be all health professionals who prescribe or use the device, as well as manufacturers, importers, distributors, and retailers.

Device users would also be notified unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notification. In this situation, the order must require that the health professional who prescribe or use the device in question personally notify the individuals involved in such a risk.

In 1973, the FDA claimed that wide publicity on the recall of dangerous medical devices might "frighten people to death" citing the example of a cardiac patient with a pacemaker. I argued that more harm would be done to the patient who is not notified of a defective medical device, especially a life-sustaining device as vital as an implanted pacemaker. I am pleased that the Interstate and Foreign Commerce Committee accepted my argument.

The provisions in H.R. 11124 to notify the device user as well as the health professionals and manufacturers stress overall protection of public health and the consumer, while still giving consideration to exceptional cases such as cardiac patients.

I urge House adoption of this bill.

Mr. CARTER. Madam Chairman, I have no further requests for time and yield back the balance of my time.

Mr. ROGERS. Madam Chairman, I simply want to particularly commend the

staff for the great work that the staff did for the majority members of the staff; Jo Anne Glisson, Mr. Gallemore, who worked so well and thoroughly on this, and my legislative counsel, Mr. David Meade. All of them deserve great credit for helping the committee draw up this legislation.

Madam Chairman, I have no further requests for time and I yield back the balance of my time.

The CHAIRMAN (Miss JORDAN). All time has expired. The Clerk will read.

The Clerk read as follows:

H.R. 11124

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE AND TABLE OF CONTENTS

SECTION 1. (a) This Act may be cited as the "Medical Device Amendments of 1975".

(b) Whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

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REGULATION OF MEDICAL DEVICES

SEC. 2. Chapter V is amended by adding after section 512 the following new sections:

"CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE

"Device Classes

"SEC. 513. (a) (1) There are established the following classes of devices intended for human use:

"(A) CLASS I, GENERAL CONTROLS.—

"(i) A device for which the controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

"(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide such assurance, but because it—

"(I) is not purported or represented to be for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health, and

"(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

"(B) CLASS II, PERFORMANCE STANDARDS.—A device which cannot be classified as a class I device because the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, for which there is sufficient information to establish a performance standard to provide such assurance, and for which it is therefore necessary to establish for the device a performance standard under section 514 to provide reasonable assurance of its safety and effectiveness.

"(C) CLASS III, PREMARKET APPROVAL.—A device which because—

"(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 are sufficient to provide reasonable assurance of the safety and effectiveness of the device and (II) cannot be classified as a class II device because insufficient information exists for the establishment of a performance standard to provide reasonable assurance of its safety and effectiveness, and

"(ii) (I) is purported or represented to be for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health, or

"(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 515, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficent information to establish a perforamance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

"(2) For purposes of this section and sections 514 and 515, the safety and effectiveness of a device are to be determined—

"(A) with respect to the person for whose use the device is represented or intended,

"(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

"(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

"(3) (A) Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 514 and 515, to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

"(B) If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A))—

"(i) which is sufficient to determine the effectiveness of a device, and

"(ii) from which it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device,

then, for purposes of this section and sections 514 and 515, the Secretary may authorize the effectiveness of the device to be determined on the basis of such evidence.

"Classification; Classification Panels

"(b) (1) For purposes of—

"(A) determining which devices intended for human use should be subject to the requirements of general controls, performance standards, or premarket approval, and

"(B) providing notice to the manufacturers and importers of such devices to enable them to prepare for the application of such requirements to devices manufactured or imported by them,

the Secretary shall classify all such devices into the classes established by subsection (a). For the purpose of securing recommendations with respect to the classification of devices, the Secretary shall establish panels of experts or use panels of experts established before the date of the enactment of this section, or both. Section 14 of the Federal Advisory Committee Act shall not apply to the duration of a panel established under this paragraph.

"(2) The Secretary shall appoint to each panel established under paragraph (1) persons who are qualified by training and experience to evaluate the safety and effectiveness of the devices to be referred to the

panel and who, to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such devices. The Secretary shall make appointments to each panel so that each panel shall consist of members with adequately diversified expertise in such fields as clinical and administrative medicine, engineering, bological and physical sciences, and other related professions. In addition, each panel shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

"(3) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, but not at rates exceeding the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day so engaged, including traveltime; and while so serving away from their homes or regular places of business each member may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently.

"(4) The Secretary shall furnish each panel with adequate clerical and other necessary assistance.

"Classification Panel Organization and Operation

"(c)(1) The Secretary shall organize the panels according to the various fields of clinical medicine and fundamental sciences in which devices intended for human use are used. The Secretary shall refer a device to be classified under this section to an appropriate panel established or authorized to be used under subsection (b) for its review and for its recommendation respecting the classification of the device and, to the extent practicable, respecting the assignment of a priority for the application of the requirements of section 514 or 515 to the device if the panel recommends that the device be classified in class II or class III. The Secretary shall by regulation prescribe the procedure to be followed by the panels in making their reviews and recommendations. In making their reviews of devices, the panels, to the maximum extent practicable, shall provide an opportunity for interested persons to submit data and views on the classification of the devices.

"(2)(A) Upon completion of a panel's review of a device referred to it under paragraph (1), the panel shall, subject to subparagraphs (B) and (C), submit to the Secretary its recommendation for the classification of the device. Any such recommendation shall (i) contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the recommendation is made, and (ii) to the extent practicable, include a recommendation for the assignment of a priority for the application of the requirements of section 514 or 515 to a device recommended to be classified in class II or class III.

"(B) A recommendation of a panel for the classification of a device in class I shall include a recommendation as to whether the device should be exempted from the requirements of section 510, 519, or 520(f).

"(C) In the case of a device which has been referred under paragraph (1) to a panel, and which—

"(i) is intended to be implanted in the human body, and

"(ii)(I) has been introduced or delivered for introduction into interstate commerce for commercial distribution on or before the date of enactment of this section, or

"(II) is within a type or device which was so introduced or delivered on or before such date and is substantially equivalent to another device within that type,

such panel shall recommend to the Secretary that the device be classified in class III unless the panel determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. If a panel does not recommend that such a device be classified in class III, it shall in its recommendation to the Secretary for the classification of the device set forth the reasons for not recommending classification of the device in such class.

"(3) The panels shall submit to the Secretary within one year of the date funds are first appropriated for the implementation of this section their recommendations respecting all devices of a type introduced or delivered for introduction into interstate commerce for commercial distribution on or before the date of the enactment of this section.

"Classification

"(d)(1) Upon receipt of a recommendation from a panel respecting a device, the Secretary shall publish in the Federal Register the panel's recommendation and a proposed regulation classifying such device and shall provide interested persons an opportunity to submit comments on such recommendation and the proposed regulation. After reviewing such comments, the Secretary shall, subject to paragraph (2), by regulation classify such device.

"(2)(A) A regulation under paragraph (1) classifying a device in class I shall prescribe which, if any, of the requirements of section 510, 519, or 520(f) shall not apply to the device.

"(B) A device described in subsection (c)(2)(C) shall be classified in class III unless the Secretary determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. A proposed regulation under paragraph (1) classifying such a device in a class other than class III shall be accompanied by a statement of the reasons of the Secretary for not classifying such device in such class.

"(3) In the case of devices classified under this subsection in class II and devices classified under this subsection in class III and described in section 515(b)(1), the Secretary may establish priorities which, in his discretion, shall be used in applying sections 514 and 515, as appropriate to such devices.

"Classification Changes

"(e) Based on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an interested person, by regulation (1) change such device's classification, and (2) revoke, because of the change in classification, any regulation or requirement in effect under section 514 or 515 with respect to such device. In the promulgation of such a regulation respecting a device's classification, the Secretary may secure from the panel to which the device was last referred pursuant to subsection (c) a recommendation respecting the proposed change in the device's classification and shall publish in the Federal Register any recommendation submitted to the Secretary by the panel respecting such change. A regulation under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 514 for such device.

"Initial Classification of Certain Devices

"(f)(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section is classified in class III unless—

"(A) the device—

"(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution on or before such date, or (II) which was not so introduced or delivered on or before such date and has been classified in class I or II, and

"(ii) is substantially equivalent to another device within such type, or

"(B) in the case of a device other than a device which is intended to be implanted in the human body, the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

A device (other than a device which is intended to be implanted in the human body) classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) classifying the device in class I or II. The Secretary may not promulgate a regulation under subsection (e) changing the classification of a device which is intended to be implanted in the human body and which is classified in class III under this paragraph before there is in effect for such device an approval under section 515 of an application for premarket approval.

"(2) The manufacturer or importer of a device classified under paragraph (1) (other than a device which is intended to be implanted in the human body) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Within one hundred and eighty days after the filing of a petition under this paragraph and after affording the petitioner an opportunity for an informal hearing, the Secretary shall, after consultation with the appropriate panel established or authorized to be used under subsection (b), by order either deny the petition or order the classification, in accordance with the criteria prescribed by subsection (a)(1)(A) or (a)(1)(B), of the device in class I or class II.

"Information

"(g) Within sixty days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this Act, the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this Act applicable to the device.

"Definitions

"(h) For purposes of this section and sections 501, 510, 514, 515, 519, and 520—

"(1) a reference to 'general controls' is a reference to the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520.

"(2) a reference to 'class I', 'class II', or 'class III' is a reference to a class of medical devices described in subparagraph (A), (B), or (C) of subsection (a)(1), and

"(3) a reference to a 'panel under section 513' is a reference to a panel established or authorized to be used under this section.

"PERFORMANCE STANDARDS

"Provisions of Standards

"SEC. 514. (a)(1) The Secretary may by regulation, promulgated in accordance with this section, establish a performance standard for a class II device. A class III device may

also be considered a class II device for purposes of establishing a standard for the device under this section if the device has been reclassified as a class II device under a regulation under section 513(e) but such regulation provides that the reclassification is not to take effect until the effective date of such a standard for the device.

"(2) A performance standard established under this section for a device—

"(A) shall include provisions to provide reasonable assurance of its safe and effective performance;

"(B) shall, where necessary to provide reasonable assurance of its safe and effective performance, include—

"(i) provisions respecting the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to such systems,

"(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of the device to the standard, provisions for the testing (on a sample basis or, if necessary, on an individual basis) by the Secretary or by another person at the direction of the Secretary,

"(iii) provisions for the measurement of the performance characteristics of the device,

"(iv) provisions requiring that before the device is introduced or delivered for introduction into interstate commerce for commercial distribution the results of each or of certain of the tests of the device required to be made under clause (ii) show that the device is in conformity with the portions of the standard for which the test or tests were required, and

"(v) a provision requiring that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 520(e); and

"(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device.

"(3) A performance standard established under this section may not include any provision not required or authorized by paragraph (2) of this subsection.

"(4) The Secretary shall provide for periodic evaluation of performance standards established under this section to determine if such standards should be changed to reflect new medical, scientific, or other technological data.

"(5) In carrying out his duties under this section, the Secretary shall, to the maximum extent practicable—

"(A) use personnel, facilities, and other technical support available in other Federal agencies,

"(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities, and

"(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, or consumer organizations who in his judgment can make a significant contribution.

"Initiation of a Proceeding for a Performance Standard

"(b)(1) A proceeding for the development of a performance standard for a device shall be initiated by the Secretary by the publication in the Federal Register of notice of the opportunity to submit to the Secretary a request (within fifteen days of the date of the publication of the notice) for a change in the classification of the device based on new information relevant to its classification.

"(2) If, after publication of a notice pursuant to paragraph (1) the Secretary receives a request for a change in the device's classification, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 513, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 513(e).

"Invitation for Standards

"(c)(1) If, after the publication of a notices under subsection (b), no action is required under paragraph (2) of such subsection or the Secretary denies a request to change the classification of the device with respect to which such notice was published, the Secretary shall publish in the Federal Register a notice inviting any person, including any Federal agency, to—

"(A) submit to the Secretary, within sixty days after the date of publication of the notice, an existing standard as a proposed performance standard for such device, or

"(B) offer, within sixty days after the date of publication of the notice, to develop such a proposed standard.

"(A) A notice published pursuant to paragraph (1) for an offer for the development of a proposed performance standard for a device—

"(A) shall specify a period within which the standard is to be developed, which period may be extended by the Secretary for good cause shown; and

"(B) shall include—

"(i) a description or other designation of the device,

"(ii) a statement of the nature of the risk or risks associated with the use of the device and intended to be controlled by a performance standard,

"(iii) a summary of the data on which the Secretary has found a need for initiation of the proceeding to develop a performance standard, and

"(iv) identification of any existing performance standard known to the Secretary which may be relevant to the proceeding.

"(3) The Secretary shall by regulation require that an offeror of an offer to develop a proposed performance standard submit to the Secretary such information concerning the offeror as the Secretary determines is relevant with respect to the offeror's qualifications to develop a proposed performance standard for a device, including information respecting the offeror's financial stability, expertise, and experience, and any potential conflicts of interest, including financial interest in the device for which the proposed standard is to be developed, which may be relevant with respect to the offeror's qualifications. Such information submitted by an offeror may not be made public by the Secretary unless required by section 552 of title 5, United States Code.

"(4) If the Secretary determines that a performance standard can be developed by any Federal agency (including an agency within the Department of Health, Education, and Welfare), the Secretary may—

"(A) if such determination is made with respect to an agency within such Department, develop such a standard in lieu of accepting any offer to develop such a standard pursuant to a notice published pursuant to subsection (c), or

"(B) if such determination is made with respect to any other agency, authorize such agency to develop such a standard in lieu of accepting any such offer.

In making such a determination respecting a Federal agency, the Secretary shall take into account the personnel and expertise within such agency. The requirements described in subparagraphs (B) and (C) of subsection (e)(4) shall apply to development of a standard under this paragraph.

"Acceptance of Certain Existing Standards

"(d)(1) If the Secretary—

"(A) determines that a performance standard has been issued or adopted or is being developed by any Federal agency or by any other qualified entity or receives a performance standard submitted pursuant to a notice published pursuant to subsection (c), and

"(B) determines that such performance standard is based upon scientific data and information and has been subjected to scientific consideration,

he may, in lieu of accepting any offer to develop such a standard pursuant to a notice published pursuant to subsection (c), accept such standard as a proposed performance standard for such device or as a basis upon which a proposed performance standard may be developed.

"(2) If a standard is submitted to the Secretary pursuant to a notice published pursuant to subsection (c) and the Secretary does not accept such standard, he shall publish in the Federal Register notice of that fact together with the reasons therefor.

"Acceptance of Offer To Develop Standard

"(e)(1) Except as provided by subsections (c)(4) and (d), the Secretary shall accept one, and may accept more than one, offer to develop a proposed performance standard for a device pursuant to a notice published pursuant to subsection (c) if he determines that (A) the offeror is qualified to develop such a standard and is technically competent to undertake and complete the development of an appropriate performance standard within the period specified in the notice, and (B) the offeror will comply with procedures prescribed by regulations of the Secretary under paragraph (4) of this subsection. In determining the qualifications of an offeror to develop a standard, the Secretary shall take into account the offeror's financial stability, expertise, experience, and any potential conflicts of interest, including financial interest in the device for which such standard is to be developed, which may be relevant with respect to the offeror's qualifications.

"(2) The Secretary shall publish in the Federal Register the name and address of each person whose offer is accepted under paragraph (1) and a summary of the terms of such offer as accepted.

"(3) If such an offer is accepted, the Secretary may, upon application which may be made prior to the acceptance of the offer, agree to contribute to the offeror's cost in developing a proposed standard if the Secretary determines that such contribution is likely to result in a more satisfactory standard than would be developed without such contribution. The Secretary shall by regulation prescribe the items of cost in which he will participate, except that such items may not include the cost of construction (except minor remodeling) or the acquisition of land or buildings. Payments to an offeror under this paragraph may be made without regard to section 3648 of the Revised Statutes (31 U.S.C. 529).

"(4) The Secretary shall prescribe regulations governing the development of proposed standards by persons whose offers are accepted under paragraph (1). Such regulations shall, notwithstanding subsection (b)(A) of section 553 of title 5, United States Code, be promulgated in accordance with the requirements of that section for notice and opportunity for participation and shall—

"(A) require that performance standards proposed for promulgation be supported by such test data or other documents or mate-

rials as the Secretary may reasonably require to be obtained;

"(B) require that notice be given to interested persons of the opportunity to participate in the development of such performance standards and require the provision of such opportunity;

"(C) require the maintenance of records to disclose (i) the course of the development of performance standards proposed for promulgation, (ii) the comments and other information submitted by any person in connection with such development, including comments and information with respect to the need for such performance standards, and (iii) such other matters as may be relevant to the evaluation of such performance standards;

"(D) provide that the Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and other records, relevant to the expenditure of any funds contributed by the Secretary under paragraph (3); and

"(E) require the submissin of such periodic reports as the Secretary may require to disclose the course of the development of performance standards proposed for promulgation.

"(5) If an offer is made pursuant to a notice published pursuant to subsection (c) and the Secretary does not accept such offer, he shall publish in the Federal Register notice of that determination together with the reasons therefor.

"Development of Standard by Secretary After Publication of Subsection (c) Notice

"(f) If the Secretary has published a notice pursuant to subsection (c) and—

"(1) no person makes an offer or submits a standard pursuant to the notice;

"(2) the Secretary has not accepted an existing performance standard under subsection (d) or accepted an offer to develop a proposed performance standard pursuant to the notice; or

"(3) The Secretary has accepted an offer or offers to develop a proposed performance standard, but determines thereafter that—

"(A) the offeror under each such offer is unwilling or unable to continue the development of the performance standard which was the subject of the offer or offers, or

"(B) the performance standard which has been developed is not satisfactory,

and publishes notice of that determination in the Federal Register together with his reasons therefor;

then the Secretary may proceed to develop a proposed performance standard. The requirements described in subparagraphs (B) and (C) of subsection (e)(4) shall apply to the development of a standard by the Secretary under this subsection.

"Establishment of a Standard

"(g)(1)(A) After publication pursuant to subsection (c) of a notice respecting a performance standard for a device, the Secretary shall either—

"(i) publish, in the Federal Register in a notice of proposed rulemaking, a proposed performance standard for the device (I) developed by an offeror under such notice and accepted by the Secretary, (II) developed under subsection (c)(4), (III) accepted by the Secretary under subsection (d), or (IV) developed by him under subsection (f), or

"(ii) issue a notice in the Federal Register that the proceeding is terminated together with the reasons for such termination.

"(B) If the Secretary issues under subparagraph (A) (ii) a notice of termination of a proceeding to establish a performance standard for a device, he shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

"(2) A notice of proposed rulemaking for the establishment of a performance standard for a device under paragraph (1)(A)(i) shall set forth proposed findings with respect to the degree of the risk of illness or injury designed to be eliminated or reduced by the proposed standard and the benefit to the public from the device.

"(3)(A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory committee under paragraph (5), the Secretary shall (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (2), or (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. If a notice of termination is published, the Secretary shall, unless such notice is issued because the device is a banned device under section 516, initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

"(B) A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless (i) the Secretary determines that an earlier effective date is necessary for the protection of the public health and safety, or (ii) such standard has been established for a device which, effective upon the effective date of the standard, has been reclassified from class III to class II. Such date or dates shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade.

"(4)(A) The Secretary, upon his own initiative or upon petition of an interested person, may by regulation, promulgated in accordance with the requirements of paragraphs (2) and (3)(B) of this subsection, amend or revoke a performance standard.

"(B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if he determines, after affording all interested persons an opportunity for an informal hearing, that making it so effective is in the public interest. A proposed amendment of a perforance standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device which conforms to such standard without the change or changes provided by such proposed amendment.

"(5)(A) The Secretary—

"(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

"(ii) shall, upon the request of an interested person unless the Secretary finds the request to be without good cause or the request is made after the expiration of the period for submission of comments on such proposed regulation,

to an advisory committee of experts, established pursuant to subparagraph (B), for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subparagraph to an advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within sixty days of the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

"(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Each such committee shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Members of an advisory committee who are not officers or employees of the United States, while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day (including traveltime) they are so engaged;, and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate one of the members of each advisory committee to serve as chairman thereof. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

"PREMARKET APPROVAL

"General Requirement

"SEC. 515. (a) A class III device—

"(1) which is subject to a regulation promulgated under subsection (b); or

"(2) which is a class III device because of section 513(f),

is required to have, unless exempt under section 520(g), an approval under this section of an application for premarket approval.

"Regulation To Require Premarket Approval

"(b)(1) In the case of a class III device which—

"(A) was introduced or delivered for introduction into interstate commerce for commercial distribution on or before the date of enactment of this section; or

"(B) is (i) of a type so introduced or delivered and (ii) is substantially equivalent to another device within that type,

the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval.

"(2)(A) A proceeding for the promulgation of a regulation under paragraph (1) respecting a device shall be initiated by (i) publication in the Federal Register of a notice of proposed rulemaking. Such notice shall contain—

rials as the Secretary may reasonably require to be obtained;

"(B) require that notice be given to interested persons of the opportunity to participate in the development of such performance standards and require the provision of such opportunity;

"(C) require the maintenance of records to disclose (i) the course of the development of performance standards proposed for promulgation, (ii) the comments and other information submitted by any person in connection with such development, including comments and information with respect to the need for such performance standards, and (iii) such other matters as may be relevant to the evaluation of such performance standards;

"(D) provide that the Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and other records, relevant to the expenditure of any funds contributed by the Secretary under paragraph (3); and

"(E) require the submissin of such periodic reports as the Secretary may require to disclose the course of the development of performance standards proposed for promulgation.

"(5) If an offer is made pursuant to a notice published pursuant to subsection (c) and the Secretary does not accept such offer, he shall publish in the Federal Register notice of that determination together with the reasons therefor.

"Development of Standard by Secretary After Publication of Subsection (c) Notice

"(f) If the Secretary has published a notice pursuant to subsection (c) and—

"(1) no person makes an offer or submits a standard pursuant to the notice;

"(2) the Secretary has not accepted an existing performance standard under subsection (d) or accepted an offer to develop a proposed performance standard pursuant to the notice; or

"(3) The Secretary has accepted an offer or offers to develop a proposed performance standard, but determines thereafter that—

"(A) the offeror under each such offer is unwilling or unable to continue the development of the performance standard which was the subject of the offer or offers, or

"(B) the performance standard which has been developed is not satisfactory,

and publishes notice of that determination in the Federal Register together with his reasons therefor;

then the Secretary may proceed to develop a proposed performance standard. The requirements described in subparagraphs (B) and (C) of subsection (e)(4) shall apply to the development of a standard by the Secretary under this subsection.

"Establishment of a Standard

"(g)(1)(A) After publication pursuant to subsection (c) of a notice respecting a performance standard for a device, the Secretary shall either—

"(i) publish, in the Federal Register in a notice of proposed rulemaking, a proposed performance standard for the device (I) developed by an offeror under such notice and accepted by the Secretary, (II) developed under subsection (c)(4), (III) accepted by the Secretary under subsection (d), or (IV) developed by him under subsection (f), or

"(ii) issue a notice in the Federal Register that the proceeding is terminated together with the reasons for such termination.

"(B) If the Secretary issues under subparagraph (A) (ii) a notice of termination of a proceeding to establish a performance standard for a device, he shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

"(2) A notice of proposed rulemaking for the establishment of a performance standard for a device under paragraph (1)(A)(i) shall set forth proposed findings with respect to the degree of the risk of illness or injury designed to be eliminated or reduced by the proposed standard and the benefit to the public from the device.

"(3)(A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory committee under paragraph (5), the Secretary shall (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (2), or (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. If a notice of termination is published, the Secretary shall, unless such notice is issued because the device is a banned device under section 516, initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

"(B) A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless (i) the Secretary determines that an earlier effective date is necessary for the protection of the public health and safety, or (ii) such standard has been established for a device which, effective upon the effective date of the standard, has been reclassified from class III to class II. Such date or dates shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade.

"(4)(A) The Secretary, upon his own initiative or upon petion of an interested person, may by regulation, promulgated in accordance with the requirements of paragraphs (2) and (3)(B) of this subsection, amend or revoke a performance standard.

"(B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if he determines, after affording all interested persons an opportunity for an informal hearing, that making it so effective is in the public interest. A proposed amendment of a perforance standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device which conforms to such standard without the change or changes provided by such proposed amendment.

"(5)(A) The Secretary—

"(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

"(ii) shall, upon the request of an interested person unless the Secretary finds the request to be without good cause or the request is made after the expiration of the period for submission of comments on such proposed regulation,

to an advisory committee of experts, established pursuant to subparagraph (B), for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subparagraph to an advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within sixty days of the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

"(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Each such committee shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Members of an advisory committee who are not officers or employees of the United States, while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate one of the members of each advisory committee to serve as chairman thereof. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

"PREMARKET APPROVAL

"General Requirement

"SEC. 515. (a) A class III device—

"(1) which is subject to a regulation promulgated under subsection (b); or

"(2) which is a class III device because of section 513(f),

is required to have, unless exempt under section 520(g), an approval under this section of an application for premarket approval.

"Regulation To Require Premarket Approval

"(b)(1) In the case of a class III device which—

"(A) was introduced or delivered for introduction into interstate commerce for commercial distribution on or before the date of enactment of this section; or

"(B) is (i) of a type so introduced or delivered and (ii) is substantially equivalent to another device within that type,

the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval.

"(2)(A) A proceeding for the promulgation of a regulation under paragraph (1) respecting a device shall be initiated by the publication in the Federal Register of a notice of proposed rulemaking. Such notice shall contain—

"(i) the proposed regulation;

"(ii) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved application for premarket approval and the benefit to the public from use of the device;

"(iii) opportunity for the submission of comments on the proposed regulation and the proposed findings; and

"(iv) opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

"(B) If, after publication of a notice under subparagraph (A), the Secretary receives a request for a change in the classification of a device, he shall, after consultation with the appropriate panel under section 513, by order published in the Federal Register either deny the request for change in classification or give notice of his intent to initiate such a change under section 513(e).

"(3) After the expiration of the period for comment on a proposed regulation and proposed findings published under paragraph (2) and after consideration of comments submitted on such proposed regulation and findings, the Secretary shall (A) promulgate such regulation and publish in the Federal Register findings on the matters referred to in paragraph (2)(A)(ii), or (B) publish a notice terminating the proceeding for the promulgation of the regulation together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

"(4) The Secretary, upon his own initiative or upon petition of an interested person, may by regulation amend or revoke any regulation promulgated under this subsection. A regulation to amend or revoke a regulation under this subsection shall be promulgated in accordance with the requirements prescribed by this subsection for the promulgation of the regulation to be amended or revoked.

"Application for Premarket Approval

"(c)(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—

"(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

"(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

"(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

"(D) an identifying reference to any performance standard under section 514 which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

"(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

"(F) specimens of the labeling proposed to be used for such device; and

"(G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 513, may require.

"(2) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary shall refer such application to the appropriate panel under section 513 for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the pplication, together with all underlying data and the reasons or basis for the recommendation.

Action on an Application for Premarket Approval

"(d)(1)(A) As promptly as possible, but in no event later than one hundred and eighty days after the receipt of an application under subsection (c) (except as provided in Section 520(1)(3)(d)(ii) or unless, in accordance with subparagraph (B)(i), an additional period is agreed upon by the Secretary and the applicant), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

"(i) issue an order approving the application if he finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

"(ii) deny approval of the application if he finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

"(B)(i) The Secretary may not enter into an agreement to extend the period in which to take action with respect to an application submitted for a device subject to a regulation promulgated under subsection (b) unless he finds that the continued availability of the device is necessary for the public health.

"(ii) An order approving an application for a device may require as a condition to such approval that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 520(e).

"(2) The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the application and any other information before him with respect to such device, the Secretary finds that—

"(A) there is a lack of a showing of reasonable assurance that such device is safe under th conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

"(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

"(C) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing and installation of such device do not conform to the requirements of section 520(f);

"(D) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

"(E) such device is not shown to conform in all respects to a performance standard in effect under section 514 compliance with which is a condition to approval of the application and there is a lack of adequate information to justify the deviation from such standard.

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary).

"(3) An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g), and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g), of an order of the Secretary approving an application.

"Withdrawal of Approval of Application

"(e)(1) The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 513, and after due notice and opportunity for informal hearing to the holder of an approved application for a device, issue an order withdrawing approval of the application if the Secretary finds—

"(A) that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

"(B) on the basis of new information before him with respect to such device, evaluated together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

"(C) that the application contained or was accompanied by an untrue statement of a material fact;

"(D) that the applicant (i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 519(a), (ii) has refused to permit access to, or copying or vertification of, such records as required by section 704, or (iii) has not complied with the requirements of section 510;

"(E) on the basis of new information before him with respect to such device, evaluated together with the evidence before him when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such device do not conform with the requirements of section 520(f) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

"(F) on the basis of information before him, evaluated together with the evidence before him when the application was approved, that the labeling of such device, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

"(G) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that such device is not shown to conform in all respects to a performance standard which is in effect under section 514 compliance with which was a condition to approval of the application and that there is a lack of adequate information to justify the deviation from such standard.

"(2) The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such withdrawal, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g).

"Product Development Protocol

"(f)(1) In the case of a class III device which is required to have an approval of an application submitted under subsection (c), such device shall be considered as having such an approval if a notice of completion of testing conducted in accordance with a product development protocol approved under paragraph (4) has been declared completed under paragraph (6).

"(2) Any person may submit to the Secretary a proposed product development protocol with respect to a device. Such a protocol shall be accompanied by data supporting it. If, within thirty days of the receipt of such a protocol, the Secretary determines that it appears to be appropriate to apply the requirements of this subsection to the device with respect to which the protocol is submitted, he shall refer the proposed protocol to the appropriate panel under section 513 for its recommendation respecting approval of the protocol.

"(3) A proposed product development protocol for a device may be approved only if—

"(A) the Secretary determines that it is appropriate to apply the requirements of this subsection to the device in lieu of the requirement of approval of an application submitted under subsection (c): and

"(B) the Secretary determines that the proposed protocol provides—

"(i) a description of the device and the changes which may be made in the device,

"(ii) a description of the preclinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the commencement of clinical trials of the device, and (II) any permissible variations in preclinical trials and the results therefrom,

"(iii) a description of the clinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the filing of a notice of completion of the requirements of the protocol, and (II) any permissible variations in such trials and the results therefrom,

"(iv) a description of the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, and, when relevant, packing and installation of the device,

"(v) an identifying reference to any performance standard under section 514 to be applicable to any aspect of such device,

"(vi) if appropriate, specimens of the labeling proposed to be used for such device,

"(vii) such other information relevant to the subject matter of the protocol as the Secretary, with the concurrence of the appropriate panel or panels under section 513, may require, and

"(viii) a requirement for submission of progress reports and, when completed, records of the trials conducted under the protocol which records are adequate to show compliance with the protocol.

"(4) The Secretary shall approve or disapprove a proposed product development protocol submitted under paragraph (2) within one hundred and twenty days of its receipt unless an additional period is agreed upon by the Secretary and the person who submitted the protocol Approval of a protocol or denial of approval of a protocol is final agency action subject to judicial review under chapter 7 of title 5, United States Code.

"(5) At any time after a product development protocol for a device has been approved pursuant to paragraph (4), the person for whom the protocol was approved may submit a notice of completion—

"(A) stating (i) his determination that the requirements of the protocol have been fulfilled and that, to the best of his knowledge, there is no reason bearing on safety or effectiveness why the notice of completion should not become effective, and (ii) the data and other information upon which such determination was made, and

"(B) setting forth the results of the trials required by the protocol and all the information required by subsection (c)(1).

"(6)(A) The Secretary may, after providing the person who has an approved protocol an opportunity for an informal hearing and at any time prior to receipt of notice of completion of such protocol, issue a final order to revoke such protocol if he finds that—

"(i) such person has failed substantially to comply with the requirements of the protocol,

"(ii) the results of the trials obtained under the protocol differ so substantially from the results required by the protocol that further trials cannot be justified, or

"(iii) the results of the trials conducted under the protocol or available new information do not demonstrate that the device tested under the protocol does not present an unreasonable risk to health and safety.

"(B) After the receipt of a notice of completion of an approved protocol the Secretary shall, within the ninety-day period beginning on the date such notice is received, by order either declare the protocol completed or declare it not completed. An order declaring a protocol not completed may take effect only after the Secretary has provided the person who has the protocol opportunity for an informal hearing on the order. Such an order may be issued only if the Secretary finds—

"(i) such person has failed substantially to comply with the requirements of the protocol,

"(ii) the results of the trials obtained under the protocol differ substantially from the results required by the protocol, or

"(iii) there is a lack of a showing of reasonable assurance of the safety and effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

"(C) A final order issued under subparagraph (A) or (B) shall be in writing and shall contain the reasons to support the conclusions thereof.

"(7) At any time after a notice of completion has become effective, the Secretary may issue an order (after due notice and opportunity for an informal hearing to the person for whom the notice is effective) revoking the approval of a device provided by a notice of completion which has become effective as provided in subparagraph (A) if he finds that any of the grounds listed in subparagraphs (A) through (G) of subsection (e)(1) of this section apply. Each reference in such subparagraphs to an application shall be considered for purposes of this paragraph as a reference to a protocol and the notice of completion of such protocol, and each reference to the time when an application was approved shall be considered for purposes of this paragraph as a reference to the time when a notice of completion took effect.

"(8) A person who has an approved protocol subject to an order issued under paragraph (6)(A) revoking such protocol, a person who has an approved protocol with respect to which an order under paragraph (6)(B) was issued declaring that the protocol had not been completed, or a person subject to an order issued under paragraph (7) revoking the approval of a device may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such order, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g).

"Review

"(g)(1) Upon petition for review of—

"(A) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

"(B) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking approval of a device,

the Secretary shall, unless he finds the petition to be without good cause or unless a petition for review of such order has been submitted under paragraph (2), hold a hearing, in accordance with section 554 of title 5 of the United States Code, on the order. The panel or panels which considered the application, protocol, or device subject to such order shall designate a member to appear and testify at any such hearing upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this requirement does not preclude any other member of the panel or panels from appearing and testifying at any such hearing. Upon completion of such hearing and after considering the record established in such hearing, the Secretary shall issue an order either affirming the order subject to the hearing or reversing such order and, as appropriate, approving or denying approval of the application, reinstating the application's approval, approving the protocol, or placing in effect a notice of completion.

"(2)(A) Upon petition for review of—

"(i) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

"(ii) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device,

the Secretary, unless he is required to provide review of such order under paragraph (1), shall refer the application or protocol subject to the order and the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order. The advisory committee shall, after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report shall be promptly supplied by the Secretary to any person who petitioned for such referral to the advisory committee.

"(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee and individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Each such committee shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Members of an advisory committee (other than officers or employees of the United States), while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent for grade GS-18 of the General Schedule for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as

authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate the chairman of an advisory committee from its members. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

"(C) The Secretary shall make public the report and recommendation made by an advisory committee with respect to an application and shall by order, stating the reasons therefor, either affirm the order referred to the advisory committee or reverse such order and, if appropriate, approve or deny approval of the application, reinstate the application's approval, approve the protocol, or place in effect a notice of completion.

"Service of Orders

"(h) Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary, or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last known address in the records of the Secretary.

"BANNED DEVICES

"General Rule

"SEC. 516. (a) Whenever the Secretary finds, on the basis of all available data and information and after consultation with the appropriate panel or panels under section 513, that—

"(1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and

"(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determines can be corrected or eliminated by labeling or change in labeling, such labeling or change in labeling was not done within a reasonable time after written notice to the manufacturer from the Secretary specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling is to be done;

he may initiated a proceeding to promulgate a regulation to make such device a banned device. The Secretary shall afford all interested persons opportunity for an informal hearing on a regulation proposed under this subsection.

"Special Effective Date

"(b) The Secretary may declare a proposed regulation under subsection (a) to be effective upon its publication in the Federal Register and until the effective date of any final action taken respecting such regulation if (1) he determines, on the basis of all available data and information, that the deception or risk of illness or injury associated with the use of the device which is subject to the regulation presents an unreasonable, direct, and substantial danger to the health of individuals, and (2) before the date of the publication of such regulation, the Secretary notifies the manufacturer of such device that such regulation is to be made so effective. If the Secretary makes a proposed regulation so effective, he shall, as expeditiously as possible, give interested persons prompt notice of his action under this subsection, provide reasonable opportunity for an informal hearing on the proposed regulation, and either affirm, modify, or revoke such proposed regulation.

"JUDICIAL REVIEW

"Application of Section

"SEC. 517. (a) Not later than thirty days after—

"(1) the promulgation of a regulation under section 513 classifying a device in class I or changing the classification of a device to class I or an order under subsection (f)(2) of such section classifying a device or denying a petition for classification of a device,

"(2) the promulgation of a regulation under section 514 establishing, amending, or revoking a performance standard for a device,

"(3) the issuance of an order under section 514(b)(2) or 515(b)(2)(B) denying a request for reclassification of a device,

"(4) the promulgation of a regulation under paragraph (3) of section 515(b) requiring a device to have an approval of a premarket application, a regulation under paragraph (4) of that section amending or revoking a regulation under paragraph (3), or an order pursuant to section 515(g)(1) or 515(g)(2)(C),

"(5) the promulgation of a regulation under section 516 (other than a proposed regulation made effective under subsection (b) of such section upon the regulation's publication) making a device a banned device,

"(6) the issuance of an order under section 520(f)(2), or

"(7) an order under section 520(g)(4) disapproving an application for an exemption of a device for investigational use or an order under section 520(g)(5) withdrawing such an exemption for a device,

any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial review of such regulation or order. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based his regulation or order as provided in section 2112 of title 28, United States Code. For purposes of this section, the term 'record' means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to such regulation or order, proceedings of any panel or advisory committee with respect to such regulation or order, any hearing held with respect to such regulation or order, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

"Additional Data, Views, and Arguments

"(b) If the petitioner applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceedings before the Secretary, the court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions. The Secretary may modify his findings, or make new findings by reason of the additional data, views, or arguments so taken and shall file with the court such modified or new findings, and his recommendation, if any, for the modification or setting aside of the regulation or order being reviewed, with the return of such additional data, views, or arguments.

Standard for Review

"(c) Upon the filing of the petition under subsection (a) of this section for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided in such chapter. A regulation described in paragraph (2) or (5) of subsection (a) and an order issued after the review provided by section 515(g) shall not be affirmed if it is found to be unsupported by substantial evidence on the record taken as a whole.

"Finality of Judgments

"(d) The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28 of the United States Code.

"Other Remedies

"(e) The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law.

"Statement of Reasons

"(f) To facilitate judicial review under this section or under any other provision of law of a regulation or order issued under section 513, 514, 515, 516, 518, 519, 520, or 521 each such regulation or order shall contain a statement of the reasons for its issuance and the basis in the record of the proceedings held in connection with its issuance, for its issuance.

"NOTIFICATION AND OTHER REMEDIES

"Notification

"SEC. 518. (a) If the Secretary determines that—

"(1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and

"(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this Act (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk. An order under this subsection shall require that the individuals exposed to the risk with respect to which the order is to be issued be included in the persons to be notified of the risk unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notification. If the Secretary makes such a determination with respect to such individuals, the order shall require that the health professionals who prescribe or use the device notify the individuals whom the health professionals treated with the device of the risk presented by the device and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

"REPAIR, REPLACEMENT, OR REFUND

"(b)(1)(A) If, after affording opportunity for an informal hearing, the Secretary determines that—

"(i) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health,

"(ii) there are reasonable grounds to believe that the device was not properly designed and manufactured with reference to the state of the art as it existed at the time of its design and manufacture,

"(iii) there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a manufacturer, importer, distributor, or retailer of the device to exercise due care in the installation, maintenance, repair, or use of the device, and

"(iv) the notification authorized by subsection (a) would not by itself be sufficient to eliminate the unreasonable risk and action described in paragraph (2) of this subsection is necessary to eliminate such risk,

the Secretary may order the manufacturer, importer, or any distributor of such device, or any combination of such persons, to submit to him within a reasonable time a plan for taking one or more of the actions described in paragraph (2). An order issued under the preceding sentence which is directed to more than one person shall specify which person may decide which action shall be taken under such plan and the person specified shall be the person who the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears such responsibility or the Secretary determines that the protection of the public health requires that such decision be made by a person (including a device user or health professional) other than the person he determines bears such responsibility.

"(B) The Secretary shall approve a plan submitted pursuant to an order issued under subparagraph (A) unless he determines (after affording opportunity for an informal hearing) that the action or actions to be taken under the plan or the manner in which such action or actions are to be taken under the plan will not assure that the unreasonable risk with respect to which such order was issued will be eliminated. If the Secretary disapproves a plan, he shall order a revised plan to be submitted to him within a reasonable time. If the Secretary determines (after affording opportunity for an informal hearing) that the revised plan is unsatisfactory or if no revised plan or no initial plan has been submitted to the Secretary within the prescribed time, the Secretary shall (i) prescribe a plan to be carried out by the person or persons to whom the order issued under subparagraph (A) was directed, or (ii) after affording an opportunity for an informal hearing, by order prescribe a plan to be carried out by a person who is a manufacturer, importer, distributor, or retailer of the device with respect to which the order was issued but to whom the order under subparagraph (A) was not directed.

"(2) The actions which may be taken under a plan submitted under an order issued under paragraph (1) are as follows:

"(A) To repair the device so that it does not present the unreasonable risk of substantial harm with respect to which the order under paragraph (1) was issued.

"(B) To replace the device with a like or equivalent device which is in conformity with all applicable requirements of this Act.

"(C) To refund the purchase price of the device (less a reasonable allowance for use if such device has been in the possession of the device user for one year or more—

"(i) at the time of notification ordered under subsection (a), or

"(ii) at the time the device user receives actual notice of the unreasonable risk with respect to which the order was issued under paragraph (1),

whichever first occurs).

"(3) No charge shall be made to any person (other than a manufacturer, importer, distributor or retailer) who avails himself of any remedy, described in paragraph (2) and provided under an order issued under paragraph (1), and the person subject to the order shall reimburse each person (other than a manufacturer, importer, distributor, or retailer) who is entitled to such a remedy for any reasonable and foreseeable expenses actually incurred by such person in availing himself of such remedy.

"Reimbursement

"(c) An order issued under subsection (b) with respect to a device may require any person who is a manufacturer, importer, distributor, or retailer of the device to reimburse any other person who is a manufacturer, importer, distributor, or retailer of such device for such other person's expenses actually incurred in connection with carrying out the order if the Secretary determines such reimbursement is required for the protection of the public health. Any such requirement shall not affect any rights or obligations under any contract to which the person receiving reimbursement or the person making such reimbursement is a party.

"Effect on Other Liability

"(d) Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

"RECORDS AND REPORTS ON DEVICES

"General Rule

"SEC. 519. (a) Every person who is a manufacturer, importer, or distributor of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed under the preceding sentence—

"(1) shall not impose 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;

"(2) which prescribe the procedure for making requests for reports or information shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

"(3) which require submission of a report or information to the Secretary shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information;

"(4) may not require that the identity of any patient be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under this Act; and

"(5) may not require a manufacturer, importer, or distributor of a class I device to—

"(A) maintain records respecting information not in the possession of the manufacturer, importer, or distributor, or

"(B) to submit to the Secrteary any report or information—

"(i) not in the possession of the manufacturer, importer, or distributor, or

"(ii) on a periodic basis,

unless such report or information is necessary to determine if the device should be reclassified or if the device is adulterated or misbranded.

In prescribing such regulations, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (4) of this subsection continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

"Person Exempt

"(b) Subsection (a) shall not apply to—

"(1) any practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of his professional practice;

"(2) any person who manufactures or imports devices intended for use in humans solely for such person's use in research or teaching and not for sale (including any person who uses a device under an exemption granted under section 520(g)); and

"(3) any other class of persons as the Secretary may by regulation exempt from subsection (a) upon a finding that compliance with the requirements of such subsection by such class with respect to a device is not necessary to (A) assure that a device is not adulterated or misbranded or (B) otherwise to assure its safety, and effectiveness.

"GENERAL PROVISIONS RESPECTING CONTROL OF DEVICES INTENDED FOR HUMAN USE

"General Rule

"SEC. 520. (a) Any requirement authorized by or under section 501, 502, 510, or 519 applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 513, 514, or 515 or under subsection (g) of this section, and any requirement established by or under section 501, 503, 510, or 519 which is inconsistent with a requirement imposed on such device under section 514 or 515 or under subsection (g) of this section shall not apply to such device.

"Custom Devices

"(b) Sections 514 and 515 do not apply to any device which, in order to comply with the order of a physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing) necessarily deviates from an otherwise applicable performance standard or requirement prescribed by or under section 514 or 515 if (1) the device is not generally available in finished form for purchase or for dispensing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and (2) such device—

"(A) (i) is intended for use by a patient named in such order of such physician or dentist (or other specially qualified person so designated), or

"(ii) is intended solely for use by (I) such physician or dentist (or other specially qualified person so designated) or (II) a person under his professional supervision in the course of the professional practice of such physician or dentist (or other specially qualified person so designated), and

"(B) is not generally available to or generally used by other physicians or dentists (or other specially qualified persons so designated).

"Trade Secrets

"(c) Any information reported to or otherwise obtained by the Secretary or his representative under section 513, 514, 515, 516, 518, 519, or 704 or under subsection (f) or (g) of this section which is exempt from disclosure pursuant to subsection (a) of section

552 of title 5, United States Code, by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device under section 513 from class III to class II or as the basis for the establishment of a performance standard under section 514 for a device reclassified from class III to class II, except that such information may be disclosed to other officers or employees concerned with carrying out this Act or when relevant in any proceeding under this Act (other than section 513 or 514 thereof).

"Notices and Findings

"(d) Each notice of proposed rulemaking under section 513, 514, 515, 516, 518, or 519, or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

"(1) the manner in which interested persons may examine data and other information on which the notice or findings is based, and

"(2) the period within which interested persons may present their comments on the notice or findings (including the need therefor) orally or in writing, which period shall be at least sixty days but may not exceed ninety days unless the time is extended by the Secretary by notice published in the Federal Register stating good cause therefor.

"Restricted Devices

"(e)(1) The Secretary may by regulation require that a device be restricted to sale or distribution—

"(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

"(B) upon such other conditions (other than any condition which would limit the use of a device to a particular category or categories of physicians defined by their training or experience) as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. A device subject to a regulation under this subsection is a restricted device.

"(2) A restricted device shall be deemed to be misbranded if its label fails to bear such appropriate statements of the restrictions as the Secretary may in such regulation prescribe.

"Good Manufacturing Practice Requirements

"(f)(1)(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this Act.

"(B) Before the Secretary may promulgate any regulation under subparagraph (A) he shall—

"(i) afford the advisory committee established under paragraph (3) an opportunity to submit recommendations to him with respect to the regulation proposed to be promulgated, and

"(ii) afford opportunity for an oral hearing.

The Secretary shall provide the advisory committee a reasonable time to make its recommendations with respect to proposed regulations under subparagraph (A).

"(2)(A) Any person subject to any requirement prescribed by regulations under paragraph (1) may petition the Secretary for an exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as he shall prescribe and shall—

"(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this Act.

"(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, facilities, and controls prescribed by the requirement, and

"(iii) contain such other information as the Secretary shall prescribe.

"(B) The Secretary may refer to the advisory committee established under paragraph (3) any petition submitted under subparagraph (A). The advisory committee shall report its recommendations to the Secretary with respect to a petition referred to it within sixty days of the date of the petition's referral. Within sixty days after—

"(i) the date the petition was submitted to the Secretary under subparagraph (A), or

"(ii) if the petition was referred to an advisory committee, the expiration of the sixty-day period beginning on the date the petition was referred to the advisory committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

"(C) The Secretary may approve—

"(i) a petition for an exemption for a device from a requirement if he determines that compliance with such requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this Act, and

"(ii) a petition for a variance for a device from a requirement if he determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, controls, and facilities prescribed by the requirement are insufficient to assure that the device will be safe and effective and otherwise in compliance with this Act.

An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of the device to be granted the variance under the petition as may be necessary to assure that the device will be safe and effective and otherwise in compliance with this Act.

"(D) After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

"(3) The Secretary shall establish an advisory committee for the purpose of advising and making recommendations to him with respect to regulations proposed to be promulgated under paragraph (1)(A) and the approval or disapproval of petitions submitted under paragraph (2). The advisory committee shall be composed of 9 members as follows:

"(A) Three of the members shall be appointed from persons who are officers or employees of any State or local government or of the Federal Government.

"(B) Two of the members shall be appointed from persons who are representative of interests of the device manufacturing industry; two of the members shall be appointed from persons who are representative of the interests of physicians and other health professionals; and two of the members shall be representative of the general public.

Members of the advisory committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate one of the members of the advisory committee to serve as its chairman. The Secretary shall furnish the advisory committee with clerical and other assistance. Section 14 of the Federal Advisory Committee Act shall not apply with respect to the duration of the advisory committee established under this paragraph.

"Exemption for Devices for Investigational Use

"(g)(1) It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

"(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on the date of the enactment of this section, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 502, 510, 514, 515, 516, 519, or 706 or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

"(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

"(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

"(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

"(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

"(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device subject to the exemption during testing conducted in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data

to obtain approval for the commercial distribution of such device.

"(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption—

"(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing—

"(i) to the local institutional review committee which has been established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

"(ii) to the Secretary, if—

"(I) no such committee exists, or

"(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the plan for such testing has been approved by such committee),

for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

"(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by a local institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

"(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

"(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except where, subject to such conditions as the Secretary may prescribe, the investigator conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative. The determination required by subparagraph (D) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

"(4)(A) An application, submitted in accordance with the procedures prescribed by regulations under paragraph (2), for an exemption for a device (other than an exemption from section 516) shall be deemed approved on the thirtieth day after the submission of the application to the Secretary unless on or before such day the Secretary by order disapproves the application and notifies the applicant of the disapproval of the application.

"(B) The Secretary may disapprove an application only if he finds that the investigation with respect to which the application is submitted does not conform to procedures and conditions prescribed under regulations under paragraph (2). Such a notification shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application and afford the applicant opportunity for an informal hearing on the disapproval order.

"(5) The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the conditions applicable to the device under this subsection for such exemption are not met. Such an order may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health.

"Release of Safety and Effectiveness Information

"(h)(1) The Secretary shall promulgate regulations under which a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the Secretary and which was the basis for—

"(A) an order under section 515(d)(1)(A) approving an application for premarket approval for the device or denying approval of such an application or an order under section 515(e) withdrawing approval of such an application for the device,

"(B) an order under section 515(f)(6)(A) revoking an approved protocol for the device, an order under section 515(f)(6)(B) declaring a protocol for the device completed or not completed, or an order under section 515(f)(7) revoking the approval of the device, or

"(C) an order approving an application under subsection (g) for an exemption for the device from section 516 or an order disapproving, or withdrawing approval of, an application for an exemption under such subsection for the device,

shall be made available to the public upon issuance of the order. Summaries of information made available pursuant to this paragraph respecting a device shall include a summary of any information respecting adverse effects on health of the device.

"(2) The Secretary shall promulgate regulations under which each advisory committee established under section 515(g)(2)(B) shall make available to the public a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the advisory committee and which was the basis for its recommendation to the Secretary made pursuant to section 515(g)(2)(A). A summary of information upon which such a recommendation is based shall be made available pursuant to this paragraph only after the issuance of the order with respect to which the recommendation was made and each such summary shall include a summary of any information respecting the adverse effects on health of the device subject to such order.

"(3) Any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection may not be used to establish the safety or effectiveness of another device for purposes of this Act by any person other than the person who submitted the information so made available.

"Proceedings of Advisory Panels and Committees

"(i) Each advisory panel under section 513 and each advisory committee established under section 514(g)(5)(B) or section 515(g) shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made pursuant to this subsection information which under subsection (c) of this section is to be considered confidential.

"Traceability Requirements

"(j) No regulation under this Act may impose on a type or class of device requirements for the traceability of such type or class of device unless such requirements are necessary to assure the protection of the public health.

"Research and Development

"(k) The Secretary may enter into contracts for research, testing, and demonstrations respecting devices and may obtain devices for research, testing, and demonstration purposes without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5).

"Transitional Provisions for Devices Considered as New Drugs or Antibiotic Drugs

"(l)(1) Any device intended for human use—

"(A) for which on the date of enactment of the Medical Device Amendments of 1975 (hereinafter in this subsection referred to as the 'enactment date') an approval of an application submitted under section 505(b) was in effect;

"(B) for which such an application was filed on or before the enactment date and with respect to which application no order of approval or refusing to approve had been issued on such date under subsection (c) or (d) of such section;

"(C) for which on the enactment date an exemption under subsection (i) of such section was in effect;

"(D) which is within a type of device described in subparagraph (A), (B), or (C) and is substantially equivalent to another device within that type;

"(E) which the Secretary in a notice published in the Federal Register before the enactment date has declared to be a new drug subject to section 505; or

"(F) with respect to which on the enactment date an action is pending in a United States court under section 302, 303, or 304 for an alleged violation of a provision of section 301 which enforces a requirement of section 505 or for an alleged violation of section 505(a),

is classified in class III unles the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

"(2) The manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Except as provided in paragraph (3)(D)(ii), within one hundred and eighty days after the filing of a petition under this paragraph and after affording the petitioner an opportunity for an informal hearing, the Secretary shall, after consultation with the appropriate panel under section 513, by order either deny the petition or order the classification, in accordance with the criteria prescribed by section 513(a)(1)(A) or 513(a)(1)(B), of the device in class I or class II.

"(3)(A) In the case of a device which is described in paragraph (1)(A) and which is in class III—

"(i) such device shall on the enactment date be considered a device with an approved application under section 515, and

"(ii) the requirements applicable to such device before the enactment date under section 505 shall continue to apply to such device until changed by the Secretary as authorized by this Act.

"(B) In the case of a device which is described in paragraph (1)(B) and which is in class III, an application for such device shall

be considered as having been filed under section 515 on the enactment date. The period in which the Secretary shall act on such application in accordance with section 515 (d) (1) shall be one hundred and eighty days (or such greater period as the Secretary and the applicant may agree upon after the Secretary has made the finding required by section 515(d) (1) (B) (i)) less the number of days in the period beginning on the date an application for such device was filed under section 505 and ending on the enactment date. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

"(C) A device which is described in paragraph (1) (C) and which is in class III shall be considered a new drug until the expiration of the ninety-day period beginning on the date of the promulgation of regulations under subsection (g) of this section. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

"(D) (i) Except as provided in clause (ii), a device which is described in subparagraph (D), (E), or (F) of paragraph (1) and which is in class III is required to have on and after the enactment date in effect an approved application under section 515.

"(ii) If—

"(I) a petition is filed under paragraph (2) for a device described in subparagraph (D), (E), or (F) of paragraph (1), or

"(II) an application for premarket approval is filed under section 515 for such a device,

within the sixty-day period beginning on the enactment date (or within such greater period as the Secretary, after making the finding required under section 515(d) (1) (E), and the petitioner or applicant may agree upon), the Secretary shall act on such petition or application in accordance with paragraph (2) or section 515 except that the period within which the Secretary must act on the petition or application shall be within the one hunderd and twenty-day period beginning on the date the petition or application is filed. If such a petition or application is filed within such sixty-day (or greater) period, clause (i) of this subparagraph shall not apply to such device before the expiration of such one hundred and twenty-day period, or if such petition is denied or such application is denied approval, before the date of such denial, whichever occurs first.

"(4) Any device intended for human use which on the enactment date was subject to the requirements of section 507 shall be subject to such requirements as follows:

"(A) In the case of such a device which is classified into class I, such requirements shall apply to such device until the effective date of the regulation classifying the device into such class.

"(B) In the case of such a device which is classified into class II, such requirements shall apply to such device until the effective date of a performance standard applicable to the device under section 514.

"(C) In the case of such a device which is classified into class III, such requirements shall apply to such device until the date on which the device is required to have in effect an approved application under section 515.

"STATE AND LOCAL REQUIREMENTS RESPECTING DEVICES

"General Rule

"SEC. 521. (a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

"(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

"(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

"Exempt Requirements

"(b) Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

"(1) the requirement is more stringent than a requirement under this Act which would be applicable to the device if an exemption were not in effect under this subsection; or

"(2) the requirement—

"(A) is required by compelling local conditions, and

"(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this Act."

CONFORMING AMENDMENTS

Amendments to Section 201

SEC. 3. (a) (1) (A) Paragraph (h) of section 201 is amended to read as follows:

"(h) (1) The term 'device' (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

"(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them.

"(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

"(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes."

(B) Section 15(d) of the Federal Trade Commission Act is amended to read as follows:

"(d) The term 'device' (except when used in subsection (a) of this section) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

"(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

"(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

"(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.".

(2) Section 201 is amended by adding at the end the following:

"(y) The term 'informal hearing' means a hearing which is not subject to section 554, 556, or 557 of title 5 of the United States Code and which provides for the following:

"(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department of Health, Education, and Welfare who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

"(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

"(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

"(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

"(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

"(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.".

Amendments to Section 301

(b) (1) Section 301 is amended by adding at the end the following new paragraphs:

"(q) (1) The failure or refusal to (A) comply with any requirement prescribed under section 518 or 520(g), or (B) furnish any notification or other material or information required by or under section 519 or 520(g).

"(2) With respect to any device, the submission of any report that is required by or under this Act that is false or misleading in any material respect.

"(r) The introduction or delivery for introduction into interstate commerce for export of a device or drug in violation of an order issued under section 801(d) (7).".

(2) Section 301(e) is amended by striking out "or" before "512" and by inserting after "(m)" a comma and the following: "515(f), or 519".

(3) Section 301(j) is amended by inserting "510," before "512", by inserting "513, 514, 515, 516, 518, 519, 520(g)," before "704", and by striking out "or 706" and inserting in lieu thereof "706, or 707".

(4) Section 301(l) is amended (A) by inserting "or device" after "drug" each time it occurs, and (B) by striking out "505" and inserting in lieu thereof "505, 515, or 520(g), as the case may be".

Amendments to Section 304

(c) Section 304(a) is amended (1) by striking out "device," in paragraph (1), and (2) by striking out "and" before "(C)" in paragraph (2), and (3) by striking out the period at the end of that paragraph and inserting in lieu thereof a comma and the following: "and (D) any adulterated or misbranded device.".

Amendments to Section 501

(d) Section 501 is amended by adding at the end the following new paragraphs:

"(e) If it is, or purports to be or is represented as, a device which is subject to a performance standard established under section 514, unless such revice is in all respects in conformity with such standard.

"(f) (1) If it is a class III device—

"(A) (i) which is required by a regulation promulgated under subsection (b) of section 515 to have an approval under such section of an application for premarket approval and which is not exempt from section 515 under section 520(g), and

"(ii) (I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the Secretary within the ninety-day period beginning on the date of the promulgation of such regulation, or

"(II) for which such an application was filed and approval of the application has been denied or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

"(B) (i) which was initially classified under section 513(f) into class III, which under section 515(a) is required to have an approval of an application for premarket approval, and which is not exempt from section 515 under section 520(g), and

"(ii) which does not have an approval under section 515 of an application for premarket approval; or

"(C) which was initially classified under section 520(l) into class III, which under such section is required to have in effect an approved application under section 515, and which does not have such an application in effect.

"(2) (A) In the case of a device initially classified under section 513(f) into class III and intended solely for investigational use, paragraph (1) (B) shall not apply with respect to such device during the period ending on the ninetieth day after the date of the promulgation of the regulations prescribing the procedures and conditions required by section 520(g) (2).

"(B) In the case of a device subject to a regulation promulgated under subsection (b) of section 515, paragraph (1) shall not apply with respect to such device during the period ending—

"(i) on the last day of the thirtieth calendar month beginning after the month in which the classification of the device in class III became effective under section 513, or

"(ii) on the ninetieth day after the date of the promulgation of such regulation,

whichever occurs later.

"(g) If it is a banned device.

"(h) If it is a device and the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 520(f) (1) or an applicable condition prescribed by an order under section 520(f) (2).

"(i) If it is a device for which an exemption has been granted under section 520(g) for investigational use and the person who was granted such an exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section."

Amendments to Section 502

(c) (1) Section 502 is amended by adding at the end the following new paragraphs:

"(q) In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold otherwise distributed in violation of regulations prescribed under section 520(e).

"(r) In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in section 502 (e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specifics made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing. Except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52-55). This paragraph shall not be applicable to any printed matter which the Secertary determines to be labeling as defined in section 201(m).

"(s) If it is a device subject to a performance standard established under section 514, unless it bears such labeling as may be prescribed in such performance standard.

"(t) If it is a device and there was a failure or refusal (1) to comply with any requirement prescribed under section 518 respecting the device, or (2) to furnish any notification or other material or information required by or under section 519 respecting the device.".

(2) Section 502(j) is amended by inserting "or manner" after "dosage".

Amendments to Section 801

(f) (1) Section 801(d) is amended to read as follows:

"(d) (1) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it—

"(A) accords to the specifications of the foreign purchaser,

"(B) is not in conflict with the laws of the country to which it is intended for export,

"(C) is labeled on the outside of the shipping package that it is intended for export, and

"(D) is not sold or offered for sale in domestic commerce.

"(2) Paragraph (1) does not apply to any device which does not comply with an applicable requirement of section 514 or 515 or which is a banned device under section 516 unless, in addition to the requirements of paragraph (1), the device meets the following requirements:

"(A) If the device is intended for export to a country which has an appropriate health agency to review the device and authorize or approve it as safe for its intended use (including investigational use) within such country, such device may be exported to such country only if—

"(i) the device is so reviewed and authorized or approved by such agency, and

"(ii) notification with respect to the export of the device has been provided the Secretary in accordance with paragraph (6).

"(B) If the device is intended for export to a country which does not have an agency described in subparagraph (A), such device may be exported to such country only if the Secretary determines, upon application and after provision to the applicant of opportunity for an informal hearing on the application, that the exportation of the device to such country is not contrary to public health and safety.

"(3) Paragraph (1) does not apply to an antibiotic drug for which a regulation or release is not in effect pursuant to section 507 unless in addition to the requirements of paragraph (1), the drug meets the following requirements:

"(A) If the drug is intended for export to a country which has an appropriate health agency to review the drug and authorize or approve it as safe for its intended use (including investigational use) within such country, such drug may be exported to such country only if—

"(i) the drug is so reviewed and authorized or approved by such agency, and

"(ii) notification with respect to the export of the drug has been provided the Secretary in accordance with paragraph (6).

"(B) If the drug is intended for export to a country which does not have an agency described in subparagraph (A), such drug may be exported to such country only if the Secretary determines, upon application and after provision to the applicant of opportunity for an informal hearing on the application that the exportation of the drug to such country is not contrary to public health and safety.

"(4) Paragraph (1) does not apply to a new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 512 unless, upon application to make that paragraph apply to such a drug or feed, the Secretary determines, after providing notice and opportunity for an informal hearing on the application, that—

"(A) the drug or feed meets the requirements of paragraph (1),

"(B) its exportation is not contrary to public health and safety of persons within the United States, and

"(C) (i) the appropriate health agency of the country to which the drug or feed is to be exported has reviewed it and authorized or approved it as safe for its intended use (including investigational use) in such country, or

"(ii) if there is no such agency, its exportation to such country is not contrary to public health and safety.

"(5) Notwithstanding section 301(d), a new drug for which an application is not in effect pursuant to section 505 may be introduced or delivered for introduction into interstate commerce for export if the new drug meets the following requirements:

"(A) The drug meets the requirements of paragraph (1).

"(B) If the drug is intended for export to a country which has an appropriate health agency to review the drug and authorize or approve it as safe for its intended use (including investigational use) within such country, such drug may be exported to such country only if—

"(i) the drug is so reviewed and authorized or approved by such agency, and

"(ii) notification with respect to the export of the drug has been provided the Secretary in accordance with paragraph (6).

"(C) If the drug is intended for export to a country which does not have an agency described in subparagraph (A), such drug may be exported to such country only if the Secretary determines, upon application and after provision to the applicant of opportunity for an informal hearing on the application, that the exportation of the drug to such country is not contrary to public health and safety.

"(6) (A) Each person who is required to register under section 510 and who proposes to introduce or deliver for introduction into interstate commerce for export—

"(i) any device which does not comply with an applicable requirement of section 514 or 515 or which is a banned device under section 516,

"(ii) any antibiotic drug for which a regulation or release is not in effect pursuant to section 507, or

"(iii) any new drug for which an application is not in effect pursuant to section 505,

shall, on an annual basis and in accordance with regulations prescribed by the Secretary submit to the Secretary the notice prescribed by subparagraph (B) if the country to which such device or drug is intended for export has an appropriate health agency to review the drug or device and to authorize or approve it as safe for its intended use (including investigational use) in such country. A notice pursuant to this subparagraph may be amended in accordance with regulations of the Secretary.

"(B) The notice required by subparagraph (A) shall—

"(i) identify each drug and device described in subparagraph (A) which is to be introduced or delivered for introduction into interstate commerce for export during the twelve-month period beginning thirty days after the date the notice is submitted,

"(ii) identify the countries to which each such drug and device will be exported, and

"(iii) demonstrate to the satisfaction of the Secretary that each such device and drug complies with the requirements of subparagraph (1) and has been reviewed by the appropriate health agency of the country to which it is being exported and such agency has authorized or approved it as safe for its intended use (including investigational use) in such country.

"(7) The Secretary may, after providing notice and opportunity for informal hearing, issue an order prohibiting the introduction or delivery for introduction in interstate commerce for export of any—

"(A) device which does not comply with an applicable requirement of section 514 or 515 or which is a banned device under section 516,

"(B) antibiotic drug for which a regulation or release is not in effect pursuant to section 507, or

"(C) new drug for which an application is not in effect pursuant to section 505,

if the country to which the device or drug is intended for export has an appropriate health agency to review the device or drug and authorize or approve it as safe for its intended use (including investigational use) within such country and if the Secretary determines that the export of such device or drug is inconsistent with the health and safety of persons within the United States.".

(2) Section 801(a)(1) is amended by inserting after "conditions" the following: "or, in the case of a device, the methods used in, and the facilities and controls used for, the manufacture, processing, and packing and installation of the device do not conform to the requirements of section 520(f)".

REGISTRATION OF DEVICE MANUFACTURERS

SEC. 4. (a) Section 510 is amended as follows:

(1) The section heading is amended by inserting "and devices" and "drugs".

(2) Subsection (a)(1) is amended by inserting "or device package" after "drug package"; by inserting "or device" after "the drug"; and by inserting "or user" after "consumer".

(3) Subsections (b), (c), and (d) are amended by inserting "or a device or devices" after "drugs" each time it occurs.

(4) Subsection (e) is amended by adding at the end the following: "The Secretary may by regulation prescribe a uniform system for the identification of devices intended for human use and may require that persons who are required to list such devices pursuant to subsection (j) shall list such devices in accordance with such system.".

(5) Subsection (g) is amended by inserting "or devices" after "drugs" each time such term occurs in paragraphs (1), (2), and (3) of such subsection.

(6) Subsection (h) is amended by inserting after "704 and" the following: "every such establishment engaged in the manufacture, propagation, compounding, or processing of a drug or drugs or of a device or devices classified in class II or III".

(7) The first sentence of subsection (i) is amended by inserting ", or a device or devices," after "drug or drugs"; and the second sentence of such subsection is amended by inserting "shall require such establishment to provide the information required by subsection (j) in the case of a device or devices and" immediately before "shall include" and by inserting "or devices" after "drugs".

(8) Subsection (j) is amended—

(A) in the matter preceding subparagraph (A) of paragraph (1), by striking out "a list of all drugs (by established name" and inserting in lieu thereof "a list of all drugs and a list of all devices and a brief statement of the basis for believing that each device included in the list is a device rather than a drug (with each drug and device in each list by its established name", and by striking out "drugs filed" and inserting in lieu thereof "drugs or devices filed";

(B) in paragraph (1)(A), by striking out "such list" and inserting in lieu thereof "the applicable list"; by inserting "or a device intended for human use contained in the applicable list with respect to which a performance standard has been established under section 514 or which is subject to section 515," after "512,"; and by inserting "or device" after "such drug" each time it appears;

(C) in paragraph (1)(B), by striking out "drug contained in such list" before clause (i) and inserting in lieu thereof "drug or device contained in an applicable list";

(D) by amending clause (i) of paragraph (1)(B) to read as follows—

"(i) which drug is subject to section 503(b)(1), or which device is a restricted device, a copy of all labeling for such drug or device, a representative sampling of advertisements for such drug or device, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product or device, or";

(E) by amending clause (ii) of paragraph (1)(B) to read as follows:

"(ii) which drug is not subject to section 503(b)(1) or which device is not a restricted device, the label and package insert for such drug or device and a representative sampling of any other labeling for such drug or device;";

(F) in paragraph (1)(C), by striking out "such list" and inserting "an applicable list" in lieu thereof;

(G) in paragraph (1)(D), by striking out "the list" and inserting in lieu thereof "a list"; by inserting "or the particular device contained in such list is not subject to a performance standard established under section 514 or to section 515 or is not a restricted device" after "512,"; and by inserting "or device" after "particular drug product"; and

(H) in paragraph (2), by inserting "or device" after "drug" each time it appears and, in paragraph (2)(C), by inserting "each" before "by established name".

(9) Such section is amended by adding after subsection (j) the following new subsection:

"(k) Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe)—

"(1) the class in which the device is classified under section 513 or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

"(2) action taken by such person to comply with requirements under section 514 or 515 which are applicable to the device.".

(b)(1) Section 301(p) is amended by striking out "510(j)," and inserting in lieu thereof "510(j) or 510(k),".

(2) Section 520(o) is amended (A) by striking out "is a drug and" and (B) by inserting before the period a comma and the following: "if it was not included in a list required by section 510(j), if a notice or other information respecting it was not provided as required by such section or section 510(k), or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 510(e) as the Secretary by regulation requires".

(3) The second sentence of section 801(a) is amended by inserting "or devices" after "drugs" each time it occurs.

DEVICE ESTABLISHED AND OFFICIAL NAMES

SEC. 5. (a)(1) Subparagraph (1) of section 502(e) is amended by striking out "subparagraph (2)" and inserting in lieu thereof "subparagraph (3)".

(2) Subparagraph (2) of such section is redesignated as subparagraph (3) and is amended by striking out "this paragraph (e)" and inserting in lieu thereof "subparagraph (1)".

(3) Such section is amended by adding after subparagraph (1) the following new subparagraph:

"(2) If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietay name, its established name (as defined in paragraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.".

(4) Such section is amended by adding after subparagraph (3) (as so redesignated) the following:

"(4) As used in subparagraph (2), the term 'established name' with respect to a device means (A) the applicable official name of the device designated pursuant to section 508, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.".

(b) Section 508 is amended (1) in subsections (a) and (e) by adding "or device" after "drug" each time it appears; (2) in subsection (b) by adding after "all supplements thereto," the following: "an at such times as he may deem necessary shall cause a review to be made of the official names by which devices are identified in any official compendium (and all supplements thereto)"; (3) in subsection (c)(2) by adding "or device" after "single drug", and by adding "or to two or more devices which are substantially equivalent in design and purpose" after "purity,"; (4) in subsection (c)(3) by adding "or device" after "useful drug", and after "drug or drugs" each time it appears; and (5) in subsection (d) by adding "or devices" after "drugs".

INSPECTIONS RELATING TO DEVICES

SEC. 6. (a) The second sentence of subsection (a) of section 704 (21 U.S.C. 374) is amended by inserting "or restricted devices" after "prescription drugs" both times it appears.

(b) The third sentence of such subsection is amended to read as follows: "No inspection authorized by the preceding sentence shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (j), section 507 (d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j))."

(c)(1) Paragraph (1) of the sixth sentence of such subsection is amended by inserting "or devices" after "drugs" each time is occurs.

(2) Paragraph (2) of that sentence is amended by inserting ", or prescribe or use devices, as the case may be," after "administer drugs"; and by inserting "or, manufacture or process devices," after "process drugs".

(3) Paragraph (3) of that sentence is amended by inserting ", or manufacture or process devices," after "process drugs".

(d) Section 704 is amended by adding at the end the following new subsection:

"(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records.".

ADMINISTRATIVE RESTRAINT

SEC. 7. (a) Section 304 is amended by adding at the end the following new subsection:

"(g)(1) If during an inspection conducted under section 704 of a facility or a vehicle, a device which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under subsection (a) or section 302, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device during the period of its detention for the purpose of identifying the device as detained. Any person who would be entitled to claim a device if it were seized under subsection (a) may appeal to the Secretary a detention of such device under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

"(2)(A) Except as authorized by subparagraph (B), a device subject to a detention order issued under paragraph (1) shall not be moved by any person from the place at which it is ordered detained until—

"(i) released by the Secretary, or

"(ii) the expiration of the detention period applicable to such order,

whichever occurs first.

"(B) A device subject to a detention order under paragraph (1) may be moved—

"(i) in accordance with regulations prescribed by the Secretary, and

"(ii) if not in final form for shipment, at the discretion of the manufacturer of the device for the purpose of completing the work required to put it in such form.".

(b) Section 301 is amended by adding after the paragraph added by section 3(b)(1) the following new paragraph:

"(s) The movement of a device in violation of an order under section 304(g) or the removal or alteration of any mark or label required by the order to identify the device as detained.".

CONFIDENTIAL INFORMATION; PRESUMPTION

SEC. 8. Chapter 7 is amended by adding at the end the following new sections:

"CONFIDENTIAL INFORMATION

"SEC. 707. The Secretary may provide any information which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section to a person other than an officer or employee of the Department if the Secretary determines such other person requires the information in connection with an activity which is undertaken under contract with the Secretary, which relates to the administration of this Act, and with respect to which the Secretary (or an officer of the Department) is not prohibited from using such information. The Secretary shall require as a condition to the provision of information under this section that the person receiving it take such security precautions respecting the information as the Secretary may by regulation prescribe.

"PRESUMPTION

"SEC. 708. In any action to enforce the requirements of this Act respecting a device the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.".

COLOR ADDITIVES

SEC. 9. (a) Section 706 is amended (1) by inserting "or device" after "drug" each time it occurs, (2) by inserting "or devices" after "drugs" each time it occurs, and (3) by adding at the end of subsection (a) the following new sentences: "A color additive for use in or on a device shall be subject to this section only if the color additive comes in direct contact with the body of man or other animals for a significant period of time. The Secretary may by regulation designate the uses of color additives in or on devices which are subject to this section.".

(b)(1) Section 501(a) is amended (A) by inserting "(3) if its" in lieu of "(3) if it is a drug and its"; (2) by inserting "(4) if (A) it bears or contains" in lieu of "(4) if (A) it is a drug which bears or contains"; and (3) by inserting "or devices" after "drugs" in subclause (B) of clause (4).

(2) Section 502(m) is amended by striking out "in or on drugs".

ASSISTANCE FOR SMALL MANUFACTURERS OF DEVICES

SEC. 10. The Secretary of Health, Education, and Welfare shall establish within the Department of Health, Education, and Welfare an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices to assist them in complying with the requirements of the Food, Drug, and Cosmetic Act, as amended by this Act.

Mr. ROGERS (during the reading). Madam Chairman, I ask unanimous consent that the bill be considered as read, printed in the RECORD, and open to amendment at any point.

The CHAIRMAN. Is there objection to the request of the gentleman from Florida?

There was no objection.

COMMITTEE AMENDMENTS

The CHAIRMAN. The Clerk will report the committee amendments.

The Clerk read as follows:

Committee amendments:

Page 1, line 5, strike out "1975" and insert "1976".

Page 1, line 6, insert "(other than in section 3(a)(1)(B))" after "Act".

Page 8, line 4, insert "(other than devices classified by subsection (f))" after "such devices".

Page 11, line 13, strike out "on or".

Page 11, line 16, strike out "on or".

Page 12, line 8, strike out "on or".

Page 14, beginning in line 13 strike out "on or before such date" and insert in lieu thereof "before such date and which is to be classified pursuant to subsection (b),".

Page 14, line 15, strike out "on or".

Page 16, line 11, insert "516," after "515,".

Page 22, line 12, insert "this" after "pursuant to"; and in line 13 on that page strike out "(c)".

Page 27, insert after the period in line 16 the following new sentence: "The authority provided by this subsection is in addition to the authority provided by subsection (c)(4)".

Page 29, line 8, insert an opening parenthesis before "unless", and in line 9 insert a closing parenthesis after "516".

Page 33, beginning in line 14 strike out "on or".

Page 37, line 18, strike out "Section 520(1)(3)(d)(ii)" and insert "section 520(1)(3)(D)(ii)".

Page 47, line 8, strike out "(A)" and insert "(B)".

Page 52, strike out lines 10 through 19 and insert in lieu thereof the following:

"(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;"

Page 62, line 11, strike out "who avails" and insert in lieu thereof "for availing".

Page 64, line 22, insert "for such a device" after "maintain".

Page 65, line 1, insert "for such a device" after "submit".

Page 66, line 19, strike out "503" and insert "502."

Page 80, beginning in line 22 strike out "a summary of any".

Page 80, line 23, insert "any" after "respecting".

Page 81, line 11, strike out "a summary of any".

Page 81, line 12, strike out "the" first time it appears and insert in lieu thereof "any".

Page 81, line 16, after "subsection" insert "(A)"; and insert before the period in line 19 the following: ", and (B) shall be made available subject to subsection (c) of this section".

Page 82, line 19, strike out "1975" and insert "1976".

Page 85, line 1, after "days" insert "from the enactment date".

Page 88, line 17, strike out "(1)".

Page 92, line 16, strike out "520(g)" and insert "520".

Page 93, line 2, strike out "any" and insert in lieu thereof "Any".

Page 94, strike out "initially" in lines 3, 10, and 15.

Page 94, line 5, strike out "an approval of an" and insert in lieu thereof "in effect an

approved"; and beginning in line 8 on that page strike out "an approval under section 515 of an application for premarket approval" and insert in lieu thereof "such an application in effect".

Page 97, beginning in line 12, strike out "notification or other".

Page 103, line 5, strike out "subparagraph" and insert in lieu thereof "paragraph".

Page 103, line 18, strike out "or".

Page 103, insert "or" at the end of line 20 and strike out lines 21 through 25 and insert in lieu thereof the following:

"(D) new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 512 and with respect to which an application has been approved under paragraph (4) of this subsection,

if the Secretary determines that the export of"

Page 104, line 1, strike out "device or drug" and insert in lieu thereof "device, drug, or animal feed".

Page 107, line 12, insert "each place it occurs" before "; and".

Page 111, line 13, strike out "or," and insert in lieu thereof ", or".

Mr. ROGERS (during the reading). Madam Chairman, I ask unanimous consent that the committee amendments be considered en bloc and be considered as read.

Madam Chairman, the committee amendments are technical in nature except the amendment to proposed new section 520(h) of the Federal Food, Drug and Cosmetic Act. This amendment—which was adopted by unanimous voice vote of the committee—makes it clear that the information relating to safety and effectiveness of a device required to be released under new section 520(h) is only to be made available subject to the protections in new section 520(c) prohibiting the disclosure of trade secret and other confidential information.

The CHAIRMAN. Is there objection to the request of the gentleman from Florida?

There was no objection.

The committee amendments were agreed to.

The CHAIRMAN. If there are no further amendments, under the rule, the Committee rises.

Accordingly, the Committee rose; and the Speaker pro tempore (Mr. BRADEMAS) having assumed the chair, Ms. JORDAN, Chairman of the Committee of the Whole House on the State of the Union, reported that that Committee, having had under consideration the bill (H.R. 11124) 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, pursuant to House Resolution 1067, she reported the bill back to the House with sundry amendments adopted by the Committee of the Whole.

The SPEAKER pro tempore. Under the rule, the previous question is ordered.

Is a separate vote demanded on any amendment? If not, the Chair will put them en gros.

The amendments were agreed to.

The SPEAKER pro tempore. The question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed and read a third time, and was read the third time.

The SPEAKER pro tempore. The question is on the passage of the bill.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. COLLINS of Texas. Mr. Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

The SPEAKER pro tempore. Evidently a quorum is not present.

The Sergeant at Arms will notify absent Members.

The vote was taken by electronic device, and there were—yeas 362, nays 32, not voting 38, as follows:

[Roll No. 98]

YEAS—362

Abdnor	Daniel, R. W.	Hicks
Abzug	Daniels, N.J.	Hightower
Adams	Danielson	Hillis
Addabbo	Davis	Holland
Alexander	de la Garza	Holtzman
Allen	Dellums	Horton
Ambro	Dent	Howe
Anderson, Calif.	Derrick	Hubbard
	Derwinski	Hughes
Anderson, Ill.	Dickinson	Hungate
Andrews, N.C.	Diggs	Hyde
Andrews, N. Dak.	Dodd	Jacobs
	Downey, N.Y.	Jeffords
Annunzio	Downing, Va.	Jenrette
Ashley	Drinan	Johnson, Calif.
AuCoin	Duncan, Oreg.	Johnson, Colo.
Badillo	Duncan, Tenn.	Johnson, Pa.
Bafalis	du Pont	Jones, Ala.
Baldus	Early	Jordan
Baucus	Eckhardt	Kasten
Beard, R.I.	Edgar	Kastenmeier
Beard, Tenn.	Edwards, Ala.	Kazen
Bedell	Edwards, Calif.	Kelly
Bennett	Eilberg	Kemp
Bergland	Emery	Ketchum
Bevill	Erlenborn	Keys
Blaggi	Evans, Colo.	Kindness
Biester	Evans, Ind.	Koch
Bingham	Evins, Tenn.	Krebs
Blanchard	Fary	LaFalce
Blouin	Fenwick	Lagomarsino
Boggs	Findley	Latta
Boland	Fish	Leggett
Bonker	Fisher	Lehman
Bowen	Fithian	Levitas
Brademas	Flood	Litton
Breaux	Florio	Lloyd, Calif.
Breckinridge	Flowers	Lloyd, Tenn.
Brinkley	Flynt	Long, La.
Brodhead	Foley	Long, Md.
Broomfield	Ford, Mich.	Lott
Brown, Calif.	Forsythe	Lujan
Brown, Mich.	Fountain	McClory
Brown, Ohio	Fraser	McCloskey
Broyhill	Frenzel	McCollister
Buchanan	Fuqua	McDade
Burgener	Gaydos	McEwen
Burke, Calif.	Giaimo	McFall
Burke, Fla.	Gibbons	McHugh
Burke, Mass.	Gilman	McKay
Burlison, Mo.	Ginn	McKinney
Burton, John	Goldwater	Macdonald
Burton, Phillip	Gonzalez	Madden
Butler	Goodling	Madigan
Carney	Gradison	Maguire
Carr	Gude	Mahon
Carter	Hagedorn	Mann
Cederberg	Haley	Martin
Chappell	Hall	Mathis
Chisholm	Hamilton	Matsunaga
Clancy	Hammer-schmidt	Mazzoli
Clawson, Del		Meeds
Clay	Hanley	Melcher
Cleveland	Hannaford	Meyner
Cochran	Harkin	Mezvinsky
Cohen	Harrington	Michel
Conable	Harris	Mikva
Conte	Harsha	Milford
Conyers	Hawkins	Miller, Calif.
Corman	Hays, Ohio	Mills
Cornell	Hébert	Mineta
Cotter	Hechler, W. Va.	Minish
Coughlin	Heckler, Mass.	Mink
D'Amours	Heinz	Mitchell, Md.
Daniel, Dan	Henderson	Mitchell, N.Y.
Moakley	Rhodes	Stark
Moffett	Richmond	Steed
Mollohan	Riegle	Steelman
Montgomery	Rinaldo	Steiger, Wis.
Moorhead, Calif.	Risenhoover	Stephens
	Robinson	Stokes
Moorhead, Pa.	Rodino	Stratton
Morgan	Roe	Studds
Mosher	Rogers	Sullivan
Moss	Roncalio	Symington
Mottl	Rooney	Talcott
Murphy, Ill.	Rose	Taylor, Mo.
Murphy, N.Y.	Rosenthal	Teague
Murtha	Rostenkowski	Thompson
Myers, Ind.	Roush	Thone
Myers, Pa.	Roybal	Thornton
Natcher	Runnels	Treen
Neal	Ruppe	Tsongas
Nedzi	Russo	Ullman
Nichols	Ryan	Van Deerlin
Nowak	St Germain	Vander Jagt
Oberstar	Santini	Vander Veen
Obey	Sarasin	Vanik
O'Brien	Sarbanes	Vigorito
O'Hara	Satterfield	Walsh
O'Neill	Scheuer	Wampler
Ottinger	Schneebeli	Weaver
Passman	Schroeder	Whalen
Patten, N.J.	Schulze	White
Patterson, Calif.	Sebelius	Whitehurst
	Seiberling	Whitten
Pattison, N.Y.	Sharp	Wiggins
Pepper	Shriver	Wilson, Bob
Perkins	Sikes	Wilson, C. H.
Peyser	Simon	Winn
Pickle	Sisk	Wirth
Pike	Skubitz	Wolff
Pressler	Slack	Wright
Preyer	Smith, Iowa	Wydler
Price	Smith, Nebr.	Wylie
Pritchard	Snyder	Yates
Quie	So.arz	Yatron
Quillen	Spellman	Young, Alaska
Railsback	Staggers	Young, Fla.
Randall	Stanton, J. William	Young, Ga.
Rangel		Young, Tex.
Regula	Stanton, James V.	Zablocki
Reuss		Zeferetti

NAYS—32

Archer	Grassley	McDonald
Armstrong	Hansen	Miller, Ohio
Ashbrook	Holt	Moore
Bauman	Hutchinson	Poage
Burleson, Tex.	Ichord	Roberts
Byron	Jarman	Rousselot
Collins, Tex.	Jones, N.C.	Shuster
Crane	Jones, Okla.	Spence
Delaney	Krueger	Symms
Devine	Landrum	Waggonner
English	Lent	

NOT VOTING—38

Aspin	Ford, Tenn.	Metcalfe
Barrett	Frey	Nix
Bell	Green	Nolan
Boiling	Guyer	Pettis
Brooks	Hayes, Ind.	Rees
Clausen, Don H.	Hefner	Shipley
	Helstoski	Steiger, Ariz.
Collins, Ill.	Hinshaw	Stuckey
Conlan	Howard	Taylor, N.C.
Dingell	Jones, Tenn.	Traxler
Esch	Karth	Udall
Eshleman	Lundine	Waxman
Fascell	McCormack	Wilson, Tex.

The Clerk announced the following pairs:

Mr. Barrett with Mr. Aspin.
Mr. Howard with Mr. Guyer.
Mr. McCormack with Mrs. Pettis.
Mr. Shipley with Mr. Stuckey.
Mr. Waxman with Mr. Metcalfe.
Mr. Brooks with Mr. Fascell.
Mr. Dingell with Mr. Bell.
Mr. Green with Mr. Hefner.
Mr. Charles Wilson of Texas with Mr. Don H. Clausen.
Mr. Jones of Tennessee with Mr. Lundine.
Mr. Karth with Mr. Esch.
Mrs. Collins of Illinois with Mr. Conlan.
Mr. Hayes of Indiana with Mr. Ford of Tennessee.
Mr. Nix with Mr. Frey.
Mr. Nolan with Mr. Eshleman.
Mr. Traxler with Mr. Rees.
Mr. Udall with Mr. Steiger of Arizona.
Mr. Helstoski with Mr. Taylor of North Carolina.

Mr. CLEVELAND changed his vote from "nay" to "yea."

So the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

The SPEAKER pro tempore. (Mr. BRADEMAS). Pursuant to the provisions of House Resolution 1067, the Committee on Interstate and Foreign Commerce is discharged from the further consideration of the Senate bill (S. 510) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety and effectiveness of medical devices.

MOTION OFFERED BY MR. ROGERS

Mr. ROGERS. Mr. Speaker, I offer a motion.

The Clerk read as follows:

Mr. ROGERS moves to strike out all after the enacting clause of the Senate bill (S. 510), and to insert in lieu thereof the provisions of H.R. 11124, as passed, as follows:

SHORT TITLE AND TABLE OF CONTENTS

SECTION 1. (a) This Act may be cited as the "Medical Device Amendments of 1976".

(b) Whenever in this Act (or other than in section 3(a)(1)(B)) an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

TABLE OF CONTENTS

REGULATION OF MEDICAL DEVICES

SEC. 2. Chapter V is amended by adding after section 512 the following new sections:

"CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE

"Device Classes

"SEC. 513. (a)(1) There are established the following classes of devices intended for human use:

"(A) CLASS I, GENERAL CONTROLS.—

"(i) A device for which the controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

"(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide such assurance, but because it—

"(I) is not purported or represented to be for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health, and

"(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

"(B) CLASS II, PERFORMANCE STANDARDS.—A device which cannot be classified as a class I device because the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, for which there is sufficient information to establish a performance standard to provide such assurance, and for which it is therefore necessary to establish for the device a performance standard under section 514 to provide reasonable assurance of its safety and effectiveness.

"(C) CLASS III, PREMARKET APPROVAL.—A device which because—

"(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 are sufficient to provide reasonable assurance of the safety and effectiveness of the device and (II) cannot be classified as a class II device because insufficient information exists for the establishment of a performance standard to provide reasonable assurance of its safety and effectiveness, and

"(ii)(I) is purported or represented to be for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health, or

"(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 515, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

"(2) For purposes of this section and sections 514 and 515, the safety and effectiveness of a device are to be determined—

"(A) with respect to the persons for whose use the device is represented or intended,

"(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

"(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

"(3)(A) Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 514 and 515, to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

"(B) If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A))—

"(i) which is sufficient to determine the effectiveness of a device, and

"(ii) from which it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device,

then, for purposes of this section and sections 514 and 515, the Secretary may authorize the effectiveness of the device to be determined on the basis of such evidence.

"Classification; Classification Panels

"(b)(1) For purposes of—

"(A) determining which devices intended for human use should be subject to the requirements of general controls, performance standards, or premarket approval, and

"(B) providing notice to the manufacturers and importers of such devices to enable them to prepare for the application of such requirements to devices manufactured or imported by them,

the Secretary shall classify all such devices (other than devices classified by subsection (f)) into the classes established by

subsection (a). For the purpose of securing recommendations with respect to the classification of devices, the Secretary shall establish panels of experts or use panels of experts established before the date of the enactment of this section, or both. Section 14 of the Federal Advisory Committee Act shall not apply to the duration of a panel established under this paragraph.

"(2) The Secretary shall appoint to each panel established under paragraph (1) persons who are qualified by training and experience to evaluate the safety and effectiveness of the devices to be referred to the panel and who, to the etxent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such devices. The Secretary shall make appointments to each panel so that each panel shall consist of members with adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. In addition, each panel shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

"(3) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, but not at rates exceeding the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day so engaged, including traveltime; and while so serving away from their homes or regular places of business each member may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently.

"(4) The Secretary shall furnish each panel with adequate clerical and other necessary assistance.

"Classification Panel Organization and Operation

"(c)(1) The Secretary shall organize the panels according to the various fields of clinical medicine and fundamental sciences in which devices intended for human use are used. The Secretary shall refer a device to be classified under this section to an appropriate panel established or authorized to be used under subsection (b) for its review and for its recommendation respecting the classification of the device and, to the extent practicable, respecting the assignment of a priority for the application of the requirements of section 514 or 515 to the device if the panel recommends that the device is classified in class II or class III. The Secretary shall by regulation prescribe the procedure to be followed by the panels in making their reviews and recommendations. In making their reviews of devices, the panels, to the maximum extent practicable, shall provide an opportunity for interested persons to submit data and views on the classification of the devices.

"(2)(A) Upon completion of a panel's review of a device referred to it under paragraph (1), the panel shall, subject to subparagraphs (B) and (C), submit to the Secretary its recommendation for the classification of the device. Any such recommendation shall (i) contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the recommendation is made, and (ii) to the extent practicable, include a recommendation for the assignment of a priority for the application of the requirements of section 514 or 515 to a device recommended to be classified in class II or class III.

"(B) A recommendation of a panel for the classification of a device in class I shall include a recommendation as to whether the device should be exempted from the requirements of section 510, 519, or 520(f).

"(C) In the case of a device which has been referred under paragraph (1) to a panel, and which—

"(i) is intended to be implanted in the human body, and

"(ii)(I) has been introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section, or

"(II) is within a type of device which was so introduced or delivered before such date and is substantially equivalent to another device within that type,

such panel shall recommend to the Secretary that the device be classified in class III unless the panel determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. If a panel does not recommend that such a device be classified in class III, it shall in its recommendation to the Secretary for the classification of the device set forth the reasons for not recommending classification of the device in such class.

"(3) The panels shall submit to the Secretary within one year of the date funds are first appropriated for the implementation of this section their recommendations respecting all devices of a type introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section.

"Classification

"(d)(1) Upon receipt of a recommendation from a panel respecting a device, the Secretary shall publish in the Federal Register the panel's recommendation and a proposed regulation classifying such device and shall provide interested persons an opportunity to submit comments on such recommendation and the proposed regulation. After reviewing such comments, the Secretary shall, subject to paragraph (2), by regulation classify such device.

"(2)(A) A regulation under paragraph (1) classifying a device in class I shall prescribe which, if any, of the requirements of section 510, 519, or 520(f) shall not apply to the device.

"(B) A device described in subsection (c)(2)(C) shall be classified in class III unless the Secretary determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. A proposed regulation under paragraph (1) classifying such a device in a class other than class III shall be accompanied by a statement of the reasons of the Secretary for not classifying such device in such class.

"(3) In the case of devices classified under this subsection in class II and devices classified under this subsection in class III and described in section 515(b)(1), the Secretary may establish priorities which, in his discretion, shall be used in applying sections 514 and 515, as appropriate, to such devices.

"Classification Changes

"(e) Based on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an interested person, by regulation (1) change such device's classification, and (2) revoke, because of the change in classification, any regulation or requirement in effect under section 514 or 515 with respect to such device. In the promulgation of such a regulation respecting a device's classification, the Secretary may secure from the panel to which the device was last referred pursuant to subsection (c) a recommendation respecting the proposed change in the device's classification and shall publish in the Federal Register any recommendation submitted to the Secretary by the panel respecting such change. A regulation under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 514 for such device.

"Initial Classification of Certain Devices

"(f)(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section is classified in class III unless—

"(A) the device—

"(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b), or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

"(ii) is substantially equivalent to another device within such type, or

"(B) in the case of a device other than a device which is intended to be implanted in the human body, the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

A device (other than a device which is intended to be implanted in the human body) classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) classifying the device in class I or II. The Secretary may not promulgate a regulation under subsection (e) changing the classification of a device which is intended to be implanted in the human body and which is classified in class III under this paragraph before there is in effect for such device an approval under section 515 of an application for premarket approval.

"(2) The manufacturer or importer of a device classified under paragraph (1) (other than a device which is intended to be implanted in the human body) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Within one hundred and eighty days after the filing of a petition under this paragraph and after affording the petitioner an opportunity for an informal hearing, the Secretary shall, after consultation with the appropriate panel established or authorized to be used under subsection (b), by order either deny the petition or order the classification, in accordance with the criteria prescribed by subsection (a)(1)(A) or (a)(1)(B), of the device in class I or class II.

"Information

"(g) Within sixty days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this Act, the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this Act applicable to the device.

"Definitions

"(h) For purposes of this section and sections 501, 510, 514, 515, 516, 519, and 520—

"(1) a reference to 'general controls' is a reference to the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520,

"(2) a reference to 'class I', 'class II', or 'class III' is a reference to a class of medical devices described in subparagraph (A), (B), or (C) of subsection (a)(1), and

"(3) a reference to a 'panel under section 513' is a reference to a panel established or authorized to be used under this section.

"PERFORMANCE STANDARDS

"Provisions of Standards

"SEC. 514. (a)(1) The Secretary may by regulation, promulgated in accordance with this section, establish a performance standard for a class II device. A class III device may also be considered a class II device for purposes of establishing a standard for the device under this section if the device has been reclassified as a class II device under a regulation under section 513(e) but such regulation provides that the reclassification is not to take effect until the effective date of such a standard for the device.

"(2) A performance standard established under this section for a device—

"(A) shall include provisions to provide reasonable assurance of its safe and effective performance;

"(B) shall, where necessary to provide reasonable assurance of its safe and effective performance, include—

"(i) provisions respecting the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to such systems,

"(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of the device to the standard, provisions for the testing (on a sample basis or, if necessary, on an individual basis) by the Secretary or by another person at the direction of the Secretary,

"(iii) provisions for the measurement of the performance characteristics of the device,

"(iv) provisions requiring that before the device is introduced or delivered for introduction into interstate commerce for commercial distribution the results of each or of certain of the tests of the device required to be made under clause (ii) show that the device is in conformity with the portions of the standard for which the test or tests were required, and

"(v) a provision requiring that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 520(e); and

"(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device.

"(3) A performance standard established under this section may not include any provision not required or authorized by paragraph (2) of this subsection.

"(4) The Secretary shall provide for periodic evaluation of performance standards established under this section to determine if such standards should be changed to reflect new medical, scientific, or other technological data.

"(5) In carrying out his duties under this section, the Secretary shall, to the maximum extent practicable—

"(A) use personnel, facilities, and other technical support available in other Federal agencies,

"(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities, and

"(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, or consumer organizations who in his judgment can make a significant contribution.

"Initiation of a Proceeding for a Performance Standard

"(b)(1) A proceeding for the development of a performance standard for a device shall be initiated by the Secretary by the publication in the Federal Register of notice of the opportunity to submit to the Secretary a request (within fifteen days of the date of the publication of the notice) for a change in the classification of the device based on new information relevant to its classification.

"(2) If, after publication of a notice pursuant to paragraph (1) the Secretary receives a request for a change in the device's classification, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 513, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 513(e).

"Invitation for Standards

"(c)(1) If, after the publication of a notice under subsection (b), no action is required under paragraph (2) of such subsection or the Secretary denies a request to change the classification of the device with respect to which such notice was published, the Secretary shall publish in the Federal Register a notice inviting any person, including any Federal agency, to—

"(A) submit to the Secretary, within sixty days after the date of publication of the notice, an existing standard as a proposed performance standard for such device, or

"(B) offer, within sixty days after the date of publication of the notice, to develop such a proposed standard.

"(2) A notice published pursuant to paragraph (1) for an offer for the development of a proposed performance standard for a device—

"(A) shall specify a period within which the standard is to be developed, which period may be extended by the Secretary for good cause shown; and

"(B) shall include—

"(i) a description or other designation of the device,

"(ii) a statement of the nature of the risk or risks associated with the use of the device and intended to be controlled by a performance standard,

"(iii) a summary of the data on which the Secretary has found a need for initiation of the proceeding to develop a performance standard, and

"(iv) identification of any existing performance standard known to the Secretary which may be relevant to the proceeding.

"(3) The Secretary shall by regulation require that an offeror of an offer to develop a proposed performance standard submit to the Secretary such information concerning the offeror as the Secretary determines is relevant with respect to the offeror's qualifications to develop a proposed performance standard for a device, including information respecting the offeror's financial stability, expertise, and experience, and any potential conflicts of interest, including financial interest in the device for which the proposed standard is to be developed, which may be relevant with respect to the offeror's qualifications. Such information submitted by an offeror may not be made public by the Secretary unless required by section 552 of title 5, United States Code.

"(4) If the Secretary determines that a performance standard can be developed by any Federal agency (including an agency within the Department of Health, Education,

"(A) if such determination is made with respect to an agency within such Department, develop such a standard in lieu of accepting any offer to develop such a standard pursuant to a notice published pursuant to this subsection, or

"(B) if such determination is made with respect to any other agency, authorize such agency to develop such a standard in lieu of accepting any such offer.

In making such a determination respecting a Federal agency, the Secretary shall take into account the personnel and expertise within such agency. The requirements described in subparagraphs (B) and (C) of subsection (e)(4) shall apply to development of a standard under this paragraph.

"Acceptance of Certain Existing Standards

"(d)(1) If the Secretary—

"(A) determines that a performance standard has been issued or adopted or is being developed by any Federal agency or by any other qualified entity or receives a performance standard submitted pursuant to a notice published to subsection (c), and

"(B) determines that such performance standard is based upon scientific data and information and has been subjected to scientific consideration,

he may, in lieu of accepting any offer to develop such a standard pursuant to a notice published pursuant to subsection (c), accept such standard as a proposed performance standard for such device or as a basis upon which proposed performance standard may be developed.

"(2) If a standard is submitted to the Secretary pursuant to a notice published pursuant to subsection (c) and the Secretary does not accept such standard, he shall publish in the Federal Register notice of that fact together with the reasons therefor.

"Acceptance of Offer To Develop Standard

"(e)(1) Except as provided by subsections (c)(4) and (d), the Secretary shall accept one, and may accept more than one, offer to develop a proposed performance standard for a device pursuant to a notice published pursuant to subsection (c) if he determines that (A) the offeror is qualified to develop such a standard and is technically competent to undertake and complete the development of an appropriate performance standard within the period specified in the notice, and (B) the offeror will comply with procedures prescribed by regulations of the Secretary under paragraph (4) of this subsection. In determining the qualifications of an offeror to develop a standard, the Secretary shall take into account the offeror's financial stability, expertise, experience, and any potential conflicts of interest, including financial interest in the device for which such standard is to be developed, which may be relevant with respect to the offeror's qualifications.

"(2) The Secretary shall publish in the Federal Register the name and address of each person whose offer is accepted under paragraph (1) and a summary of the terms of such offer as accepted.

"(3) If such an offer is accepted, the Secretary may, upon application which may be made prior to the acceptance of the offer, agree to contribute to the offeror's cost in developing a proposed standard if the Secretary determines that such contribution is likely to result in a more satisfactory standard than would be developed without such contribution. The Secretary shall by regulation prescribe the items of cost in which he will participate, except that such items may not include the cost of construction (except minor remodeling) or the acquisition of land or buildings. Payments to an offeror under this paragraph may be made without regard to section 3648 of the Revised Statutes (31 U.S.C. 529).

"(4) The Secretary shall prescribe regulations governing the development of proposed standards by persons whose offers are accepted under paragraph (1). Such regula-

tions shall, notwithstanding subsection (b) (A) of section 553 of title 5, United States Code, be promulgated in accordance with the requirements of that section for notice and opportunity for participation and shall—

"(A) require that performance standards proposed for promulgation be supported by such test data or other documents or materials as the Secretary may reasonably require to be obtained;

"(B) require that notice be given to interested persons of the opportunity to participate in the development of such performance standards and require the provision of such opportunity;

"(C) require the maintenance of records to disclose (i) the course of the development of performance standards proposed for promulgation, (ii) the comments and other information submitted by any person in connection with such development, including comments and information with respect to the need for such performance standards, and (iii) such other matters as may be relevant to the evaluation of such performance standards;

"(D) provide that the Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and other records, relevant to the expenditure of any funds contributed by the Secretary under paragraph (3); and

"(E) require the submission of such periodic reports as the Secretary may require to disclose the course of the development of performance standards proposed for promulgation.

"(5) If an offer is made pursuant to a notice published pursuant to subsection (c) and the Secretary does not accept such offer, he shall publish in the Federal Register notice of that determination together with the reasons therefor.

"Development of Standard by Secretary After Publication of Subsection (c) Notice

"(f) If the Secretary has published a notice pursuant to subsection (c) and—

"(1) no person makes an offer or submits a standard pursuant to the notice;

"(2) the Secretary has not accepted an existing performance standard under subsection (d) or accepted an offer to develop a proposed performance standard pursuant to the notice; or

"(3) the Secretary has accepted an offer or offers to develop a proposed performance standard, but determines thereafter that—

"(A) the offeror under each such offer is unwilling or unable to continue the development of the performance standard which was the subject of the offer or offers, or

"(B) the performance standard which has been developed is not satisfactory,

and publishes notice of that determination in the Federal Register together with his reasons therefor;

then the Secretary may proceed to develop a proposed performance standard. The authority by this subsection is in addition to the authority provided by subsection (c) (4). The requirements described in subparagraphs (B) and (C) of subsection (e) (4) shall apply to the development of a standard by the Secretary under this subsection.

"Establishment of a Standard

"(g) (1) (A) After publication pursuant to subsection (c) of a notice respecting a performance standard for a device, the Secretary shall either—

"(i) publish, in the Federal Register in a notice of proposed rulemaking, a proposed performance standard for the device (I) developed by an offeror under such notice and accepted by the Secretary, (II) developed under subsection (c) (4), (III) accepted by the Secretary under subsection (d), or (IV) developed by him under subsection (f), or

"(ii) issue a notice in the Federal Register that the proceeding is terminated together with the reasons for such termination.

"(B) If the Secretary issues under subparagraph (A) (ii) a notice of termination of a proceeding to establish a performance standard for a device, he shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

"(2) A notice of proposed rulemaking for the establishment of a performance standard for a device published under paragraph (1) (A) (i) shall set forth proposed findings with respect to the degree of the risk of illness or injury designed to be eliminated or reduced by the proposed standard and the benefit to the public from the device.

"(3) (A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory committee under paragraph (5), the Secretary shall (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (2), or (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

"(B) A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless (i) the Secretary determines that an earlier effective date is necessary for the protection of the public health and safety, or (ii) such standard has been established for a device which, effective upon the effective date of the standard, has been reclassified from class III to class II. Such date or dates shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade.

"(4) (A) The Secretary, upon his own initiative or upon petition of an interested person, may by regulation, promulgated in accordance with the requirements of paragraphs (2) and (3) (B) of this subsection, amend or revoke a performance standard.

"(B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if he determines, after affording all interested persons an opportunity for an informal hearing, that making it so effective is in the public interest. A proposed amendment of a performance standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device which conforms to such standard without the change or changes provided by such proposed amendment.

"(5) (A) The Secretary—

"(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

"(ii) shall, upon the request of an interested person unless the Secretary finds the request to be without good cause or the request is made after the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,

to an advisory committee of experts, established pursuant to subparagraph (B), for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subparagraph to an advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within sixty days of the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

"(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Each such committee shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Members of an advisory committee who are not officers or employees of the United States, while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate one of the members of each advisory committee to serve as chairman thereof. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

"PREMARKET APPROVAL

"General Requirement

"SEC. 515. (a) A class III device—

"(1) which is subject to a regulation promulgated under subsection (b); or

"(2) which is a class III device because of section 513(f),

is required to have, unless exempt under section 520(g), an approval under this section of an application for premarket approval.

"Regulation To Require Premarket Approval

"(b) (1) In the case of a class III device which—

"(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section; or

"(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type,

the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval.

"(2)(A) A proceeding for the promulgation of a regulation under paragraph (1) respecting a device shall be initiated by the publication in the Federal Register of a notice of proposed rulemaking. Such notice shall contain—

"(i) the proposed regulation;

"(ii) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved application for premarket approval and the benefit to the public from use of the device;

"(iii) opportunity for the submission of comments on the proposed regulation and the proposed findings; and

"(iv) opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

"(B) If, after publication of a notice under subparagraph (A), the Secretary receives a request for a change in the classification of a device, he shall, after consultation with the appropriate panel under section 513, by order published in the Federal Register either deny the request for change in classification or give notice of his intent to initiate such a change under section 513(e).

"(3) After the expiration of the period for comment on a proposed regulation and proposed findings published under paragraph (2) and after consideration of comments submitted on such proposed regulation and findings, the Secretary shall (A) promulgate such regulation and publish in the Federal Register findings on the matters referred to in paragraph (2)(A)(ii), or (B) publish a notice terminating the proceeding for the promulgation of the regulation together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

"(4) The Secretary, upon his own initiative or upon petition of an interested person, may by regulation amend or revoke any regulation promulgated under this subsection. A regulation to amend or revoke a regulation under this subsection shall be promulgated in accordance with the requirements prescribed by this subsection for the promulgation of the regulation to be amended or revoked.

"Application for Premarket Approval

"(c)(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—

"(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

"(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

"(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

"(D) an identifying reference to any performance standard under section 514 which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

"(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

"(F) specimens of the labelling proposed to be used for such device; and

"(G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 513, may require.

"(2) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary shall refer such application to the appropriate panel under section 513 for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.

"Action on an Application for Premarket Approval

"(d)(1)(A) As promptly as possible, but in no event later than one hundred and eighty days after the receipt of an application under subsection (c) (except as provided in section 520(l)(3)(D)(ii) or unless, in accordance with subparagraph (B)(i), an additional period is agreed upon by the Secretary and the applicant), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

"(i) issue an order approving the application if he finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

"(ii) deny approval of the application if he finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

"(B)(i) The Secretary may not enter into an agreement to extend the period in which to take action with respect to an application submitted for a device subject to a regulation promulgated under subsection (b) unless he finds that the continued availability of the device is necessary for the public health.

"(ii) An order approving an application for a device may require as a condition to such approval that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 520(e).

"(2) The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the application and any other information before him with respect to such device, the Secretary finds that—

"(A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

"(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

"(C) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing and installation of such device do not conform to the requirements of section 520(f);

"(D) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

"(E) such device is not shown to conform in all respects to a performance standard in effect under section 514 compliance with which is a condition to approval of the application and there is a lack of adequate information to justify the deviation from such standard.

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary).

"(3) An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g), and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g), of an order of the Secretary approving an application.

"Withdrawal of Approval of Application

"(e)(1) The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 513, and after due notice and opportunity for informal hearing to the holder of an approved application for a device, issue an order withdrawing approval of the application if the Secretary finds—

"(A) that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

"(B) on the basis of new information before him with respect to such device, evaluated together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

"(C) that the application contained or was accompanied by an untrue statement of a material fact;

"(D) that the applicant (i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 519(a), (ii) has refused to permit access to, or copying or verification of, such records as required by section 704, or (iii) has not complied with the requirements of section 510;

"(E) on the basis of new information before him with respect to such device, evaluated together with the evidence before him when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such device do not conform with the requirements of section 520(f) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

"(F) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that the labeling of such device, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

"(G) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that such device is not shown to conform in all respects to a performance standard which is in effect under section 514 compliance with which was a condition to approval of the application and that there is

a lack of adequate information to justify the deviation from such standard.

"(2) The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such withdrawal, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g).

"Product Development Protocol

"(f)(1) In the case of a class III device which is required to have an approval of an application submitted under subsection (c), such device shall be considered as having such an approval if a notice of completion of testing conducted in accordance with a product development protocol approved under paragraph (4) has been declared completed under paragraph (6).

"(2) Any person may submit to the Secretary a proposed product development protocol with respect to a device. Such a protocol shall be accompanied by data supporting it. If, within thirty days of the receipt of such a protocol, the Secretary determines that it appears to be appropriate to apply the requirements of this subsection to the device with respect to which the protocol is submitted, he shall refer the proposed protocol to the appropriate panel under section 513 for its recommendation respecting approval of the protocol.

"(3) A proposed product development protocol for a device may be approved only if—

"(A) the Secretary determines that it is appropriate to apply the requirements of this subsection to the device in lieu of the requirement of approval of an application submitted under subsection (c); and

"(B) the Secretary determines that the proposed protocol provides—

"(i) a description of the device and the changes which may be made in the device,

"(ii) a description of the preclinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the commencement of clinical trials of the device, and (II) any permissible variations in preclinical trials and the results therefrom,

"(iii) a description of the clinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the filing of a notice of completion of the requirements of the protocol, and (II) any permissible variations in such trials and the results therefrom,

"(iv) a description of the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, and, when relevant, packing and installation of the device,

"(v) an identifying reference to any performance standard under section 514 to be applicable to any aspect of such device,

"(vi) if appropriate, specimens of the labeling proposed to be used for such device,

"(vii) such other information relevant to the subject matter of the protocol as the Secretary, with the concurrence of the appropriate panel or panels under section 513, may require, and

"(viii) a requirement for submission of progress reports and, when completed, records of the trials conducted under the protocol which records are adequate to show compliance with the protocol.

"(4) The Secretary shall approve or disapprove a proposed product development protocol submitted under paragraph (2) within one hundred and twenty days of its receipt unless an additional period is agreed upon by the Secretary and the person who submitted the protocol. Approval of a protocol or denial of approval of a protocol is final agency action subject to judicial review under chapter 7 of title 5, united States Code.

"(5) At any time after a product development protocol for a device has been approved pursuant to paragraph (4), the person for whom the protocol was approved may submit a notice of completion—

"(A) stating (i) his determination that the requirements of the protocol have been fulfilled and that, to the best of his knowledge, there is no reason bearing on safety or effectiveness why the notice of completion should not become effective, and (ii) the data and other information upon which such determination was made, and

"(B) setting forth the results of the trials required by the protocol and all the information required by subsection (c)(1).

"(6)(A) The Secretary may, after providing the person who has an approved protocol an opportunity for an informal hearing and at any time prior to receipt of notice of completion of such protocol, issue a final order to revoke such protocol if he finds that—

"(i) such person has failed substantially to comply with the requirements of the protocol,

"(ii) the results of the trials obtained under the protocol differ so substantially from the results required by the protocol that further trials cannot be justified, or

"(iii) the results of the trials conducted under the protocol or available new information do not demonstrate that the device tested under the protocol does not present an unreasonable risk to health and safety.

"(B) After the receipt of a notice of completion of an approved protocol the Secretary shall, within the ninety-day period beginning on the date such notice is received, by order either declare the protocol completed or declare it not completed. An order declaring a protocol not completed may take effect only after the Secretary has provided the person who has the protocol opportunity for an informal hearing on the order. Such an order may be issued only if the Secretary finds—

"(i) such person has failed substantially to comply with the requirements of the protocol,

"(ii) the results of the trials obtained under the protocol differ substantially from the results required by the protocol, or

"(iii) there is a lack of a showing of reasonable assurance of the safety and effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

"(C) A final order issued under subparagraph (A) or (B) shall be in writing and shall contain the reasons to support the conclusions thereof.

"(7) At any time after a notice of completion has become effective, the Secretary may issue an order (after due notice and opportunity for an informal hearing to the person for whom the notice is effective) revoking the approval of a device provided by a notice of completion which has become effective as provided in subparagraph (B) if he finds that any of the grounds listed in subparagraphs (A) through (G) of subsection (e)(1) of this section apply. Each reference in such subparagraphs to an application shall be considered for purposes of this paragraph as a reference to a protocol and the notice of completion of such protocol, and each reference to the time when an application was approved shall be considered for purposes of this paragraph as a reference to the time when a notice of completion took effect.

"(8) A person who has an approved protocol subject to an order issued under paragraph (6)(A) revoking such protocol, a person who has an approved protocol with respect to which an order under paragraph (6)(B) was issued declaring that the protocol had not been completed, or a person subject to an order issued under paragraph (7) revoking the approval of a device may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such order, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g).

"Review

"(g)(1) Upon petition for review of—

"(A) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

"(B) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device,

the Secretary shall, unless he finds the petition to be without good cause or unless a petition for review of such order has been submitted under paragraph (2), hold a hearing, in accordance with section 554 of title 5 of the United States Code, on the order. The panel or panels which considered the application, protocol, or device subject to such order shall designate a member to appear and testify at any such hearing upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this requirement does not preclude any other member of the panel or panels from appearing and testifying at any such hearing. Upon completion of such hearing and after considering the record established in such hearing, the Secretary shall issue an order either affirming the order subject to the hearing or reversing such order and, as appropriate, approving or denying approval of the application, reinstating the application's approval, approving the protocol, or placing in effect a notice of completion.

"(2)(A) Upon petition for review of—

"(i) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

"(ii) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device,

the Secretary, unless he is required to provide review of such order under paragraph (1), shall refer the application or protocol subject to the order and the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order. The advisory committee shall, after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report shall be promptly supplied by the Secretary to any person who petitioned for such referral to the advisory committee.

"(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Each such committee shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Members of an advisory committee (other than officers or employees

of the United States), while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent for grade GS-18 of the General Schedule for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate the chairman of an advisory committee from its members. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

"(C) The Secretary shall make public the report and recommendation made by an advisory committee with respect to an application and shall by order, stating the reasons therefor, either affirm the order referred to the advisory committee or reverse such order and, if appropriate, approve or deny approval of the application, reinstate the application's approval, approve the protocol, or place in effect a notice of completion.

"Service of Orders

"(h) Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary, or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last known address in the records of the Secretary.

"BANNED DEVICES

"General Rule

"SEC. 516. (a) Whenever the Secretary finds, on the basis of all available data and information and after consultation with the appropriate panel or panels under section 513, that—

"(1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and

"(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;

he may initiate a proceeding to promulgate a regulation to make such device a banned device. The Secretary shall afford all interested persons opportunity for an informal hearing on a regulation proposed under this subsection.

"Special Effective Date

"(b) The Secretary may declare a proposed regulation under subsection (a) to be effective upon its publication in the Federal Register and until the effective date of any final action taken respecting such regulation if (1) he determines, on the basis of all available data and information, that the deception or risk of illness or injury associated with the use of the device which is subject to the regulation presents an unreasonable, direct, and substantial danger to the health of individuals, and (2) before the date of the publication of such regulation, the Secretary notifies the manufacturer of such device that such regulation is to be made so effective. If the Secretary makes a proposed regulation so effective, he shall, as expeditiously as possible, give interested persons prompt notice of his action under this subsection, provide reasonable opportunity for an informal hearing on the proposed regulation, and either affirm, modify, or revoke such proposed regulation.

"JUDICIAL REVIEW

"Application of Section

"SEC. 517. (a) Not later than thirty days after—

"(1) the promulgation of a regulation under section 513 classifying a device in class I or changing the classification of a device to class I or an order under subsection (f)(2) of such section classifying a device or denying a petition for classification of a device,

"(2) the promulgation of a regulation under section 514 establishing, amending, or revoking a performance standard for a device,

"(3) the issuance of an order under section 514 (b)(2) or 515(b)(2)(B) denying a request for reclassification of a device,

"(4) the promulgation of a regulation under paragraph (3) of section 515 (b) requiring a device to have an approval of a premarket application, a regulation under paragraph (4) of that section amending or revoking a regulation under paragraph (3), or an order pursuant to section 515(g)(1) or 515(g)(2)(C),

"(5) the promulgation of a regulation under section 516 (other than a proposed regulation made effective under subsection (b) of such section upon the regulation's publication) making a device a banned device,

"(6) the issuance of an order under section 520 (f)(2), or

"(7) an order under section 520(g)(4) disapproving an application for an exemption of a device for investigational use or an order under section 520(g)(5) withdrawing such an exemption for a device,

any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial review of such regulation or order. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based his regulation or order as provided in section 2112 of title 28, United States Code. For purposes of this section, the term 'record' means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to such regulation or order, proceedings of any panel or advisory committee with respect to such regulation or order, any hearing held with respect to such regulation or order, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

"Additional Data, Views, and Arguments

"(b) If the petitioner applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceedings before the Secretary, the court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions. The Secretary may modify his findings, or make new findings by reason of the additional data, views, or arguments so taken and shall file with the court such modified or new findings, and his recommendation, if any, for the modification or setting aside of the regulation or order being reviewed, with the return of such additional data, views, or arguments.

"Standard for Review

"(c) Upon the filing of the petition under subsection (a) of this section for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided in such chapter. A regulation described in paragraph (2) or (5) of subsection (a) and an order issued after the review provided in section 515(g) shall not be affirmed if it is found to be unsupported by substantial evidence on the record taken as a whole.

"Finality of Judgments

"(d) The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28 of the United States Code.

"Other Remedies

"(e) The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law.

"Statement of Reasons

"(f) To facilitate judicial review under this section or under any other provision of law of a regulation or order issued under section 513, 514, 515, 516, 518, 519, 520, or 521 each such regulation or order shall contain a statement of the reason for its issuance and the basis, in the record of the proceedings held in connection with its issuance, for its issuance.

"NOTIFICATION AND OTHER REMEDIES

"Notification

"SEC. 518. (a) If the Secretary determines that—

"(1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and

"(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this Act (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk. An order under this subsection shall require that the individuals exposed to the risk with respect to which the order is to be issued be included in the persons to be notified of the risk unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notification. If the Secretary makes such a determination with respect to such individuals, the order shall require that the health professionals who prescribe or use the device notify the individuals whom the health professionals treated with the device of the risk presented by the device and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

"Repair, Replacement, or Refund

"(b)(1)(A) If, after affording opportunity for an informal hearing, the Secretary determines that—

"(i) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health,

"(ii) there are reasonable grounds to believe that the device was not properly designed and manufactured with reference to the state of the art as it existed at the time of its design and manufacture,

"(iii) there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a manufacturer, importer, distributor, or retailer of the device to exercise due care in the installation, maintenance, repair, or use of the device, and

"(iv) the notification authorized by subsection (a) would not by itself be sufficient to eliminate the unreasonable risk and action described in paragraph (2) of this subsection is necessary to eliminate such risk,

the Secretary may order the manufacturer, importer, or any distributor of such device, or any combination of such persons, to submit to him within a reasonable time a plan for taking one or more of the actions described in paragraph (2). An order issued under the preceding sentence which is directed to more than one person shall specify which person may decide which action shall be taken under such plan and the person specified shall be the person who the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears such responsibility or the Secretary determines that the protection of the public health requires that such decision be made by a person (including a device user or health professional) other than the person he determines bears such responsibility.

"(B) The Secretary shall approve a plan submitted pursuant to an order issued under subparagraph (A) unless he determines (after affording opportunity for an informal hearing) that the action or actions to be taken under the plan or the manner in which such action or actions are to be taken under the plan will not assure that the unreasonable risk with respect to which such order was issued will be eliminated. If the Secretary disapproves a plan, he shall order a revised plan to be submitted to him within a reasonable time. If the Secretary determines (after affording opportunity for an informal hearing) that the revised plan is unsatisfactory or if no revised plan or no initial plan has been submitted to the Secretary within the prescribed time, the Secretary shall (i) prescribe a plan to be carried out by the person or persons to whom the order issued under subparagaph (A) was directed, or (ii) after affording an opportunity for an informal hearing, by order prescribe a plan to be carried out by a person who is a manufacturer, importer, distributor, or retailer of the device with respect to which the order was issued but to whom the order under subparagraph (A) was not directed.

"(2) The actions which may be taken under a plan submitted under an order issued under paragraph (1) are as follows:

"(A) To repair the device so that it does not present the unreasonable risk of substantial harm with respect to which the order under paragraph (1) was issued.

"(B) To replace the device with a like or equivalent device which is in conformity with all applicable requirements of this Act.

"(C) To refund the purchase price of the device (less a reasonable allowance for use if such device has been in the possession of the device user for one year or more—

"(i) at the time of notification ordered under subsection (a), or

"(ii) at the time the device user receives actual notice of the unreasonable risk with respect to which the order was issued under paragraph (1),

whichever first occurs).

"(3) No charge shall be made to any person (other than a manufacturer, importer, distributor or retailer) for availing himself of any remedy, described in paragraph (2) and provided under an order issued under paragraph (1), and the person subject to the order shall reimburse each person (other than a manufacturer, importer, distributor, or retailer) who is entitled to such a remedy for any reasonable and foreseeable expenses actually incurred by such person in availing himself of such remedy.

"Reimbursement

"(c) An order issued under subsection (b) with respect to a device may require any person who is a manufacturer, importer, distributor, or retailer of the device to reimburse any other person who is a manufacturer, importer, distributor, or retailer of such device for such other person's expenses actually incurred in connection with carrying out the order if the Secretary determines such reimbursement is required for the protection of the public health. Any such requirement shall not affect any rights or obligations under any contract to which the person receiving reimbursement or the person making such reimbursement is a party.

"Effect on Other Liability

"(d) Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plantiff in such action of any remedy provided him under such order shall be taken into account.

"RECORDS AND REPORTS ON DEVICES

"General Rule

"SEC. 519. (a) Every person who is a manufacturer, importer, or distributor of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed under the preceding sentence—

"(1) shall not impose 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;

"(2) which prescribe the procedure for making requests for reports or information shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

"(3) which require submission of a report or information to the Secretary shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information;

"(4) may not require that the identity of any patient be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under this Act; and

"(5) may not require a manufacturer, importer, or distributor of a class I device to—

"(A) maintain for such a device records respecting information not in the possession of the manufacturer, importer, or distributor, or

"(B) to submit for such a device to the Secretary any report or information—

"(i) not in the possession of the manufacturer, importer, or distributor, or

"(ii) on a periodic basis,

unless such report or information is necessary to determine if the device should be reclassified or if the device is adulterated or misbranded.

In prescribing such regulations, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (4) of this subsection continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

"Persons Exempt

"(b) Subsection (a) shall not apply to—

"(1) ay practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of his professional practice;

"(2) any person who manufactures or imports devices intended for use in humans solely for such person's use in research or teaching and not for sale (including any person who uses a device under an exemption granted under section 520(g)); and

"(3) any other class of persons as the Secretary may by regulation exempt from subsection (a) upon a finding that compliance with the requirements of such subsection by such class with respect to a device is not necessary to (A) assure that a device is not adulterated or misbranded or (B) otherwise to assure its safety, and effectiveness.

"GENERAL PROVISIONS RESPECTING CONTROL OF DEVICES INTENDED FOR HUMAN USE

"General Rule

"SEC. 520. (a) Any requirement authorized by or under section 501, 502, 510, or 519 applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 513, 514, or 515 or under subsection (g) of this section, and any requirement established by our under section 501, 502, 510, or 519 which is inconsistent with a requirement imposed on such device under section 514 or 515 or under subsection (g) of this section shall not apply to such device.

"Custom Devices

"(b) Sections 514 and 515 do not apply to any device which, in order to comply with the order of a physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing) necessarily deviates from an otherwise applicable performance standard or requirement prescribed by or under section 514 or 515 if (1) the device is not generally available in finished form for purchase or for dispensing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and (2) such device—

"(A)(i) is intended for use by a patient named in such order of such physician or dentist (or other specially qualified person so designated), or

"(ii) is intended solely for use by (I) such physician or dentist (or other specially qualified person so designated) or (II) a person under his professional supervision in the course of the professional practice of such phyician or dentist (or other specially qualified person so designated), and

"(B) is not generally available to or generally used by other physicians or dentists

(or other specially qualified persons so designated).

"Trade Secrets

"(c) Any information reported to or otherwise obtained by the Secretary or his representative under section 513, 514, 515, 516, 518, 519, or 704 or under subsection (f) or (g) of this section which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device under section 513 from class III to class II or as the basis for the establishment or amendment of a performance standard under section 514 for a device reclassified from class III to class II, except that such information may be disclosed to other officers or employees concerned with carrying out this Act or when relevant in any proceeding under this Act (other than section 513 or 514 thereof).

"Notices and Findings

"(d) Each notice of proposed rulemaking under section 513, 514, 515, 516, 518, or 519, or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

"(1) the manner in which interested persons may examine data and other information on which the notice or findings is based, and

"(2) the period within which interested persons may present their comments on the notice or findings (including the need therefor) orally or in writing, which period shall be at least sixty days but may not exceed ninety days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefor.

"Restricted Devices

"(e)(1) The Secretary may by regulation require that a device be restricted to sale or distribution—

"(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

"(B) upon such other conditions (other than any condition which would limit the use of a device to a particular category or categories of physicians defined by their training or experience) as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. A device subject to a regulation under this subsection is a restricted device.

"(2) A restricted device shall be deemed to be misbranded if its label fails to bear such appropriate statements of the restrictions as the Secretary may in such regulation prescribe.

"Good Manufacturing Practice Requirements

"(f)(1)(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this Act.

"(B) Before the Secretary may promulgate any regulation under subparagraph (A) he shall—

"(i) afford the advisory committee established under paragraph (3) an opportunity to submit recommendations to him with respect to the regulation proposed to be promulgated, and

"(ii) afford opportunity for an oral hearing.

The Secretary shall provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A).

"(2)(A) Any person subject to any requirement prescribed by regulations under paragraph (1) may petition the Secretary for an exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as he shall prescribe and shall—

"(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this Act,

"(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, facilities, and controls prescribed by the requirement, and

"(iii) contain such other information as the Secretary shall prescribe.

"(B) The Secretary may refer to the advisory committee established under paragraph (3) any petition submitted under subparagraph (A). The advisory committee shall report its recommendations to the Secretary with respect to a petition referred to it within sixty days of the date of the petition's referral. Within sixty days after—

"(i) the date the petition was submitted to the Secretary under subparagraph (A), or

"(ii) if the petition was referred to an advisory committee, the expiration of the sixty-day period beginning on the date the petition was referred to the advisory committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

"(C) The Secretary may approve—

"(i) a petition for an exemption for a device from a requirement if he determines that compliance with such requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this Act, and

"(ii) a petition for a variance for a device from a requirement if he determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to assure that the device will be safe and effective and otherwise in compliance with this Act.

An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of the device to be granted the variance under the petition as may be necessary to assure that the device will be safe and effective and otherwise in compliance with this Act.

"(D) After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

"(3) The Secretary shall establish an advisory committee for the purpose of advising and making recommendations to him with respect to regulations proposed to be promulgated under paragraph (1)(A) and the approval or disapproval of petitions submitted under paragraph (2). The advisory committee shall be composed of 9 members as follows:

"(A) Three of the members shall be appointed from persons who are officers or employees of any State or local government or of the Federal Government.

"(B) Two of the members shall be appointed from persons who are representative of interests of the device manufacturing industry; two of the members shall be appointed from persons who are representative of the interests of physicians and other health professionals; and two of the members shall be representative of the interests of the general public.

Members of the advisory committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 United States Code for persons in the Government service employed intermittently. The Secretary shall designate one of the members of the advisory committee to serve as its chairman. The Secretary shall furnish the advisory committee with clerical and other assistance. Section 14 of the Federal Advisory Committee Act shall not apply with respect to the duration of the advisory committee established under this paragraph.

"Exemption for Devices for Investigational Use

"(g)(1) It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

"(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on the date of the enactment of this section, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 502, 510, 514, 515, 516, 519, or 706 or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

"(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

"(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

"(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

"(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

"(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing

to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device subject to the exemption during testing conducted in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data to obtain approval for the commercial distribution of such device.

"(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption—

"(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing—

"(i) to the local institutional review committee which has been established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

"(ii) to the Secretary, if—

"(I) no such committee exists, or

"(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the plan for such testing has been approved by such committee),

for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

"(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by a local institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

"(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

"(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except where, subject to such conditions as the Secretary may prescribe, the investigator conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative.

The determination required by subparagraph (D) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

"(4) (A) An application, submitted in accordance with the procedures prescribed by regulations under paragraph (2), for an exemption for a device (other than an exemption from section 516) shall be deemed approved on the thirtieth day after the submission of the application to the Secretary unless on or before such day the Secretary by order disapproves the application and notifies the applicant of the disapproval of the application.

"(B) The Secretary may disapprove an application only if he finds that the investigation with respect to which the application is submitted does not conform to procedures and conditions prescribed under regulations under paragraph (2). Such a notification shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application and afford the applicant opportunity for an informal hearing on the disapproval order.

"(5) The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the conditions applicable to the device under this subsection for such exemption are not met. Such an order may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health.

"Release of Safety and Effectiveness Information

"(h)(1) The Secretary shall promulgate regulations under which a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the Secretary and which was the basis for—

"(A) an order under section 515(d)(1)(A) approving an application for premarket approval for the device or denying approval of such an application or an order under section 515(e) withdrawing approval of such an application for the device,

"(B) an order under section 515(f)(6)(A) revoking an approved protocol for the device an order under section 515(f)(6)(B) declaring a protocol for the device completed or not completed, or an order under section 515(f)(7) revoking the approval of the device, or

"(C) an order approving an application under subsection (g) for an exemption for the device from section 516 or an order disapproving, or withdrawing approval of, an application for an exemption under such subsection for the device,

shall be made available to the public upon issuance of the order. Summaries of information made available to this paragraph respecting a device shall include information respecting any adverse effects on health of the device.

"(2) The Secretary shall promulgate regulations under which each advisory committee established under section 515(g)(2)(B) shall make available to the public a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the advisory committee and which was the basis for its recommendation to the Secretary made pursuant to section 515(g)(2)(A). A summary of information upon which such a recommendation is based shall be made available pursuant to this paragraph only after the issuance of the order with respect to which the recommendation was made and each such summary shall include information respecting any adverse effects on health of the device subject to such order.

"(3) Any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) may not be used t oestablish the safety or effectiveness of another device for purposes of this Act by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section.

"Proceedings of Advisory Panels and Committees

"(i) Each advisory panel under section 513 and each advisory committee established under section 514(g)(5)(B) or section 515(g) shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made pursuant to this subsection information which under subsection (c) of this section is ot be considered confidential.

"Traceability Requirements

"(j) No regulation under this Act may impose on a type or class of device requirements for the traceability of such type or class of device unless such requirements are necessary to assure the protection of the public health.

"Research and Development

"(k) The Secretary may enter into contracts for research, testing, and demonstrations respecting devices and may obtain devices for research, testing, and demonstration purposes without regard to section 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5).

"Transitional Provisions for Devices Considered as New Drugs or Antibiotic Drugs

Drugs or Antibiotic Drugs

"(l)(1) Any device intended for human use—

"(A) for which on the date of enactment of the Medical Device Amendments of 1976 (hereinafter in this subsection referred to as the 'enactment date') an approval of an application submitted under section 505(b) was in effect;

"(B) for which such an approval was filed on or before the enactment date and with respect to which application no order of approval or refusing to approve had been issued on such date under subsection (c) or (d) of such section;

"(C) for which on the enactment date an exemption under subsection (i) of such section was in effect;

"(D) which is within a type of device described in subparagraph (A), (B), or (C) and is substantially equivalent to another device within that type;

"(E) which the Secretary in a notice published in the Federal Register before the enactment date has declared to be a new drug subject to section 505; or

"(F) with respect to which on the enactment date an action is pending in a United States court under section 302, 303, or 304 for an alleged violation of a provision of section 301 which enforces a requirement of section 505 or for an alleged violation of section 505(a),

is classified in class III unless the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

"(2) The manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Except as provided in paragraph (3)(D)(ii), within one hundred and eighty days after the filing of a petition under this paragraph and after affording the petitioner an opportunity for an informal hearing, the Secretary shall, after consultation with the appropriate panel under section 513, by order either deny the petition or order the classification, in accordance with the criteria prescribed by section 513(a)(1)(A) or 513(a)(1)(B), of the device in class I or class II.

"(3)(A) In the case of a device which is described in paragraph (1)(A) and which is in class III—

"(i) such device shall on the enactment date be considered a device with an approved application under section 515, and

"(II) the requirements applicable to such device before the enactment date under section 505 shall continue to apply to such device until changed by the Secretary as authorized by this Act.

"(B) In the case of a device which is described in paragraph (1)(B) and which is in class III, an application for such device shall be considered as having been filed under section 515 on the enactment date. The period in which the Secretary shall act on such application in accordance with section 515(d)(1) shall be one hundred and eighty days from the enactment date (or such greater period as the Secretary and the applicant may agree upon the after the Secretary has made the finding required by section 515(d)(1)(B)(i)) less the number of days in the period beginning on the date an application for such device was filed under section 505 and ending on the enactment date. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

"(C) A device which is described in paragraph (1)(C) and which is in class III shall be considered a new drug until the expiration of the ninety-day period beginning on the date of the promulgation of regulations under subsection (g) of this section. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

"(D)(i) Except as provided in clause (ii), a device which is described in subparagraph (D), (E), or (F) of paragraph (1) and which is in class III is required to have on and after the enactment date in effect an approved application under section 515.

"(ii) If—

"(I) a petition is filed under paragraph (2) for a device described in subparagraph (D), (E), or (F) of paragraph (1), or

"(II) an application for premarket approval is filed under section 515 for such a device,

within the sixty-day period beginning on the enactment date (or within such greater period as the Secretary, after making the finding required under section 515(d)(1)(B), and the petitioner or applicant may agree upon), the Secretary shall act on such petition or application in accordance with paragraph (2) or section 515 except that the period within which the Secretary must act on the petition or application shall be within the one hundred and twenty-day period beginning on the date the petition or application is filed. If such a petition or application is filed within such sixty-day (or greater) period, clause (i) of this subparagraph shall not apply to such device before the expiration of such one hundred and twenty-day period, or if such petition is denied or such application is denied approval, before the date of such denial, whichever occurs first.

"(4) Any device intended for human use which on the enactment date was subject to the requirements of section 507 shall be subject to such requirements as follows:

"(A) In the case of such a device which is classified into class I, such requirements shall apply to such device until the effective date of the regulation classifying the device into such class.

"(B) In the case of such a device which is classified into class II, such requirements shall apply to such device until the effective date of a performance standard applicable to the device under section 514.

"(C) In the case of such a device which is classified into class III, such requirements shall apply to such device until the date on which the device is required to have in effect an approved application under section 515.

"STATE AND LOCAL REQUIREMENTS RESPECTING DEVICES

"General Rule

"SEC. 521. (a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

"(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

"(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

"Exempt Requirements

"(b) Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

"(1) the requirement is more stringent than a requirement under this Act which would be applicable to the device if an exemption were not in effect under this subsection; or

"(2) the requirement—

"(A) is required by compelling local conditions, and

"(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this Act."

CONFORMING AMENDMENTS

Amendments to Section 201

SEC. 3. (a)(1)(A) Paragraph (h) of section 201 is amended to read as follows:

"(h) The term 'device' (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

"(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

"(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

"(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes."

(B) Section 15(d) of the Federal Trade Commission Act is amended to read as follows:

"(d) The term 'device' (except when used in subsection (a) of this section) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

"(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

"(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

"(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.".

(2) Section 201 is amended by adding at the end the following:

"(y) The term 'informal hearing' means a hearing which is not subject to section 554, 556, or 557 of title 5 of the United States Code and which provides for the following:

"(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department of Health, Education, and Welfare who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

"(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

"(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

"(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

"(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

"(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.".

Amendments to Section 301

(b)(1) Section 301 is amended by adding at the end the following new paragraphs:

"(q)(1) The failure or refusal to (A) comply with any requirement prescribed under section 518 or 520(g), or (B) furnish any notification or other material or information required by or under section 519 or 520(g).

"(2) With respect to any device, the submission of any report that is required by or under this Act that is false or misleading in any material respect.

"(r) The introduction or delivery for introduction into interstate commerce for export of a device or drug in violation of an order issued under section 801(d)(7).".

(2) Section 301(e) is amended by striking out "or" before "512" and by inserting after "(m)" a comma and the following: "515(f), or 519".

(3) Section 301(j) is amended by inserting "510," before "512", by inserting "513, 514, 515, 516, 518, 519, 520," before "704", and by striking out "or 706" and inserting in lieu thereof "706, or 707".

(4) Section 301(l) is amended (A) by inserting "or device" after "drug" each time it occurs, and (B) by striking out "505" and inserting in lieu thereof "505, 515, or 520(g), as the case may be".

Amendments to Section 304

(c) Section 304(a) is amended (1) by striking out "device," in paragraph (1), and (2)

by striking out "and" before "(C)" in paragraph (2), and (3) by striking out the period at the end of that paragraph and inserting in lieu thereof a comma and the following: "and (D) Any adulterated or misbranded devices.".

Amendments to Section 501

(d) Section 501 is amended by adding at the end the following new paragraphs:

"(e) If it is, or purports to be or is represented as, a device which is subject to a performance standard established under section 514, unless such device is in all respects in conformity with such standard.

"(f)(1) If it is a class III device—

"(A)(i) which is required by a regulation promulgated under subsection (b) of section 515 to have an approval under such section of an application for premarket approval and which is not exempt from section 515 under section 520(g), and

"(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the Secretary within the ninety-day period beginning on the date of the promulgation of such regulation, or

"(II) for which such an application was filed and approval of the application has been denied or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

"(B)(i) which was classified under section 513(f) into class III, which under section 515(a) is required to have in effect an approved application for premarket approval, and which is not exempt from section 515 under section 520(g), and

"(ii) which does not have such an application in effect; or

"(C) which was classified under section 520(l) into class III, which under such section is required to have in effect an approved application under section 515, and which does not have such an application in effect.

"(2)(A) In the case of a device classified under section 513(f) into class III and intended solely for investigational use, paragraph (1)(B) shall not apply with respect to such device during the period ending on the ninetieth day after the date of the promulgation of the regulations prescribing the procedures and conditions required by section 520(g)(2).

"(B) In the case of a device subject to a regulation promulgated under subsection (b) of section 515, paragraph (1) shall not apply with respect to such device during the period ending—

"(i) on the last day of the thirtieth calendar month beginning after the month in which the classification of the device in class III became effective under section 513, or

"(ii) on the ninetieth day after the date of the promulgation of such regulation,

whichever occurs later.

"(g) If it is a banned device.

"(h) If it is a device and the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 520(f)(1) or an applicable condition prescribed by an order under section 520(f)(2).

"(i) If it is a device for which an exemption has been granted under section 520(g) for investigational use and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section.".

Amendments to Section 502

(e)(1) Section 502 is amended by adding at the end the following new paragraphs:

"(q) In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold or otherwise distributed in violation of regulations prescribed under section 520(e).

"(r) In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing. Except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52-55). This paragraph shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m).

"(s) If it is a device subject to a performance standard established under section 514, unless it bears such labeling or may be prescribed in such performance standard.

"(t) If it is a device and there was a failure or refusal (1) to comply with any requirement prescribed under section 518 respecting the device, or (2) to furnish any material or information required by or under section 519 respecting the device.".

(2) Section 502(j) is amended by inserting "or manner" after "dosage".

Amendments to Section 801

(f)(1) Section 801(d) is amended to read as follows:

"(d)(1) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it—

"(A) accords to the specifications of the foreign purchaser,

"(B) is not in conflict with the laws of the country to which it is intended for export,

"(C) is labeled on the outside of the shipping package that it is intended for export, and

"(D) is not sold or offered for sale in domestic commerce.

"(2) Paragraph (1) does not apply to any device which does not comply with an applicable requirement of section 514 or 515 or which is a banned device under section 516 unless, in addition to the requirements of paragraph (1), the device meets the following requirements:

"(A) If the device is intended for export to a country which has an appropriate health agency to review the device and authorize or approve it as safe for its intended use (including investigational use) within such country, such device may be exported to such country only if—

"(i) the device is so reviewed and authorized or approved by such agency, and

"(ii) notification with respect to the export of the device has been provided the Secretary in accordance with paragraph (6).

"(B) If the device is intended for export to a country which does not have an agency described in subparagraph (A), such device may be exported to such country only if the Secretary determines, upon application and after provision to the applicant of opportunity for an informal hearing on the application, that the exportation of the device to such country is not contrary to public health and safety.

"(3) Paragraph (1) does not apply to an antibiotic drug for which a regulation or release is not in effect pursuant to section 507 unless in addition to the requirements of paragraph (1), the drug meets the following requirements:

"(A) If the drug is intended for export to a country which has an appropriate health agency to review the drug and authorize or approve it as safe for its intended use (including investigational use) within such country, such drug may be exported to such country only if—

"(i) the drug is so reviewed and authorized or approved by such agency, and

"(ii) notification with respect to the export of the drug has been provided the Secretary in accordance with paragraph (6).

"(B) If the drug is intended for export to a country which does not have an agency described in subparagraph (A), such drug may be exported to such country only if the Secretary determines, upon application and after provision to the applicant of opportunity for an informal hearing on the application, that the exportation of the drug to such country is not contrary to public health and safety.

"(4) Paragraph (1) does not apply to a new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 512 unless, upon application to make that paragraph apply to such a drug or feed, the Secretary determines, after providing notice and opportunity for an informal hearing on the application, that—

"(A) the drug or feed meets the requirements of paragraph (1),

"(B) its exportation is not contrary to public health and safety of persons within the United States, and

"(C)(i) the appropriate health agency of the country to which the drug or feed is to be exported has reviewed it and authorized or approved it as safe for its intended use (including investigational use) in such country, or

"(ii) if there is no such agency, its exportation to such country is not contrary to public health and safety.

"(5) Notwithstanding section 301(d), a new drug for which an application is not in effect pursuant to section 505 may be introduced or delivered for introduction into interstate commerce for export if the new drug meets the following requirements:

"(A) The drug meets the requirements of paragraph (1).

"(B) If the drug is intended for export to a country which has an appropriate health agency to review the drug and authorize or approve it as safe for its intended use (including investigational use) within such country, such drug may be exported to such country only if—

"(i) the drug is so reviewed and authorized or approved by such agency, and

"(ii) notification with respect to the export of the drug has been provided the Secretary in accordance with paragraph (6).

"(C) If the drug is intended for export to a country which does not have an agency described in subparagraph (A), such drug may be exported to such country only if the Secretary determines, upon application and after provision to the applicant of opportunity for an informal hearing on the application, that the exportation of the drug to such country is not contrary to public health and safety.

"(6)(A) Each person who is required to

register under section 510 and who proposes to introduce or deliver for introduction into interstate commerce for export—

"(i) any device which does not comply with an applicable requirement of section 514 or 515 or which is a banned device under section 516,

"(ii) any antibiotic drug for which a regulation or release is not in effect pursuant to section 507, or

"(iii) any new drug for which an application is not in effect pursuant to section 505,

shall, on an annual basis and in accordance with regulations prescribed by the Secretary submit to the Secretary the notice prescribed by subparagraph (B) if the country to which such device or drug is intended for export has an appropriate health agency to review the drug or device and to authorize or approve it as safe for its intended use (including investigational use) in such country. A notice pursuant to this subparagraph may be amended in accordance with regulations of the Secretary.

"(B) The notice required by subparagraph (A) shall—

"(i) identify each drug and device described in subparagraph (A) which is to be introduced or delivered for introduction into interstate commerce for export during the twelve-month period beginning thirty days after the date the notice is submitted,

"(ii) identify the countries to which each such drug and device will be exported, and

"(iii) demonstrate to the satisfaction of the Secretary that each such device and drug complies with the requirements of paragraph (1) and has been reviewed by the appropriate health agency of the country to which it is being exported and such agency has authorized or approved it as safe for its intended use (including investigational use) in such country.

"(7) The Secretary may, after providing notice and opportunity for informal hearing, issue an order prohibiting the introduction or delivery for introduction in interstate commerce for export of any—

"(A) device which does not comply with an applicable requirement of section 514 or 515 or which is a banned device under section 516,

"(B) antibiotic drug for which a regulation or release is not in effect pursuant to section 507,

"(C) new drug for which an application is not in effect pursuant to section 505, or

"(D) new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 512 and with respect to which an application has been approved under paragraph (4) of this subsection,

if the Secretary determines that the export of such device, drug, or animal feed is inconsistent with the health and safety of persons within the United States.".

(2) Section 801(a)(1) is amended by inserting after "conditions" the following: "or, in the case of a device, the methods used in, and the facilities and controls used for, the manufacture, processing, and packing and installation of the device do not conform to the requirements of section 520(f)".

REGISTRATION OF DEVICE MANUFACTURERS

SEC. 4. (a) Section 510 is amended as follows:

(1) The section heading is amended by inserting "AND DEVICES" after "DRUGS".

(2) Subsection (a)(1) is amended by inserting "or device package" after "drug package"; by inserting "or device" after "the drug"; and by inserting "or user" after "consumer".

(3) Subsections (b), (c), and (d) are amended by inserting "or a device or devices" after "drugs" each time it occurs.

(4) Subsection (e) is amended by adding at the end the following: "The Secretary may by regulation prescribe a uniform system for the identification of devices intended for human use and may require that persons who are required to list such devices pursuant to subsection (j) shall list such devices in accordance with such system.".

(5) Subsection (g) is amended by inserting "or devices" after "drugs" each time such term occurs in paragraphs (1), (2), and (3) of such subsection.

(6) Subsection (h) is amended by inserting after "704 and" the following: "every such establishment engaged in the manufacture, propagation, compounding, or processing of a drug or drugs or of a device or devices classified in class II or III".

(7) The first sentence of subsection (i) is amended by inserting ", or a device or devices," after "drug or drugs"; and the second sentence of such subsection is amended by inserting "shall require such establishment to provide the information required by subsection (j) in the case of a device or devices and" immediately before "shall include" and by inserting "or devices" after "drugs".

(8) Subsection (j) is amended—

(A) in the matter preceding subparagraph (A) of paragraph (1), by striking out "a list of all drugs (by established name" and inserting in lieu thereof "a list of all drugs and a list of all devices and a brief statement of the basis for believing that each device included in the list is a device rather than a drug (with each drug and device in each list listed by its established name", and by striking out "drugs filed" and inserting in lieu thereof "drugs or devices filed";

(B) in paragraph (1)(A), by striking out "such list" and inserting in lieu thereof "the applicable list"; by inserting "or a device intended for human use contained in the applicable list with respect to which a performance standard has been established under section 514 or which is subject to section 515," after "512,"; and by inserting "or device" after "such drug" each time it appears;

(C) in paragraph (1)(B), by striking out "drug contained in such list" before clause (i) and inserting in lieu thereof "drug or device contained in an applicable list";

(D) by amending clause (i) of paragraph (1)(B) to read as follows—

"(i) which drug is subject to section 503(b)(1), or which device is a restricted device, a copy of all labeling for such drug or device, a representative sampling of advertisements for such drug or device, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product or device, or";

(E) by amending clause (ii) of paragraph (1)(B) to read as follows:

"(ii) which drug is not subject to section 503(b)(1) or which device is not a restricted device, the label and package insert for such drug or device and a representative sampling of any other labeling for such drug or device;";

(F) in paragraph (1)(C), by striking out "such list" and inserting "an applicable list" in lieu thereof;

(G) in paragraph (1)(D), by striking out "the list" and inserting in lieu thereof "a list"; by inserting "or the particular device contained in such list is not subject to a performance standard established under section 514 or to section 515 or is not a restricted device" after "512,"; and by inserting "or device" after "particular drug product" each place it occurs; and

(H) in paragraph (2), by inserting "or device" after "drug" each time it appears and, in paragraph (2)(C), by inserting "each" before "by established name".

(9) Such section is amended by adding after subsection (j) the following new subsection:

"(k) Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe)—

"(1) the class in which the device is classified under section 513 or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

"(2) action taken by such person to comply with requirements under section 514 or 515 which are applicable to the device.".

(b)(1) Section 301(p) is amended by striking out "510(j)," and inserting in lieu thereof "510(j) or 510(k),".

(2) Section 502(o) is amended (A) by striking out "is a drug and" and (B) by inserting before the period a comma and the following: "if it was not included in a list required by section 510(j), if a notice or other information respecting it was not provided as required by such section or section 510(k), or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 510(e) as the Secretary by regulation requires".

(3) The second sentence of section 801(a) is amended by inserting "or devices" after "drugs" each time it occurs.

DEVICE ESTABLISHED AND OFFICIAL NAMES

SEC. 5. (a)(1) Subparagraph (1) of section 502(e) is amended by striking out "subparagraph (2)" and inserting in lieu thereof "subparagraph (3)".

(2) Subparagraph (2) of such section is redesignated as subparagraph (3) and is amended by striking out "this paragraph (e)" and inserting in lieu thereof "subparagraph (1)".

(3) Such action is amended by adding after subparagraph (1) the following new subparagraph:

"(2) If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name (as defined in paragraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.".

(4) Such action is amended by adding after subparagraph (3) (as so redesignated) the following:

"(4) As used in subparagraph (2), the term 'established name' with respect to a device means (A) the applicable official name of the device designated pursuant to section 508, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.".

(b) Section 508 is amended (1) in subsections (a) and (c) by adding "or device" after "drug" each time it appears; (2) in subsection (b) by adding after "all supplements thereto," the following: "and at such times as he may deem necessary shall cause a review to be made of the official names by which devices are identified in any official compendium (and all supplements thereto)"; (3) in subsection (c)(2) by adding "or device" after "single drug", and by adding "or to two or more devices which are substantially equivalent in design and purpose" after "purity,"; (4) in subsection (c)(3) by adding "or device" after "useful drug", and after "drugs or drugs" each time it appears;

and (5) in subsection (d) by adding "or devices" after "drugs".

INSPECTIONS RELATING TO DEVICES

SEC. 6. (a) The second sentence of subsection (a) of section 704 (21 U.S.C. 374) is amended by inserting "or restricted devices" after "prescription drugs" both times it appears.

(b) The third sentence of such subsection is amended to read as follows: "No inspection authorized by the preceding sentence shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions to this Act), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (j), section 507(d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)."

(c)(1) Paragraph (1) of the sixth sentence of such subsection is amended by inserting "or devices" after "drugs" each time it occurs.

(2) Paragraph (2) of that sentence is amended by inserting ", or prescribe or use devices, as the case may be," after "administer drugs"; and by inserting "or manufacture or process devices," after "process drugs".

(3) Paragraph (3) of that sentence is amended by inserting ", or manufacture or process devices," after "process drugs".

(d) Section 704 is amended by adding at the end the following new subsection:

"(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records.".

ADMINISTRATIVE RESTRAINT

SEC. 7. (a) Section 304 is amended by adding at the end the following new subsection:

"(g)(1) If during an inspection conducted under section 704 of a facility or a vehicle, a device which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under subsection (a) or section 302, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device during the period of its detention for the purpose of identifying the device as detained. Any person who would be entitled to claim a device if it were seized under subsection (a) may appeal to the Secretary a detention of such device under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

"(2)(A) Except as authorized by subparagraph (B), a device subject to a detention order issued under paragraph (1) shall not be moved by any person from the place at which it is ordered detained until—

"(i) released by the Secretary, or

"(ii) the expiration of the detention period applicable to such order,

whichever occurs first.

"(B) A device subject to a detention order under paragraph (1) may be moved—

"(i) in accordance with regulations prescribed by the Secretary, and

"(ii) if not in final form for shipment, at the discretion of the manufacturer of the device for the purpose of completing the work required to put it in such form.".

(b) Section 301 is amended by adding after the paragraph added by section 3(b)(1) the following new paragraph:

"(s) The movement of a device in violation of an order under section 304(g) or the removal or alteration of any mark or label required by the order to identify the device as detained.".

CONFIDENTIAL INFORMATION; PRESUMPTION

SEC. 8. Chapter 7 is amended by adding at the end the following new sections:

"CONFIDENTIAL INFORMATION

"SEC. 707. The Secretary may provide any information which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section to a person other than an officer or employee of the Department if the Secretary determines such other person requires the information in connection with an activity which is undertaken under contract with the Secretary, which relates to the administration of this Act, and with respect to which the Secretary (or an officer or employee of the Department) is not prohibited from using such information. The Secretary shall require as a condition to the provision of information under this section that the person receiving it take such security precautions respecting the information as the Secretary may by regulation prescribe.

"PRESUMPTION

"SEC. 708. In any action to enforce the requirements of this Act respecting a device the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.".

COLOR ADDITIVES

SEC. 9. (a) Section 706 is amended (1) by inserting "or device" after "drug" each time it occurs, (2) by inserting "or devices" after "drugs" each time it occurs, and (3) by adding at the end of subsection (a) the following new sentences: "A color additive for use in or on a device shall be subject to this section only if the color additive comes in direct contact with the body of man or other animals for a significant period of time. The Secretary may by regulation designate the uses of color additives in or on devices which are subject this section.".

(b)(1) Section 501(a) is amended (A) by inserting "(3) if its" in lieu of "(3) if it is a drug and its"; (2) by inserting "(4) if (A) it bears or contains" in lieu of "(4) if (A) it is a drug which bears or contains"; and (3) by inserting "or devices" after "drugs" in subclause (B) of clause (4).

(2) Section 502(m) is amended by striking out "in or on drugs".

ASSISTANCE FOR SMALL MANUFACTURERS OF DEVICES

SEC. 10. The Secretary of Health, Education, and Welfare shall establish within the Department of Health, Education, and Welfare an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices to assist them in complying with the requirements of the Food, Drug, and Cosmetic Act, as amended by this Act.

The motion was agreed to.

The Senate bill was ordered to be read a third time, read the third time, and passed, and a motion to reconsider was laid on the table.

The title was amended to read as follows: "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."

A motion to reconsider was laid on the table.

A similar House bill (H.R. 11124) was laid on the table.

GENERAL LEAVE

Mr. ROGERS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks on the bill just passed.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Florida?

There was no objection.

FURTHER MESSAGE FROM THE SENATE

A further message of the Senate by Mr. Sparrow, one of its clerks announced that Mr. CHURCH and Mr. SYMINGTON be additional conferees, on the part of the Senate, on the bill (S. 2662) entitled "An act to amend the Foreign Assistance Act of 1961 and the Foreign Military Sales Act, and for other purposes."

SUMMER YOUTH UNEMPLOYMENT

(Mr. MITCHELL of Maryland asked and was given permission to address the House for 1 minute, to revise and extend his remarks and include extraneous matter.)

Mr. MITCHELL of Maryland. Mr. Speaker, you and most of my colleagues here in the Congress are painfully aware of the massive problem of unemployment which currently besets our Nation. With the national unemployment rate hovering around 8 percent and rates among certain categories of blacks approaching as much as 40 to 50 percent, slow congressional action juxtaposed with recalcitrant administration policy weakens the faith of millions of Americans in their Government as each day passes.

Soon, very soon, the already unbearable unemployment problem will be greatly aggravated as school systems across the country close their doors for the summer and, therefore, leave millions of young people with idle hands and empty pockets. This situation has been accurately defined in a Baltimore television editorial as "dynamite."

The editorial, presented by WJZ-TV 13 General Manager Joel A. Segall aptly describes the desperation of this situation in my city of Baltimore by pointing out:

If you're currently supporting yourself and a family, do you remember when everybody plagued you with the question, 'What are you going to do when you grow up?' Well, today for millions of young potential wage earners in this so-called affluent society, that question is loaded with dynamite. Let's take the Baltimore area alone, where the problem of unemployed youths has intensified racial resentment and the already frightening crime