The original documents are located in Box 45, folder "5/28/76 S510 Medical Device Amendments of 1976 (2)" of the White House Records Office: Legislation Case Files at the Gerald R. Ford Presidential Library.

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MEDICAL DEVICE AMENDMENTS OF 1975

MARCH 11, 1975.—Ordered to be printed

Mr. KENNEDY, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany S. 510]

The Committee on Labor and Public Welfare, to which was referred the 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 services, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

I. INTRODUCTION

One year ago, on February 1, 1974, the Senate passed the Medical Device Amendments of 1973, which would have provided the Food and Drug Administration, for the first time, the authority to require that all medical devices are safe and effective before they are allowed in the marketplace. Unfortunately, the House of Representatives was unable to complete its deliberation on this important piece of legislation.

On January 28, 1975, the Health Subcommittee conducted a hearing which once again underlined the urgency of enacting medical device legislation. The hearing focused on the Dalkon shield, an IUD which was used by two million American women, and hundreds of thousands of women overseas, before the very significant health hazards of the device became known. All witnesses before the Committee, including the Commissioner of the Food and Drug Administration, testified that many of the deaths and much of the illness attributed to this device could have been prevented if medical device legislation, as provided in the reported bill, had been in effect when the Dalkon shield was developed.

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Today the Food and Drug Administration only has limited authority to act with respect to a medical device in the market place which has been proven dangerous and patients have been injured. Medical device legislation is intended to assure that medical devices such as these IUD's meet the requirements of safety and effectiveness before they are put in widespread use throughout the United States.

The United States is generally recognized throughout the world as having the highest standards of safety and efficacy for prescription drugs. These standards have been made possible by Congress' decision to give the Food and Drug Administration sufficient authority to require that drugs be shown to be safe and effective before they are allowed on the market.

As medicine progresses, as research makes new breakthroughs, an increasing number of sophisticated, critically important medical devices are being developed and used in the United States. These devices hold the promise of improving the health and longevity of the American people. The Committee wants to encourage their research and development. The Committee also wants to be sure that the FDA has the proper authority to regulate that process so that Americans are not put at risk from the use of unsafe and ineffective medical devices. Therefore, the Committee believes it is a matter of utmost importance for the Senate to re-enact the Medical Device Amendments of 1975, which bill is identical to the legislation which passed last year.

What follows is the substance of a report filed last year by the Committee respecting S. 2368, which was favorably reported by the Committee and passed by the Senate. The Committee has reindorsed the report and the only changes that have been made are to substitute S. 510 for S. 2368 and to make conforming changes in the Section of the Committee's report respecting the tabulation of votes in the Committee.

II. History of Regulation of Medical Devices and Need for Legislation

Federal authority to regulate medical devices was first provided in the Federal Food, Drug, and Cosmetic Act of 1938. There had been no provisions in the Food and Drugs Act of 1906 to regulate device safety and claims made for devices. During the 1930's reformers pressed for enactment of legislation to enable the Food and Drug Administration (FDA) to undertake the same kind of effort against unsafe or quack devices as the 1906 Act had allowed against impure or fraudulent drugs.

The 1938 Act defined "device" and provided the same basic authority over devices as applied to drugs, with the important exception of preclearance authority which was only provided for new drugs. From legislative history it is clear the term "device" was intended to include both quack machines and legitimate articles such as surgical instruments, trusses, prosthetic devices, ultraviolet lights, contraceptives, and orthopedic shoes. No additional authority has been provided since 1938 to improve public protection against unsafe or unreliable devices.

At the time the 1938 Act became law, many of the legitimate devices were relatively simple items which applied basic scientific concepts so that experts using them could recognize whether the device was functioning. The major concern with these devices was assuring truthful labeling. In the early years, FDA's activity concerned grossly hazardous products such as lead nipple shields which exposed nursing infants to danger of lead poisoning. FDA also attacked nasal vaporizors and stem pessaries used in contraception or for producing abortion which had the potential for causing puncture or infection. FDA efforts against thermometers which failed to record properly stimulated the development of standards for these products which greatly improved their reliability. Similarly, FDA actions against prophylactics (condoms) forced industry measures to reduce the incidence of defects in these products.

Immediately after enactment of the 1938 Act, FDA made numerous seizures of misbranded devices. During World War II, however, regulatory activity in this area dropped off because war needs resulted in scarcity of metals and other materials used to make nonessential devices. When metals and other materials were again available after the war, numerous devices again appeared, many of which were in violation of the Act.

Many of FDA's legal actions involved fraudulent devices. Since ancient times, mankind has used various kinds of gadgetry to cure or ward off serious ailments. Charms and talismans have been used throughout recorded history by people who have attributed magical qualities to them. Inventive individuals have sought to apply the latest scientific discoveries to the alleviation of health conditions. For example, after Benjamin Franklin's discovery of the electrical force present in lightning, numerous individuals sought to use electrical energy to treat human ailments. At the time of the American Revolution, a gadget known as the Perkins Tractor became quite popular. This device was claimed to be capable of drawing disease out of the body by its electrical current. Although the construction and fantastic claims made for many quack devices over the years often seem quite amusing, use of these devices can have serious health consequences. Whether sold to a consumer or a health professional, a device which does not perform as promised may pose a risk to health as well as an economic detriment to the purchaser. Reliance on unwarranted claims made for a device, recommending use in serious disease conditions, may induce the purchaser to forego seeking timely and appropriate medical treatment. Fraudulent devices were a major concern of Congress in 1938 when it gave FDA authority to regulate devices.

A quack device which was the subject of FDA action in the late 1940's was the Spectochrome, of one Dinshah P. Ghadiali, which consisted of a 1,000-watt lamp, in a cabinet supplied with colored glass slides to fit an aperture through which the light bathed the patient. By becoming a member of Ghadiali's "Institute" for a fee of $90 a person could obtain the lamp plus voluminous literature which sought to cloak the scheme in oriental mysticism and sanctity. Claims were made for its value in treating such diseases as diabetes, cancer, tuberculosis and syphilis, and several thousand lamps were distributed. The first action against the lamp was a single seizure. After a trial which lasted thirty days, the jury rendered a verdict for the Government,

and the court enjoined distribution of the lamp. Ghadiali, nevertheless, continued to ship it. Multiple seizures followed which did not stop him. Criminal prosecution was then filed against Ghadiali and his corporation. After a trial, in which the Government presented an array of physicians and relatives of victims who had used the device and died from the diseases it was represented to cure. After a verdict of guilty, the court imposed against Ghadiali and his corporation fines totaling $20,000 and a three-year prison sentence against Ghadiali, but imprisonment was suspended on the condition that the business be stopped.

The Spectochrome case is related in detail, since it indicates the vast amount of effort the Government must expend in stopping the marketing of bogus devices.

Another type of device which was the subject of FDA action was the "Zerret Applicator," popularly called the "Plastic Dumbell," which consisted of two plastic water tumblers filled partially with water, sealed with paraffin, joined at their mouths by scotch tape, and set into paraffin in the handle of plastic baby rattles. It was claimed to introduce in the human body the energy given off by "expanded hydrogen atoms" or "Z rays" alleged to be present in the liquid sealed in the tumblers. The user was to hold the article in his hands keeping the feet flatly on the floor without crossing the legs, or while reclining. This it was claimed, caused the atoms of the body to expand and bring health through the hands. This article costing $50, was offered to correct obesity and abnormal thinness due to glandular malfunctioning, correct diarrhea and constipation, reverse the aging process, rejuvenate the user, and cure "any disease known to mankind."

The "Vrilium Tube" was a small pencil-shaped tube containing a glass vial of a white granular substance (barium chloride) worth one two-thousandths of a cent, but this tiny gadget, also called the "Magic Spike," was sold for $300 to gullible sick people. They were told that it had radioactive powers that would cure disease when it was worn on the body, and these trusting purchasers were using it for cancer, diabetes, leukemia, ulcers, and other serious diseases.

One popular area for quack devices has been diagnostic products. During the 1950's, the biggest source of such devices was the Electronic Medical Foundation of San Francisco. On March 16, 1954, an injunction barred shipment in interstate commerce of "Blood Specimen Carriers" for use in the Foundation's diagnostic machine, the "Radioscope." There were estimated to be about 5,000 of the devices throughout the country. The diagnostic service was based upon the theory that any ailment can be diagnosed by measuring enanations from a dried blood spot on sterile paper. Practitioners who mailed in the blood spots taken from their patients received, for a fee, a diagnosis blank filled in with the diseases which the patient was supposed to have, their location in the body, and the recommended "dial settings" for treatment with the Foundation's devices. The blood-spotted paper was put into a slot of the electrical device called the "Radioscope" while the operator stroked with a wand the abdomen of a person holding metal plates connected to the device. If a wand "stuck" to a particular location, that was supposed to be a manifestation of an "electronic reaction," and the operator determined from this the identity, kind, location, and significance of any disease present. Investigation disclosed that this diagnostic service was incapable of distinguishing the blood of animals or birds from that of man, or that of the living from the dead. Even a spot of coal-tar dye was reported as indicating systematic toxemia. The Foundation's literature listed hundreds of disease conditions which could be treated by their machines once the diagnoses had been made by means of the "Radioscope." Other devices for which diagnostic as well as therapeutic claims were made were the "Drown Radio Therapeutic Instrument," the "Magnetic Affinitizer," and the "Neuromicrometer." These devices involved their own bizarre intricacies of operation.

A considerable number of devices for applying electricity to the body were subject to regulatory action. This included: (1) devices which produced galvanic (direct) current of low voltage by means of dry cells or batteries ("Electreat," "Acme Electric Machine"), (2) devices which used alternating current with a transformer to reduce the voltage ("Sinuothermic," "Elector-Way"), (3) devices in which alternating current as added to galvanic in order to obtain a rippled or pulsating galvanic current ("Facial and Body Genie," "Vitalitone," "Elector-Pulse"). Other devices sought to use radioactivity, ultrasonic energy, or infrared, or ultraviolet light to diagnose or treat disease.

Some fraudulent devices have been sold to practitioners rather than consumers. One such device as the Micro-Dynameter, a string galvanometer for measuring minute electrical currents which was claimed to be capable of allowing diagnosis of particular diseases based on each disease's electrical potential. Nearly 1,200 units of the product were destroyed during one 12-month period after FDA obtained an injunction against continued shipment of the device in 1963.

FDA began focusing more attention on hazards from legitimate medical devices around 1960. The post-war era was characterized by many new medical discoveries and saw the development of a vast array of new and complicated medical equipment. Inventions included heart pacemakers, kidney dialysis units, and artificial blood vessels and heart valves.

Although many lives have been saved or improved by the new discoveries, the potential for harm to consumers has been heightened by the critical medical conditions in which sophisticated modern devices are used and by the complicated technology involved in their manufacture and use. In the search to expand medical knowledge, new experimental approaches have sometimes been tried without adequate premarket clinical or animal testing, quality control in materials selected, or obtaining patient consent.

The present law's inadequacy has become a matter of acute concern because of the rapid technological change in the medical device field. The sophistication of modern medical devices makes careful testing necessary to determine if a device operates safely and as claimed. In early regulatory actions FDA was able to carry its burden of proof that a device is unsafe or misbranded through expert testimony; more recently FDA has had to undertake testing of devices suspected of violating the law. Many devices are so intricate that skilled health professionals are unable to ascertain whether they are defective. Increasing numbers of patients have been exposed to increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used.

S. 2368 recognizes the benefits that medical research and experimentation to develop devices offers to mankind. It recognizes, too, the need for regulation to assure that the public is protected and that health professionals can have more confidence in the performance of devices.

The need for device legislation is demonstrated by the history of several cases against unsafe devices undertaken by FDA during the past few years. Hundreds of thousands of consumers bought a device called Relaxicisor during the 1950's and 1960's. This device was represented as an aid in reducing weight and operated by sending shocks through the muscles. Testing revealed the device could aggravate muscular, gastrointestinal, and other disorders. It took FDA five years to complete court proceedings necessary to eliminate Relaxicisors from the market. FDA expended some half-million dollars in this effort.

FDA's experience eliminating the Diapulse device from the market is another case demonstrating the unwieldy procedures and lack of preventive provisions of present law. Diapulse was a heat-generating device which was marketed to medical practitioners for some 121 therapuetic claims. The firm lacked scientifically valid data to substantiate the efficacy of the device in any of the conditions for which it was promoted. The first seizure of a Diapulse device occurred in December 1965. As a result of lengthy court proceedings against the device and company appeals it was not until 1972 that injunction against the manufacturer was obtained. During fiscal year 1973, FDA seized over 350 Diapulse devices.

In the late 1960's two important court decisions indicated that certain products which are in the legal grey area between drugs and devices may be considered drugs and hence subject to premarket clearance. In *Amp, Inc.* v. *Gardner*, 389 F. 2d 825 (2 Cir. 1968), the Court of Appeals for the Second Circuit held that a nylon suture was a new drug and not a device. Shortly thereafter the Supreme Court held that an antibiotic sensitivity disc was a drug in *United States* v. *An Article of Drug . . . Bacto-Unidisk*, 395 U.S. 954 (1968). As a result of these decisions FDA classified as drugs soft contact lenses, a pregnancy kit, and intrauterine contraceptive devices which contain drugs or trace metals. FDA has administratively developed a distinction between drug and device, which favors classifying a product as a drug if its intended action is chemical, or based on highly complex technology potential hazards of which may be reduced through new drug controls. FDA has tried to avoid lengthy court battles that could tie up the rest of its efforts.

The need for more comprehensive authority to regulate medical devices has been recognized by Presidents Kennedy, Johnson, and Nixon. In 1969, Dr. Theodore Cooper, Director of the National Heart and Lung Institute, headed a panel to review the need for additional medical device legislation. That panel reported its results in 1970. The Cooper committee searched the scientific literature for accounts of injuries from medical devices. Some 10,000 injuries were recorded, of which 731 resulted in death. For example, 512 deaths and 300 injuries were attributed to heart valves; 89 deaths and 186 injuries to heart pacemakers; 10 deaths and 8,000 injuries to intrauterine devices. After hearing the views of the medical community, the industry and consumer representatives, the Cooper Committee agreed with past proposals calling for device legislation to provide for standard-setting for certain devices and premarket clearance for others. A third category would be exempt from standards or preclearance. The Cooper committee also recommended that a balance be struck between the need for continuing research and the need for improved patient protection through a system of independent peer review for experimental devices.

III. Hearings

The Committee held two days of hearings on medical device legislation in 1973 and received testimony from twenty witnesses representing the Administration, industry groups, consumer groups, and professional groups. All witnesses agreed that there was a general need for medical device legislation although each had specific recommendations for changes in the Chairman of the Health Subcommittee, Senator Kennedy's bill, S. 2368; S. 1446, the Administration's bill introduced by Senator Javits; and S. 1337, introduced by Senator Nelson.

Congressman L. H. Fountain, Chairman of the House Intergovernmental Relations Subcommittee testified that "medical device legislation is sorely needed." In his testimony, he reviewed the findings of 5 days of hearings before his Subcommittee concerned with issues regarding the safety and effectiveness of particular medical devices; intrauterine contraceptive devices.

The Administration was represented by Assistant Secretary for Health Charles C. Edwards, who was accompanied by Dr. Alexander M. Schmidt, Commissioner of the Food and Drug Administration. Dr. Edwards stated "we support this legislation and urge its prompt enactment." His testimony recounted the experience FDA has had in trying to regulate medical devices in the absence of specific device legislation. Dr. Edwards' testimony also reviewed the findings of the "Cooper Committee," established by the Department of Health, Education, and Welfare in 1969 to review the need for medical device legislation. After a thorough search of the scientific literature for injuries associated with medical devices, the "Cooper Committee" reported that there were 10,000 serious injuries of which 731 resulted in death. The "Cooper Committee" also endorsed the need for medical device legislation. Dr. Edwards testified that "the increasing sophistication of medical devices has outpaced the Department's ability to protect the public from those that are faulty. One reason for this is that current law imposes no duty upon medical device manufacturers to establish a safety or efficacy of their products prior to marketing." Dr. Edwards went on to testify that the Department did not "have authority to prescribe standards of safety to which devices must conform."

Dr. Sidney Wolfe testified on behalf of the Health Research Group of Washington, D.C. Dr. Wolfe's testimony described the hazards associated with the use of life-supporting medical devices which had been developed without any regulatory oversight. He expressed the view that the premarket clearance section of the legislation was the key to appropriate safeguarding of the public health, and questioned whether standard setting would provide an adequate guarantee of safety or efficacy.

Dr. Russel J. Thompson, M.D., of the Silas B. Hayes Army Hospital at Fort Ord testified about his experience with the intrauterine device. He felt that the history of the development of IUDs illustrated the need for device regulation and testified:

> * * * under current standards of nonregulation in the United States, I could take a paperclip and fashion it into an IUD. I could begin inserting it into women without even informing them that it is an experimental and never-tested IUD, and I would not even have to inform the FDA of my newly invented IUD.

The testimony of Joel J. Noble, the Director of the Emergency Care Research Institute in Philadelphia also endorsed the need for medical device legislation. He testified about the results of his research which showed that:

> * * * the problems associated with most medical devices which may lead to adverse affects, including injury or death, are, in order of decreasing incidence: (1) operator error resulting from inadequate training, (2) deficiencies in repair maintenance inspection and control of devices within health care facilities, (3) fundamental design deficiencies, (4) deficiencies in manufacturing quality control.

Foster Whitlock, Vice Chairman, Board of Directors, Johnson and Johnson and the Chairman-Elect of the Board of Directors of the Pharmaceutical Manufacturers Association, spoke on behalf of an industry panel which consisted of Kenneth Marshall of the Health Industries Association; James D. Weirman of the Medical Surgical Manufacturers Association; Thomas E. Holleran of the National Electrical Manufacturers Association; Rodney R. Munsey of the Pharmaceutical Manufacturers Association; and Adrian L. Ringuette of the Scientific Apparatus Makers Association. Mr. Whitlock, on behalf of the panel, testified:

> Let me start by saying that in our opinion, S. 510 is in most respects responsive to the needs of the public. We are in basic accord with its major provisions.

Mr. Whitlock and each of the panel members presented a series of specific recommendations for changes in S. 510, each of which was considered by the Committee during its Executive Committee consideration of the measure, and many of which were incorporated into the Committee-reported bill.

Dr. Ralph B. Wolfe testified on behalf of the Planned Parenthood Federation of America. He responded to the concerns raised by Russell Thompson about the safety and effectiveness of IUDs and recounted the experience of his organization using the IUD. With regard to the specific legislation, Dr. Wolfe testified overall that:

> * * * The proposed legislation is comprehensive and meritorious. It should satisfy the long overdue need for strict regulation in an increasingly important area related to the public's well-being.

Dr. George Meyers representing the American Dental Association testified to the effect that the House of Delegates of the ADA had not

yet formally reviewed the legislation, but that he personally endorsed it and that it was appropriate for the dental industry to be included in its jurisdiction. Mr. James Murray represented the American Dental Trade Association. In his testimony, he agreed that there was a need for medical devices legislation but argued that dental devices should be exempted from the provisions of the legislation. He pointed out that most dental devices do not have great potential for harm and are not life-threatening, and that the market for dental products is very small. He testified:

> * * * To subject dental devices to the costly premarket clearance provision of the proposed legislation would seriously impair the improvement of existing dental devices and the development of new ones.

Carl Parker represented the Dental Manufacturers of America. His testimony also opposed the inclusion of the dental industry under the jurisdiction of this legislation.

Dr. Arthur Beall, Professor of Surgery at the Baylor College of Medicine represented the American College of Chest Physicians, the American College of Cardiology and the Society of Thorasic Surgery. Dr. Beall testified, "at the outset Mr. Chairman, let me say that S. 510 is fundamentally a sound and helpful piece of legislation." Dr. Beall's testimony presented specific suggestions for improvement in the legislation all of which were considered by the Committee during its Executive session consideration of the measure and many of the suggestions were incorporated into the Committee-reported bill.

Dr. Gerald Ranier, a practicing thorasic and cardiovascular surgeon and Associate Clinical Professor of Surgery on Voluntary Faculty of the University of Colorado Medical School, testified on behalf of the Association for the Advancement of Medical Instrumentation. In his testimony, he stated that "AAMI supports, in principle, this legislation." His testimony also offered several specific suggestions for improvements, which were reviewed by the Committee during its Executive session consideration of the bill.

The final witness was Dr. Richard E. Palmer, member of the Board of Trustees of the American Medical Association. He testified on behalf of the AMA that:

> We support the principles and many of the provisions contained in your bill, S. 510, which are similar to a House counterpart bill, but we would like to offer in our supplementary statements suggestions for modifications with respect to the bill for the consideration of the Committee.

He also testified that:

> We believe that the general approach taken in the legislation should be supported. We think it is advisable that devices should be defined, identified and classified. Similarly, it is beneficial that provision should be made for maximum use not only of the expertise within the FDA, but also significant expertise which is to be found in the medical scientific and manufacturing communities. We are pleased that the legislation provides for the use of expert consultation on

recommendations in the classification and evaluation of evidence upon which determination for safety effectiveness and proper classification are based.

Based upon the widespread support for the Committee's bill and the urgent need for medical device legislation, the Committee considers the hearing record to be adequate.

IV. Committee Views on the Medical Devices Bill

Committee Views—Section 511

The Committee recognizes the great diversity among the various medical devices and their varying potentials for harm as well as their potential benefit to improved health. Therefore the Committee recommends that all medical devices be classified into one of three categories based upon the degree of risk to the public health and safety represented by each individual device or class of devices. The Committee believes that those devices for which insufficient information exists to assure effectiveness or to assure that exposure to such devices will not cause unreasonable risk of illness or injury, and for which standards or other means may not be appropriate to reduce or eliminate such risk of illness or injury, should be subject to the most rigorous kind of premarket scientific review. The Committee believes that in respect to other devices, if the nation's experts, who will be well represented on the classification panels, determine that it is appropriate to establish reasonable performance standards relating to safety and effectiveness in order to protect the public health and safety, then the devices may be placed in the standard-setting category. Finally, the Committee believes that if the panels conclude that still other devices are safe and effective when used in conjunction with instructions for usage and warnings of limitation, then neither the premarket clearance nor standard-setting mechanism should be necessary to protect the public health and safety.

It is the Committee's intent that the widest range of national expertise in the medical devices area should be utilized in the establishment of classification panels. The Committee recognizes that experts from the industry could significantly contribute to the work of such panels because of their knowledge of industry practices and available technology. The Committee was concerned, however, about potential conflict of interest if industry representatives were to have ultimate decision-making responsibilities in an area that could vitally affect their own interest and perhaps their employment. The Committee therefore has provided that industry members may serve on the panels, but has specified that they be *non-voting* members.

The Committee was equally concerned that representatives of consumer interests be able to participate on the panels. The Committee has therefore designated a non-voting consumer panel member for each of the panels.

The Committee is aware that the Food and Drug Administration has already begun a preliminary classification of medical devices. In this regard, there have been considerable questions with regard to the appropriate weight that should be given to classifications already made by the panels now in existence under present law. These panels have not fully utilized or adhered to the criteria for classifications as embodied in this bill. Therefore the Committee does not believe that prior classifications should be accepted as such, but that a review of the work of these existing panels should be carried out. On the other hand, the Committee believes that the work of these panels has been most valuable and should wherever applicable, be utilized. Therefore, the Committee has authorized the Secretary to utilize the existing panels, and the information and findings developed by such panels, wherever review determines that to be the appropriate procedure.

The Committee recognizes the importance of the classification process. The report of the panel is considered to be a preliminary classification. This is to avoid a conflict which could arise if a device was classified by a panel under one classification and yet later failed to meet the statutory prerequisites for being so classified or met the statutory prerequisites for a different classification. The Committee wishes to make it clear that the classification report is to be used as guidance by the Secretary in pursuing the procedures set out in other sections for permanently subjecting devices to particular regulatory procedures. This preliminary report is intended to serve as notice to manufacturers and others of the intent to proceed in a certain direction and thereby provide industry with an opportunity to begin developing any data or information which may be needed later to support continued marketing of a device. Because of the preliminary nature of the classification there is no need to provide full administrative safeguards for this process, which thereby facilitates and expedites the chore of classifying thousands of devices. The Committee has provided for full administrative safeguards once classification is final and a course of action has been embarked upon.

The Committee believes that a manufacturer who thinks he has developed a significantly new or modified medical device should have the opportunity to petition for a classification of that new device. Until such time as that new product is classified the manufacturer may not market the product. The purpose of this provision is not intended to be strictly comparable to the new drug provisions in the Food, Drug and Cosmetic Act. This section is simply intended to provide a mechanism whereby devices which are new or which significantly differ from those devices previously classified, can be brought to the attention of the Secretary for the purpose of classification prior to marketing.

Section 513

This section authorizes the Secretary to establish standards for medical devices. The Committee purposely added the word "performance" before the word "standards" in this section. It is not the intention of the Committee to simply authorize the establishment of standards for the purpose of mechanically standardizing medical devices. The Committee believes that standards must relate to the safety or effectiveness (including reliability over time) of the device or other "performance" characteristics. The Committee intends that performance standards shall also go to questions of indicated uses, proper labeling, instructions for use, warnings and uniformity of manufacture when those are in the interest of safety or proper and effective use.

The Committee recognizes that the state of the art in the medical devices field is rapidly changing and continually improving and has

therefore provided that the Secretary shall undertake a periodic evaluation of the adequacy of all performance standards to be sure that they reflect changes in technology or medical science.

The Committee believes that maximum use should be made of standards that have already been developed by other Federal agencies and other nationally recognized standard-setting agencies or organizations. The Committee believes that the Secretary should review existing standards and should determine their applicability to meeting the requirements of this section.

The Committee has provided for procedural safeguards in the standard-setting process. There is time to comment upon the published notice of the need to develop a standard. If after reviewing those comments the Secretary publishes findings which are not responsive to the comments, a mechanism is provided for an appeal of the Secretary's findings to the Court of Appeals and eventually to the Supreme Court. There is further review once a standard has been developed and the Secretary has issued a proposal to promulgate a standard. At that point interested parties may comment upon the proposal or can request referral of the proposal to an independent scientific advisory committee for review. There is further recourse in terms of appealing the order establishing the standard to the Court of Appeals and, if necessary, to the Supreme Court. The Committee believes that the availability of these safeguards will protect and balance the rights of the different interests involved in the regulation of medical devices.

The Committee believes that the development of standards requires the application of sophisticated knowledge. It is recognized that a considerable amount of expertise in this area exists outside the Government. The Committee wanted to use this expertise and yet at the same time guard against a potential conflict of interest which might result if a standard were developed by a party having a proprietary interest in the nature of that standard. Therefore, the Committee-reported bill provides that when more than one offer to develop a standard is received, and where each offer is technically competent, the Secretary shall give priority to offerors who have no proprietary interest in the device for which the standard is to be developed. The Committee believes that, when nongovernmental groups (offerors) offer to develop standards for the Secretary's consideration, members of such groups should be required to disclose certain information in order to minimize the potential for conflict of interest that might arise. Such information, as required by regulation, shall be made publically available at such time as an offer is accepted by the Secretary, in order to aid in the assessment of a proposed standard. The language in the bill is derived from the guidelines used by the National Academy of Sciences in requiring disclosure by committee members "On Potential Sources of Bias." The Committee intends that the Secretary shall be guided by these guidelines, and by the Conflict of Interest provisions of Public Law 87–849 (18 U.S.C. 202(a), in drafting regulations under this section.

The Committee has authorized the Secretary, under this Section, to impose individual lot-testing where it is necessary and where no more practical means to achieve consistency or reliability are available. The Committee's intent is not to thwart the use of this procedure, but rather to insure that it will not be required as a regular part of each and every standard. To the extent that safety, effectiveness and reliability can reasonably be achieved without imposing individual lot-testing, the Committee intends that the procedure not be used.

The Committee was impressed by testimony at the hearings to the effect that the skill of the user of the medical device has a direct and significant bearing on the safety and effectiveness of that device. Therefore the Committee intends that the evaluation of the safety and efficacy of a device be done in relation to the skill of the person who is to utilize it. The Committee intends that if a device is safe only in the hands of eminently qualified specialists, that that device will be restricted to use by those specialists.

The Committee believes it necessary to specifically prohibit manufacturers from stockpiling devices from the date of promulgation of a performance standard and the effective date of such a standard. This is analogous to provisions of the Consumer Product Safety Act and is intended to prohibit manufacturers or distributors from building abnormal inventories of products which would not meet an appropriate standard.

The Committee wishes to make it clear that standards and premarket approval mechanisms are not mutually exclusive. A component of a device which is subject to premarket clearance may also be required to conform to an applicable standard. The basic intent of the legislation is to assure safe and effective devices and the Secretary is authorized to use all of the authorities contained in this Act in any combination deemed necessary to protect the public health and safety.

The Committee has specifically exempted all veterinary devices from the purview of this legislation.

The Committee is aware of the special relationship that each health practitioner has with his patients. It is also aware of the need to develop special customized devices to meet the particular needs of a given patient. It is also aware of the need for individual research on medical devices. Therefore the Committee exempts custom devices from the standard setting requirements and from premarket scientific review. This exemption shall apply only for devices ordered by physicians and the other health professionals designated by regulation, according to their own specifications. Those medical devices which are ordered for individual patients, to qualify for this exemption, may not be used as a course of conduct and may not be generally available through commercial channels to the professions. It is the intent of these provisions to allow physicians to order custom-made products but not to permit manufacturers to circumvent standards-setting and scientific review requirements by commercially exploiting these products. The phrase "devices not being used as course of conduct" does not prohibit a physician from ordering a custom instrument and using it in his practice on several patients. This exemption has been a cause of serious concern for the Committee, although it recognizes the need to exempt such devices so that innovation is not stifled and so that custom fitting or sizing would not be prohibited. It is not the intent of this exemption to allow for the development of customized "quack" devices or devices known to be unsafe or ineffective.

The Committee has approached the problem of "quack" or worthless devices in an additional way, by authorizing the ban of certain devices which present a risk of illness, inqury, disability or deception and for which feasible standards could not be established and premarket scientific review would not be adequate. This section is aimed primarily at quack, worthless or totally unproven devices, but the Committee envisions that there will be other instances in which the banning of devices would be the appropriate regulatory action to be pursued. The Committee has also included a provision to authorize the seizure of devices which are distributed wholly in intrastate commerce. This provision will be applicable to all devices and will assist enforcement by doing away with the cumbersome and time consuming task of establishing interstate shipment. This provision will be particularly useful against quack devices.

The Committee recognizes the rapidly changing nature of the devices field and therefore feels that provisions must be made to amend standards on the basis of improved technology or new scientific evidence. Such amendments should be made in an expedited fashion so that appropriate changes can be rapidly implemented. The purpose of this authority is to permit new or improved devices to be marketed without delay so that the public may have such beneficial devices available to them as soon as possible.

Section 514

This section provides for the premarket scientific review of medical devices. The Committee spent a great deal of time deciding upon the criteria to be used in determining whether or not a particular device should be subject to premarket scientific review. The Administration's bill would have restricted such review to devices used in "life threatening situations" among other preconditions for such review. The Committee believes that this approach would be too restrictive because many devices could cause serious illness or injury which are not necessarily used in life threatening situations. The Committee believes that the potential for harm inherent in a certain device may not be determined solely on the basis of its intended use. Therefore the Committee has provided that the Secretary may declare a device subject to premarket clearance if, after consultation with appropriate panels, such review is found appropriate to insure safety and effectiveness or to reduce or eliminate unreasonable risk of illness or injury. The Committee intends that devices which are considered to be "life supporting or life sustaining" shall be subject to premarket scientific review. In addition, the Committee believes that the Secretary should have the authority to declare a device subject to scientific review whenever the Secretary feels that such a classification would be appropriate to protect the public health and safety. This authority would enable the Secretary to require premarket review even if the classification panels had not recommended such review. Additionally, the Committee has provided that premarket scientific review should be imposed only when there is no more practical means available to reduce or eliminate such risk of illness or injury. However, the Committee wishes to make clear that this latter criteria should not be viewed in the absolute. It is not intended to impose upon the Secretary that he establish beyond any doubt that there is no other means available to accomplish the goals of safety and effectiveness. Rather, he must reasonably find that other readily available means do not offer the same assurance of success or probability of success as premarket review does.

In the course of its deliberations the Committee was guided by the decisions that have been made by the classification panel on the review of cardiovascular devices already in existence. In particular the minutes of the panel meeting on October 9, 1973 said:

> The panel also reviewed the classification results for all of the cardiovascular devices. It was pointed out that since the scientific review or premarket clearance process may be the only method available to the panel by which it may request and analyze data pertinent to a device's safety and efficacy, that several different types of devices may show up in this proposed regulatory category. Obviously those devices which are life supporting, life sustaining or potentially hazardous to health, and which at the same time are in a stage of rapid development need premarket clearance in order to insure their safety and efficacy. Other devices which are also potentially hazardous to health or life supporting or life sustaining may also be placed in the scientific review category even though their widespread clinical use may generally be considered safe and effective. It is not expected that this latter group of devices would require the same type of review as the first group of devices mentioned. However, under proposed legislation, placing them in scientific review would give the Secretary and the advisory panel the opportunity to request and analyze the safety and efficacy data when this appears necessary in order to protect the public health.
>
> Pacemakers and artificial heart valves are examples of life supporting devices which are in a stage of development which is rapidly changing and which would require scientific review. Monitoring devices used in an intensive care unit and a number of devices used to diagnose cardiac function are examples of the latter group of scientific review devices discussed in the paragraph above.

The Committee understands that the decision to require premarket clearance is one of the most crucial decisions to be made under this Act. It has therefore constructed appropriate appeal mechanisms into the legislation. Once a regulation has been published declaring that a device shall be subject to scientific review, a mechanism is provided whereby that decision may be appealed to the Court of Appeals and eventually the Supreme Court.

The Committee believes that the scientific review process must be one that is characterized by the highest standards of scientific excellence. In order to avoid a proliferation of scientific panels under this Section, the Committee has decided that the panels used for classification shall, to the extent possible, be utilized during the process of premarket scientific review. These panels will be subject to the Federal Advisory Committee Act.

The Committee has built further appeals mechanisms into the scientific review process. Once an application for scientific review has been submitted and reviewed under this Section, the applicant may appeal

a negative decision by requesting that his application be referred to an independent advisory committee (in lieu of a hearing). If the independent advisory committee concurs in the decision to deny the applicant's proposal or if the Secretary does not concur in the committee's recommendation to permit marketing, the applicant may seek review by the Court of Appeals and eventually appeal to the Supreme Court.

The Committee recognizes the necessity to encourage scientific investigation in the medical devices field and has attempted to provide optimum freedom for individual scientific investigators in their pursuit of that objective. The Committee has therefore provided an exemption to qualified scientific investigators from the requirements of this Section during the time of the investigational use of devices in order that they may collect sufficient data to establish that the device should be on the market. The Secretary may, by regulation, (after an opportunity for an informal hearing), establish procedures governing this exemption in addition to those set out in the legislation. The Committee has provided in the reported bill that the Secretary shall have thirty days after the receipt of a submission under this Section to determine whether or not the investigation is appropriate. The Secretary may not delay the beginning of an investigation beyond thirty days unless he finds that the investigation does not or will not conform to this Section or to the regulations issued thereunder and has notified the sponsor of such findings. The Committee has also specifically defined the meaning of informed consent which must be obtained in all but exceptional cases from any individual being used in investigations under this Section.

The Committee was impressed by the argument presented by the devices industry of the need to establish a mechanism for the approval of devices subject to rapid obsolescence or frequent modification. Therefore, the Committee has established in the reported bill the product development protocol mechanism for such devices. The decision on whether or not this provision should be used in a particular case rests solely with the Secretary and in his discretion. The Committee wishes to make it clear that only an informal hearing shall be provided for a revocation of a product development protocol before the Secretary has approved a notice of completion. However, once a notice of completion is approved, the applicant shall have the same administrative rights as the holder of an approval under scientific review.

Section 515

The Committee has been guided in the development of this Section by the provisions of the Federal Hazardous Substances Act and the Consumer Product Safety Act. The Committee believes that producers, assemblers, distributors and importers of devices should immediately notify the Secretary of any defect which could create a substantial risk to the public health or safety or fails to comply with the established standards. The Committee wants to make it clear that information or statements exclusively derived from the notification required by this Section cannot be used as evidence in any proceeding brought against a natural person pursuant to Section 303 of the Federal Food, Drug and Cosmetic Act with respect to a violation of law occurring prior to or concurrently with a notification. The Committee feels that the Secretary should have considerable discretion in determining whether or not users of devices must be notified of defects in any given case. The Committee believes, however, that notice of defective devices should go to the general public unless the Secretary determines that such notification would endanger the public health or is unwarranted because of the insignificant nature of the deviation from the standard.

Section 501

The Committee has amended Section 501 of the Federal Food, Drug and Cosmetic Act to authorize the Secretary to issue substantive current good manufacturing practice regulations which will be applicable to medical devices and establishments manufacturing, processing or handling medical devices. The Committee believes that both industry and consumers have a vital interest in these regulations and that each should have a full opportunity to participate in the development of such regulations.

Section 502

The Committee believes that the Secretary of Health, Education, and Welfare should have authority to regulate prescription medical device advertising. Therefore, the Committee has provided that the Federal Trade Commission Act (15 U.S.C. 52–57) will not be applicable to the advertising of prescription medical devices. The Committee believes that the Secretary of HEW in administering this new law will develop significantly more expertise in the area of medical devices than the Federal Trade Commission and that therefore the regulation of prescription device advertising is more properly vested in the agency most knowledgeable about the area and the one that is truly charged with matters affecting public health and thus assuring the safety and efficacy of medical devices.

Section 709

The Committee recognizes that the medical device field is a rapidly expanding industry. The Committee feels that the Secretary should be authorized to provide for (either directly or through contracts) new research and investigation into the safety and effectiveness of devices and the causes and prevention of injuries or other health impairments associated with exposure to or use of such devices. In addition, research should be carried out to lead to the development and improvement of device performance standards. The Committee recognizes that a device is only as good as the expert who uses it and therefore authorizes the Secretary to conduct programs for the education and training of individuals with respect to proper installation and use of devices.

Section 201

The Committee recognizes that there is confusion at the present time about whether certain articles are to be treated as devices or drugs under the Food, Drug and Cosmetic Act. Therefore, the Committee reported bill has carefully defined "device" so as to specifically include implants, in-vitro diagnostic products and other similar or related articles. In vitro diagnostic products include those products which are not ingested and which are used to assist in the diagnosis of disease or other conditions of the body.

Section 801

The Committee reported bill has amended Section 801 of the Food, Drug and Cosmetic Act, which relates to the exportation of devices.

The Committee does not believe that substandard or unsafe or ineffective devices should be permitted to be exported to foreign nations and has thus provided in its bill that the Secretary may deny export of any devices which do not fully conform to the provisions of this Act. The Committee has, however, found that in many instances, articles subject to the Federal Food, Drug and Cosmetic Act which may not meet domestic standards for one reason or another might properly and significantly benefit foreign nations. The Committee has therefore provided in this section of the bill that such articles may be exported to foreign countries when the Secretary finds that the non-compliance is not of such a nature as to expose the populations of foreign nations to undue risks of the public health and provided that the foreign nation specifically approves of such an export.

General

The Committee wishes to take specific note of the testimony of a number of witnesses, both within and without the industry who expressed concern about the impact of this legislation on the small manufacturer of medical devices. The concern stemmed from the importance of the small innovative manufacturer in the invention and development of new medical devices and the inability of these firms, because of limited financial resources, to sustain the high level of administrative costs demanded of a highly regulated industry. The Committee believes that these concerns are legitimate, as long as they are concerns for the preservation of small business consistent with the public's need for safe and effective medical devices. The Committee is confident that the administration of this new law will also take into account the need to preserve the small manufacturer's role in the device industry.

V. Tabulation of Votes Cast in Committee

Pursuant to section 133(b) of the Legislative Reorganization Act of 1949, as amended, the following is a tabluation of votes in Committee:

There were no rollcall votes cast in the Committee and the bill was ordered reported to the Senate unanimously.

VI. Cost Estimate Pursuant to Section 252 of the Legislative Reorganization Act of 1970

In accordance with Section 252(a) of the Legislative Reorganization Act of 1970 (Public Law 91-510, 91st Congress) the Committee estimates that the cost which would be incurred in carrying out this bill is as follows:

No new funds are authorized by this legislation. The administration estimated that supplemental funds in the amount of $14 million would be requested in order to carry out the provisions of this act.

VII. Section-by-Section Analysis of S. 510

Section 1. Short title "Medical Device Amendments of 1973."

TITLE I—PRELIMINARY CLASSIFICATION OF MEDICAL DEVICES

Section 101. Amends chapter V of the Federal Food, Drug, and Cosmetic Act to add a new section 511 as follows:

Section. 511. (a) Requires Secretary, within 60 days following first appropriation of funds for this purpose, to appoint panels of scientific experts to review and classify devices into appropriate categories based on safety and effectiveness. Panels are required to submit their findings to the Secretary within one year of their appointment. To the maximum extent practical, panels are to provide opportunities for any interested persons to present their views on device classifications. Authorizes use of any existing expert panels formed prior to enactment of this Act for purposes of classification. Classification panels shall also serve as scientific review panels referred to in a later section of the bill.

(b)(1) Members are to be skilled in use of or experienced in development, manufacture, perfection or utilization of devices. In addition to such experts, panels shall include as nonvoting members, representatives of consumer and industry interests. Panel members may be nominated by appropriate scientific, trade, and consumer organizations.

(2) Members are to have adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences or relating professions. The Secretary shall designate one member of each panel as Chairman. Sets methods of compensation for members.

(c) Panels are required to submit recommendations for the classification of devices into one of the three following categories, and to the extent practicable, assign priorities within such classes:

(1) Devices subject to premarket scientific review—Those devices for which insufficient information exists to (A) assure effectiveness or assure that the device will not cause unreasonable risk of illness or injury and (B) standards or other means may not be appropriate to eliminate such risk. Premarket scientific review shall be required for any such device if the panels determine the device is life sustaining or life supporting.

(2) Devices subject to standards—those devices for which standards are appropriate to eliminate unreasonable risk and for which other means may not be appropriate.

(3) Exempt devices—Those devices which are safe and effective when used in accord with directions (which are adequate for intended users) and which present minimum risk.

(d) Requires Secretary to publish report on device classification scheme in the Federal Register and to allow for comment by interested persons. After reviewing comments, Secretary is required to provide by regulation for preliminary classification of devices. Allows Secretary to establish priorities for implementing regulatory action war-

ranted by such classification and to defer such action until an appropriate time consistent with expeditious implementation of the provisions.

(e) Permits Secretary to reclassify devices upon a specific finding and with advice of the appropriate panel.

Such findings shall be published in the *Federal Register* and interested persons shall have an opportunity to comment thereon.

TITLE II—AUTHORITY TO ESTABLISH PERFORMANCE STANDARDS

SEC. 513. (a) (1) Authorizes Secretary to issue a performance standard (including uniformity and compatibility with systems or environments) for any device for which a standard has been deemed appropriate, whenever such action is appropriate to reduce or eliminate unreasonable risk of illness or injury and when other means of reducing such risks may not be appropriate.

Standard is to relate to safety, effectiveness over time, including where appropriate, reference to any one or more of the following: Composition, construction, properties, uniform identification, or performance of such device.

Standard may also include: Provision for testing and measurement of characteristics, including where necessary, individual lot testing by or at direction of the Secretary.

Secretary may require the use of and prescribe the form and content of instructions or warnings for proper installation, maintenance, operation and use of device.

(2) A performance standard may require device (or components) to be marked, tagged or accompanied by adequate warning and instruction for protection of health or safety.

(3) Secretary shall provide for periodic review of standards to be sure they keep pace with changes in the state of the art.

(4) When devices are intended for use by surgeons or other specially qualified persons, their safety and effectiveness shall be determined in the context of such intended use.

(b) (1) Prior to and during development of proposals for performance standards, Secretary would be required to consult with and consider relevant standards published by other Federal agencies of nationally or internationally recognized standard-setting agencies or organizations. Secretary may invite participation through conferences or other means of informed persons representative of scientific, professional, industry, or consumer organizations.

(2) In carrying out his duties under this section, the Secretary to the maximum practicable extent shall utilize the personnel, facilities and technical support available in other Federal agencies.

(c) (1) Requires Secretary to publish in the *Federal Register* a notice that proceedings are being initiated to promulgate a device performance standard. The notification shall contain:

(A) Description of device, or type or class of device, to which proceeding to promulgate a standard relates.

(B) Nature of risk to be controlled.

(C) Summary of data on which need for initiation of proceeding is based.

(D) Identification of any existing standard which may be relevant.

(E) Invitation to any person or Federal agency to submit a proposed standard within 60 days of notice or to offer to develop a proposed standard in accordance with prescribed procedures.

(2) Prior to an order to promulgate a performance standard the Secretary shall consider:

(A) The degree of risk of harm associated with the device.

(B) Approximate number of devices subject to the order.

(C) The device's benefit to public and probable effect standard will have on utility, cost or availability of the device.

(D) Means of achieving objectives with minimum market disruption.

(E) Data and comments submitted.

(3) Findings required by paragraph (2) above shall be published in *Federal Register*. Such findings shall be made only after review of the report of the appropriate panel and the preliminary classification of the device. The findings may be appealed to the Courts within 30 days after their publication.

(d) In lieu of accepting an offer to develop a standard, Secretary could publish as a proposed device standard an existing standard published by any Federal agency or other qualified agency if reference to such standard was made in the initial notice in *Federal Register* and if such standard were substantially acceptable.

(e) (1) Except as otherwise provided, directs Secretary to accept one or more offers to develop a proposed performance standard. In accepting such offers, Secretary would determine whether offeror is technically competent to undertake and complete development of standard within the period of time specified in the invitation and whether offeror has capacity to comply with prescribed regulations governing development of proposed standards. Where more than one offer is received the Secretary, wherever possible, will give priority to offerors with no proprietary interest in the device to be subject to the standard. The Secretary shall by regulation require that each offeror (and appropriate officials of an offeror company) disclose:

(A) All current industrial or commercial affiliations.

(B) Sources of research support.

(C) Companies in which offeror has a financial interest.

(2) The Secretary shall publish the name and address of offeror(s) accepted and terms of offer as accepted.

(3) Secretary could agree to contribute to offeror's cost in developing a standard if Secretary determines such contribution would likely result in a more satisfactory standard and that offeror is financially responsible. Regulations would set forth acceptable items of cost, except that such items could not include construction (except minor remodeling) or acquisition of land or building.

(4) Directs Secretary to prescribe regulations governing development of proposed standards, so as to require that:

(A) Recommended standards be supported by test data or other documents as Secretary may require;

(B) Recommended standards contain testing methods appropriate for measurement of compliance with standard;

(C) Interested persons be afforded an opportunity to participate in development of standard;

(D) Records be maintained to disclose the course of the development of the standard;

(E) Secretary and Comptroller General shall have access to offeror's records, documents, etc. for purposes of audit regarding any contribution.

(f) If no person accepted invitation to develop a proposed standard, or the Secretary did not accept a proposed standard, or the Secretary accepted an offer but found that offeror was unwilling or unable to continue development of standard, Secretary could then develop a proposed standard according to procedures and regulations governing such development.

(g)(1)(A) Within one year after period for submitting a proposed performance standard or offer to develop standard (which time may be extended for cause), the Secretary shall either publish a proposal to promulgate a standard or terminate the procedure. A proposal to promulgate a standard shall set forth the standard and the manner in which persons may examine the background data and the manner in which they may present comments thereon (orally or in writing). The period for comment shall be at least 60 days but not more than 90 days (except for cause).

(B) Within 90 days after such period for comment expires the Secretary shall publish an order establishing a performance standard or terminate the proceeding. The order shall include the Secretary's reasoning for the standard and the date(s) it will be effective. Effective dates shall, consistent with public health protection, be established so as to minimize market disruption. If the standard in the order is substantially different from the proposal, 30 days for comment shall be permitted.

(C) The Secretary may, in such order, include findings in addition to those required.

(2) Secretary may revoke a standard by notice in the *Federal Register* stating his reasons for determining that the performance standard (or portion thereof) may no longer be in the public interest, the manner in which persons may examine underlying data and how they may present their views (orally or in writing). As soon as practical thereafter the Secretary shall act on such proposed revocation, publish his reasons therefor, and set the effective date(s).

(3) Secretary may on his own or on petition amend a performance standard which shall be published in the *Federal Register* and subject to 5 U.S.C. 553, judicial appeal and referral to an advisory committee.

(4) 5 U.S.C. 553 (regarding administrative procedure) shall, consistent with this section, apply to all proceedings to promulgate, amend or revoke a performance standard.

(5)(A) In the case of controversy concerning an order to promulgate, amend, revoke or ban, adversely affected person may (within 30 days) petition an appropriate United States Court of Appeals. A copy of the petition shall be transmitted to the Secretary by the Court, whereupon the Secretary shall file with the Court the record upon which the order is based.

(B) Petitioner may apply for leave to adduce additional evidence which shall be granted upon a satisfactory showing of the need and

appropriateness of additional evidence. The Secretary, based on such additional evidence, may modify or set aside his original order.

(C) The Court shall have jurisdiction to affrm or set aside (in whole or in part) the order, temporarily or permanently. If the order of the Secretary refuses to issue, amend or repeal a regulation and such order is not in accordance with law the Court may order the Secretary to take action in accordance with law. The findings of the Secretary, if supported by substantial evidence, shall be conclusive.

(D) Appeal to the Supreme Court.

(E) Such action shall survive notwithstanding changes of vacancies in the Office of the Secretary.

(F) A certified copy of the record of proceedings before the Secretary shall be furnished at cost to interested persons and shall be admissible in any criminal libel for condemnation (except imports) or other proceeding arising under this Act notwithstanding proceedings with respect to the order which may have been previously instituted or become final under this section.

(6) The Secretary may by regulation prohibit the stockpiling of nonconforming devices between date of promulgating the order and the effective date.

(h)(1) Authorizes Secretary to appoint independent advisory committees to which could be referred any matters involved in a proposed device standard which requires the exercise of scientific judgment, prior to or after its publication in the *Federal Register*. Secretary could refer such proposals on his own initiative, and would be directed to refer such proposals when requested by any interested persons showing good cause.

For the purpose of such referral the Secretary shall establish an advisory committee (which may be a standing advisory scientific review panel) and shall refer to it, together with all underlying data, the matter in question for a report and recommendation. After independent study, the committee shall certify a report and recommendations to the Secretary together with all its underlying data and reasons for it recommendations. After considering all data before him including the Committee's report, the Secretary shall by order affirm or modify or act on the order in question.

(2) Secretary shall appoint qualified persons as members of the advisory committee. Such persons shall be of appropriate diversified professional background. Members (other than regular Government employees) may receive compensation (not to exceed GS–18 rate) and travel and per diem allowances.

(i)(1) Manufacturers of devices subject to standards would have to assure the Secretary that such devices comply with any testing methods prescribed in the standard or that device has been manufactured in accordance with current good manufacturing practice designed to assure such compliance.

(2) To assure that devices are in conformance with standards, Secretary is directed to review and evaluate on a continuing basis the testing and quality control programs carried out by manufacturers of devices subject to standards.

(j) Exempts from compliance with otherwise applicable standard any device: Intended solely for use in the diagnosis, cure, mitigation,

treatment, or prevention of disease in animals or to affect structure or function of animals; declared subject to scientific review, except for those characteristics of a device made subject to an existing standard under an application approved through scientific review, or a particular device which the Secretary finds pursuant to regulations (issued after opportunity for a hearing) may notwithstanding an applicable standard be marketed pursuant to premarket scientific review approval.

(k) Directs Secretary to issue regulations permitting interstate shipment of devices varying from an applicable standard for the purpose of testing or investigation, prior to amendment of the standard.

(l) Exempts custom made devices ordered by a physician (or other specially qualified person as authorized by regulations of the Secretary) for individual patients.

(m) (1) After consultant with the appropriate panel and after affording interested persons an opportunity for an informal hearing Secretary may, by regulation, ban a device if he finds the device presents an unreasonable risk of harm or deception and that performance standards or premarket approval would not adequately protect the public.

(2) Secretary may declare a proposed regulation banning a device on an interim basis pending administration and judicial appeals if (after opportunity for informed hearing) he finds such banning will expeditiously reduce risk of harm to public or gross deception.

(n) Secretary may amend performance standard on an interim basis, pending completion of standard setting procedure, if he determines (after opportunity for informal hearing) that amendment is needed to permit rapid implementation of desirable changes or expeditiously reduce risk of harm but thereby shall not prohibit devices conforming to existing standards.

SEC. 202. (a) A device is adulterated unless it conforms to an applicable standard or if it is a banned device.

(b) A device is misbranded unless its labeling bears warning, etc. required by standard or if it fails to comply with the quality testing or measurement required under section 513(i).

TITLE III—SCIENTIFIC REVIEW OF CERTAIN MEDICAL DEVICES

SEC. 301. (a) A device is adulterated if it is unsafe under section 513 (scientific review).

(b) Amends Chapter V of Federal, Food, Drug, and Cosmetic Act by adding a new section 514 as follows:

SEC. 514. (a) Secretary may declare a device, for which scientific review has been deemed appropriate according to the device classification scheme, subject to such review, if after consulting with appropriate scientific review panels he finds that: Scientific review is appropriate to ensure safety and effectiveness or is appropriate to reduce or eliminate unreasonable risk of illness or injury associated with exposure to or use of a device or if he determines that scientific review is appropriate to protect public health and other means may not be appropriate to reduce the risk of harm. To the maximum extent practicable,

the Secretary shall provide interested persons an opportunity to submit data and views on the matter. The declaration shall be by regulation and shall set forth and be based on the report, recommendations and comments developed as part of the classification scheme. Promulgation of a regulation declaring a device subject to scientific review may be appealed to appropriate Court of Appeals. A device declared subject to scientific review shall be deemed unsafe unless—

1. An approval is in effect,
2. It is exempt, or
3. It is intended solely for veterinary use.

(b) Secretary shall utilize the standing advisory panels for review applications, plans and protocols under this section.

(c) (1) Scientific review of a device declared subject to such review may be obtained by submitting to the Secretary an application containing the following:

(A) Reports of all information concerning investigations to determine safety, reliability, or effectiveness of devices which are known or reasonably should be known to the applicant.

(B) Statement of composition, properties, construction, and principles of operation of device.

(C) Description of methods used in, and facilities and controls used for, manufacture, processing, and when relevant, packing and installation of device.

(D) Identification of any standard applicable to such device, or its component, and adequate information either to show device meets such standard or to justify any deviation.

(E) Samples of device and its components.

(F) Specimens of proposed labeling.

(G) Any other relevant information as Secretary upon advice of the appropriate panel may require.

(2) Directs the Secretary to refer application, upon receipt, to appropriate panel(s) for report and recommendations within such period as he may establish.

(d) No later than 120 days after receipt of application, unless additional period agreed upon by Secretary and applicant. Secretary is required, after considering panel's recommendations, either to approve application, advise applicant that application is not in appropriate form and inform applicant of measures required to receive approval, or deny approval if device fails to meet criteria set forth below.

(e) (1) Secretary shall deny application, if on basis of information submitted or other information before him and after opportunity for review by an advisory committee he finds:

(A) Device is not shown to be safe for use under conditions prescribed, recommended, or suggested in proposed labeling;

(B) The method used in, and facilities and controls used for, manufacture, processing, packing, and installation do not conform to current good manufacturing practices;

(C) There is a lack of adequate scientific evidence to show device will have effect it purports or is represented to have under conditions on the label;

(D) The labeling itself is false or misleading.

(E) The device is not shown to conform with an applicable standard.

In making such determination Secretary shall weigh the benefit to the public from the use of the device against any hazard to the public health which would probably result from its use.

(2) "Adequate scientific evidence" is defined as evidence consisting of sufficient well-controlled investigations, including clinical investigations where appropriate, by qualified scientific experts, on the basis of which it could fairly and responsibly be concluded that device will have effect it purports or is represented to have under conditions prescribed in its proposed labeling. However, Secretary may determine that other valid scientific evidence is sufficient to establish effectiveness of device.

(3) The safety and effectiveness of devices intended for use by physicians, surgeons or other specially qualified persons shall be determined in light of such intended use.

(4) (A) Applicant may, within 30 days of denial of application, obtain review by an independent scientific advisory committee and Secretary shall give its report appropriate weight in reviewing the application.

(B) In lieu of review by independent advisory committee, applicant may receive review pursuant to 5 U.S.C. 554 (relating to administrative procedures).

(f) (1) Secretary may, after obtaining advice from a panel(s) if appropriate, and after giving due notice and opportunity for hearing to the applicant, withdraw approval if he finds:

(A) (i) Clinical or other experience or tests show device to be no longer safe, for use under conditions previously approved;

(ii) Evidence of clinical experience, not contained in original application or not available until after application was approved, or tests by new methods or methods not reasonably applicable at time application was approved show device to be no longer safe;

(B) New information, evaluated together with evidence on which application was originally approved, shows lack of adequate scientific evidence that device will have effect it purports;

(C) Original application contains untrue statement of material fact;

(D) Applicant fails to establish system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or make required reports, or has refused to permit access to such records;

(E) New information, together with evidence in original application, show methods used in, or facilities or controls used for, not in conformance with good manufacturing practice, and were not brought into conformance within reasonable time after formal notification;

(F) New information shows labeling is false or misleading and not corrected within a reasonable time; or

(G) New information shows device to be in non-compliance with an applicable standard.

(2) Secretary may immediately suspend approval if he finds an imminent health or safety hazard is involved. Applicant is to be notified promptly and given opportunity for expedited hearing. This authority may not be delegated.

(3) An order under this section shall state the findings upon which it is based.

(g) Whenever Secretary finds that facts so require, he shall revoke any previous orders denying, withdrawing or suspending approval of application and shall approve or reinstate such approval of an application.

(h) Order of the Secretary may be served by a designee or by registered or certified mail to applicant's last known address in Secretary's records.

(i) (1) An applicant may petition Secretary to obtain review of application of Secretary's action by an independent advisory committee of experts. Secretary may also refer an application to such a committee on his own initiative. Committee shall after independent study certify a report and recommendations to Secretary (a copy of which shall be sent to applicant or petitioner). Applicant and representatives of the Department would have the right to consult with the committee. Secretary is to consider findings of the independent committee and thereupon may conform or modify any prior order.

(2) Provision for establishing independent advisory committee in standards section (Sec. 513(h)) shall apply here.

(3) Paragraph (3) of Sec. 513(h) shall apply in case of referral to advisory committee under this section.

(j) Judicial review to Court of Appeals is provided with respect to final orders denying or withdrawing approval.

(k) (1) Declaration that purpose of this subsection is to encourage discovery and development of useful devices and maintain optimum freedom for individual scientific investigators, consistent with protection of public health and safety and with professional ethics. Information required to be submitted shall be concise and no more burdensome than necessary.

(2) Devices intended solely for investigational use (in an appropriate scientific environment) by qualified experts are exempt from scientific review.

(3) Secretary shall promulgate regulations (after opportunity for a hearing) relating to the application of such exemption to any device intended for clinical testing in humans in developing data to support an application.

(4) Such regulations may condition such exemption upon:

(A) Submission of outline of plan of initial clinical testing to either a local institutional review committee established to supervise clinical testing in the facility where initial testing is to occur, or to the Secretary for review by appropriate standing scientific review panel.

(B) Prompt notification to Secretary of approval of plan by review panel.

(C) Submission to either a local institutional review committee or the Secretary of an adequate protocol for clinical testing to be conducted by separate groups of investigators under essentially

same protocol, together with report of prior investigations of device, including tests on animals, adequate to justify the proposed testing.

(D) Obtaining of signed agreements from investigators that humans upon whom device to be used will be under their personal supervision.

(E) Establishment and maintenance of records, and making of such reports obtained from investigational use of device, as Secretary finds will enable him to evaluate safety and effectiveness of device.

(F) Other conditions relating to protection of public health and safety as Secretary may deem necessary.

Nothing in this subsection shall be construed to require investigators to submit directly to the Secretary reports on investigations. Secretary shall determine if investigation conforms to this section within 30 days of a submission or notification under this section, and the investigation shall not begin until sponsor receives notice from Secretary that investigation conforms to this section *provided* Secretary may delay beginning of investigation unless he so finds and notifies sponsor of such finding(s). Secretary may exempt investigation from all or part of this subsection in the public interest.

(5) Regulations must assure that—

Rights and welfare of subjects are adequately protected;

Risks are outweighed by potential benefits or importance of knowledge to be obtained; and

Informed consent of participants is to be obtained by adequate methods in all but exceptional cases.

(A) The term "informed consent" means consent of a person, or his legal representative, so situated as to be able to exercise free power of choice without intervention of any element of force, fraud, deceit, duress, etc. Such consent shall be evidenced by an agreement signed by such person or his legal representative. Such agreement shall include:

(1) Explanation of procedures, including any of an experimental nature;

(2) Description of any discomforts and risks which can be reasonably expected;

(3) Fair explanation of likely results if experiment fails;

(4) Description of reasonably expected benefits;

(5) Disclosure of alternative procedures potentially advantageous for the subject;

(6) Offer to answer any inquiries concerning procedures; and

(7) Instruction to subject regarding his freedom to discontinue participation at any time.

Consent agreement must contain no language through which subject waives any legal rights or releases the institution or its agents from liability for negligence. Requires that permanent record be kept of such consent.

(B) "Exceptional cases" to be construed strictly, permits waiver of only those elements of consent in subparagraph (A), 1–7, as justified by circumstances, and requires written concurrence by two physicians not involved in the research unless there is a life-threatening situation and such concurrence is not feasible.

(6) Whenever Secretary finds device being investigated on humans which fails to meet conditions for exemption he shall notify such sponsor of his determination, and reason therefor and the exemption shall not apply until failure to comply is corrected.

(7) In determining applicability of this subsection to any device and/or its compliance therewith, Secretary may obtain advice of experts not employed in carrying out this Act (except as consultants).

(l) Exempts custom devices ordered by physician (or other specially qualified persons as determined in regulations) for individual patients.

(m) (1) A device intended for use by a practitioner which is subject to frequent modifications, rapid obsolescence or which will not be produced in substantial volume may be exempted from scientific review if it is to be developed in accord with a product development protocol.

(2) Any person may petition Secretary to establish a product development protocol for such a device. Secretary may, within 30 days, refer petition to an expert panel, which may, within 60 days or such other times as agreed upon by panel and petitioner, approve an appropriate protocol. If approved, protocol must stipulate:

(A) Investigational procedures required prior to clinical trials on device;

(B) That institutional review committee make written finding of risk-to-benefit ratio and continually monitor and report on clinical trials;

(C) Type and quantity of clinical trials required prior to filing notice of completion of protocol;

(D) Maintenance of records to show compliance with protocol;

(E) Informed consent from all human subjects; and

(F) That copies of all required records be available to Secretary upon his request.

(3) If panel does not approve a protocol within 60 days, Secretary may consider and approve protocol (with or without modification) within next 60 days. If neither panel nor Secretary approves a protocol, a final order will be issued denying petition and stating reasons.

(4) After approval of protocol, petitioner may submit notice of completion of the requirements of protocol, indicating that to the best of his knowledge, no reasons exist relating to safety, effectiveness, or other public health considerations why device should not be marketed. The Secretary shall approve or disapprove such notice within 90 days.

(5) Secretary may at any time prior to approving a product development protocol and after providing petitioner with opportunity for informal hearing, revoke a protocol or object to notice of completion, if he finds in writing:

(A) Petitioner failed to comply with protocol requirements; or

(B) Results of clinical trials differ so substantially from results required in protocol that further trials are unjustifiable; or

(C) Device is not safe for use under conditions prescribed in labeling; or

(D) A lack of adequate scientific evidence showing device to have effect it purports to have on label.

(6) Allows Secretary to immediately revoke an exemption pertaining to a device subject to a product development protocol, if an im-

minent hazard to public health or safety is caused by existence of such exemption.

(7) Secretary may also revoke an exemption, after a notice of completion of protocol requirements has become effective, if he finds that any grounds listed in subsection referring to withdrawal of approval of application under scientific review apply.

(8) Secretary may reconsider an order revoking an exemption under this section and reinstate such exemption.

(n) (1) Devices in use the day before such device is declared subject to scientific review, will be considered adulterated (unless approved) on the closing date or, if sooner, with respect to an applicant the date his application is approved.

(2) Defines "closing date" shall be 30 months after date device is declared subject to scientific review, except Secretary may extend period to sixty months but may terminate such extension if progress reports etc., and not supplied.

SEC. 302. (a) Makes it a prohibited act to fail to establish, maintain, or make a report under the investigation device section or the section requiring records and reports.

(b) Prohibits any representation that a device has been approved under section 514.

TITLE IV—NOTIFICATION OF DEFECTIVE DEVICES; REPAIR OR REPLACEMENT

SEC. 401. Amends Federal Food, Drug, and Cosmetic Act by adding new section 515 as follows:

SEC. 515. (a) (1) Every person acquiring information which reasonably supports the conclusion that a device produced, assembled, distributed, or imported by him to contain a defect which could create a substantial risk to the public health or safety, or to be in noncompliance with an applicable standard would be required to notify the Secretary of such defect or failure if device has left control of the manufacturer. Information received under this section (except for required records) shall not be used in prosecuting natural persons under the Federal Food, Drug, and Cosmetic Act.

(2) Notification shall contain a clear description of the defect evaluation of the hazards and measures being taken to correct defect and protection against the hazard.

(3) The term "defect" as it relates to a device means a deficiency in design, materials, or workmanship, and does *not include* any deficiency resulting from use of improper accessories, improper installation, maintenance, repair, or use of device, or deficiency resulting from normal use of device after expiration of lifetime represented by manufacturer.

(b) (1) If Secretary determines device presents substantial hazard, he may make certain adequate notification is made by most appropriate persons and means to all persons including manufacturers, distributors, health professionals, and users.

(2) If Secretary determines users need not be notified he will notify health professionals who may comment on advisability of notifying general public. Thirty days thereafter he will notify public if he determines notification will not endanger public health.

(3) If the Secretary determines after opportunity for a hearing that device presents substantial hazard he may order manufacturer or distributor or retailer to take following action at his election to extent purchaser's (and, if appropriate his physician) consent is obtained. Those actions are (1) bring device into compliance (2) replace device, and (3) refund purchase price (less depreciation if over one year old) Secretary may require submission of plan for carrying out this requirement.

(d) (1) No charge will be made of persons availing themselves of this remedy and they shall be paid for expenses necessary to do so.

(2) The Secretary may require manufacturer, distributor, or retailer to reimburse another manufacturer, distributor, or retailer if in the public interest.

(3) An order requiring repair, replacement or refund may only be made after opportunity for an informal hearing. If interested person wishing to participate in hearing is one of a class that is represented, the Secretary may limit his participation to such representative.

(e) Remedies under this shall be in addition to and not in substitution for any other legal remedies.

SEC. 402. Failure to furnish notification or information under sections 515 or 516 or failure to comply with an order under section 515 are made prohibited acts.

SEC. 403. Conforming technical amendment.

TITLE V—REQUIREMENT OF GOOD MANUFACTURING PRACTICE

SEC. 501. Amends section 501 of Federal Food, Drug, and Cosmetic Act to provide that a device is adulterated if it is manufactured, processed, or installed except in accord with current good manufacturing practice as determined by the Secretary's regulations issued under section 701(a) of the Federal Food, Drug, and Cosmetic Act.

TITLE VI—RECORDS AND REPORTS INSPECTION AND REGISTRATION OF ESTABLISHMENTS; OFFICIAL NAMES

SEC. 601. Amends Chapter V of the Federal Food, Drug, and Cosmetic Act by adding a new section 516 as follows:

SEC. 516. (a) (1) Requires persons manufacturing, processing, repacking, labeling, or distributing a device subject to a standard which is subject to an approved application for scientific review, to maintain records and make reports to the Secretary on clinical experience and other data relating to safety or effectiveness of such device, or possibility of adulteration or misbranding, etc. Regulations under this section are to have due regard for professional medical ethics and interests of patients.

(2) Persons required to maintain such records must allow employees of Secretary to have access to any copy and verify such records.

(b) Exempts from the requirement of records the following:

(1) Licensed practitioners who manufacture or process devices solely for use in their professional practice.

(2) Persons manufacturing or processing devices solely for use in research or teaching and not for sale.

(3) Other classes of persons as Secretary may exempt.

(c) Every person engaged in manufacuring devices shall on request furnish to the Secretary pertinent technical data.

SEC. 602. Provides that authorized inspection of establishments processing or holding prescription devices may extend to all things therein, including records, files, papers, processes, controls, facilities, etc. but not to financial, sales or pricing data or personnel (except for qualifications of technical and professional personnel). Such inspection is not authorized with respect to pharmacies, medical practitioners, researchers, and other persons exempted by Secretary.

SEC. 603. Each device establishment is required to register annually with the Secretary and submit a list of all devices processed therein (which list may be updated) and submit certain labeling and advertising for such listed devices.

Requires device label to bear (in type at least half the size of type used for brand name) the established name of the device (unless exempted). Defines "established name" to mean name designated by Secretary, name of device as it appears in an official compendium or its common or usual name.

Provides that device establishments engaged solely in intrastate commerce are subject to registration as well as those engaged in interstate commerce.

TITLE VII—GENERAL PROVISIONS

SEC. 701. Amends chapter VII of the Federal Food, Drug, and Cosmetic Act by adding new section 708 as follows:

SEC. 708. (a) Establishes Advisory Council on Devices to advise Secretary on policy matters relating to carrying out provisions of the Act. Members appointed by the Secretary are to be manufacturers, scientists, engineers, and members of the professions using such devices, as well as consumers and other persons knowledgeable about problems involved in device regulation.

(b) Secretary may, without regard to civil service and classification laws, appoint other advisory committees and council as he deems desirable.

(c) Sets methods of compensation of Council members.

SEC. 702. Amends chapter VII of the Federal Food, Drug, and Cosmetic Act to add a new section 709 as follows:

SEC. 709. (a) Authorizes Secretary to conduct, either directly or through contracts with public or private agencies, organizations or individuals, research, studies, and education and training in areas related to device safety, development of standards, testing methods, etc.

(b) Directs Secretary to cooperate with and invite participation by other Federal or State agencies and interested professional or industrial organizations; to collect and publish results of research and other activities. Authorizes Secretary to obtain devices for research and testing purposes.

SEC. 703. Amends section 705 of the Federal Food, Drug, and Cosmetic Act to permit Secretary to disseminate information regarding

device standards, testing facilities and methods, other information on nature and extent of device hazards.

SEC. 704. Amends chapter IX of the Federal Food, Drug, and Cosmetic Act; add new section 903 as follows:

SEC. 903. (a) Prohibits States from establishing or maintaining standards or regulations for any device which is specifically subject to an official Federal standard or scientific review, unless State requirements are identical to the Federal requirements.

(b) Specifically allows Federal, State, and local governments to establish safety requirements applicable to a device for their own use, if such requirements impose a higher performance standard than otherwise required by applicable Federal law.

(c) Allows Secretary to exempt a State proposed safety requirement from preceding provision if proposed requirement:

Imposes higher performance level than Federal standard;
Is required by compelling local conditions; *and*
Does not unduly burden interstate commerce.

SEC. 705. Amends section 301(j) of the Federal Food, Drug, and Cosmetic Act to provide that information on methods or processes which are trade secret received in submission under the Act shall not be disclosed outside the Department except that trade secret information may be given to contractors under appropriate security provisions for a use in furtherance of the purposes of the Act.

SEC. 706. Amends section 201 of the Federal Food, Drug, and Cosmetic Act to define "device" as follows:

The term "device" means instruments, apparatus, implements, machines, contrivances, implants, in vitro reagents, or similar articles, including their components, parts, and accessories which are:

(a) Recognized in the official U.S. Pharmacopeia or National Formulary, or any supplement to them; or

(b) Intended for use in diagnosis, treatment, or prevention of disease in man or other animals; or

(c) Intended to affect structure or any function of the body of man or other animals; and

(d) Which do not achieve any of their principal purposes through chemical action within or on the body of man or other animals and which are not dependent upon being metabolized for achievement of their principal purposes.

SEC. 707. Provides that a prescription device is misbranded if its advertising is false or misleading or unless the advertising contains the established name, full description of its components or qualitative formula; and a brief summary of side effects, contraindications, and effectiveness (as provided in Secretary's regulations.) Prior approval of advertising shall not be required except in extraordinary circumstances. Prescription device advertisements shall not be subject to sections 12–17 of the Federal Trade Commission Act.

SEC. 708. Defines the term "prescription device" to mean any device so designated by the Secretary as being restricted to sale or distribution only upon written or oral authorization of licensed practitioner. A device shall not be designated as prescription unless because of its potential harm it is not safe for use except under supervision of licensed practitioner or unless it is limited to prescription sale pursuant to approval of an application for scientific review.

SEC. 709. Amends section 304 of the Federal Food, Drug, and Cosmetic Act to permit the seizure of adulterated or misbranded devices found in any State.

SEC. 710. Amends section 801 of the Federal Food, Drug, and Cosmetic Act to prohibit the exportation of noncomplying devices. The Secretary may permit export of articles not in compliance with the Federal Food, Drug, and Cosmetic Act if he determines that such export is in the interest of public health and has the approval of the country to which it is to be exported.

SEC. 711. (a) Except as provided in subsection (b) the Act will take effect on its enactment.

(b) Provision that device is adultered without approval becomes effective in one year or on date of approval of application with respect to certain uses of the device.

(c) Person owning device establishment prior to the enactment date shall have seven months to register such establishment. If such initial registration takes place in 1975 such establishment will be deemed registered for that year.

VIII. CHANGES IN EXISTING LAW

In compliance with subsection (4) of rule XXIX of the Standing Rules of the Senate, changes in existing law made by titles I through III of the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets; new matter printed in italic):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

CHAPTER II—DEFINITIONS

SEC. 201. * * *

[(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 instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals]

(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 instruments, apparatus, implements, machines, contrivances, implants, in vitro reagents, and other similar or related articles, including their components, parts, and accessories (1) recognized in the official National Formulary, the official United States pharmacopeia or any supplement to them; or (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 (4) which do not achieve any of their principal intended purposes through chemical action within or on the body of man or other animals

and which are not dependent upon being metabolized for the achievement of any of their principal intended purposes.

* * * * *

(y) The term "prescription device" means any device which the Secretary shall designate by regulation as being restricted to sale or distribution only upon the written or oral authorization of a practitioner licensed by law to administer or use such device and under such other conditions as the Secretary may by regulation prescribe. The Secretary may designate as a prescription device, pursuant to the preceding sentence, only a device which:

(1) because of its potentiality for harmful effect, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer or use such device; or

(2) is limited by an approved application under section 514 to use under the professional supervision of a practitioner licensed by law to administer or use such device.

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. * * *

(e) The refusal to permit access to or copying of any record as required by section 703; or the failure to establish or maintain any record, or make any report, required under section 505 (i) or (j), 507 (d) or (g) [or] 512(j), (l), or (m), *514(k), or 516(a)* or the refusal to permit access to or verification or copying of any such required record.

* * * * *

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 505, 506, 507, *511*, 512, *513*, *514*, *515*, *516*, 704, or 706 concerning any method or process which as a trade secret is entitled to protection. *The Secretary may provide any information which contains or relates to a trade secret or other matter referred to in this section or in section 1905 of title 18, United States Code, to a contractor in furtherance of the provisions of this Act, and such contractor shall take such security precautions as are prescribed in regulations promulgated by the Secretary and shall be subject to the provisions and penalties established in this Act and in section 1905 of title 18, United States Code.*

* * * * * * *

(L) The using, on the labeling of any drug *or device* or in any advertising relating to such drug *or device*, of any representation or suggestion that approval of an application with respect to such drug *or device* is in effect under section *505 or 514, as the case may be*, [505] or that such drug *or device* complies with provisions of such section.

* * * * * * *

(q)(1) The failure or refusal to furnish any notification or other material or information as required by section 515 or 516; or (2) the

failure or refusal to comply with any requirement prescribed under authority of section 515(e).

* * * * * * *

SEIZURE

SEC. 304. (a)(1)

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(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found: (A) Any drug that is a counterfeit drug, (B) Any container of a counterfeit drug, [and] (C) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs [.], *and (D) Any adulterated or misbranded device.*

* * * * * * *

CHAPTER V—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501. A drug or device shall be deemed to be adulterated—

(a) * * *

* * * * * * *

(e)(1) If it is, or purports to be or is represented as, a device with respect to which, or with respect to any component, part, or accessory of which there has been promulgated a performance standard under section 513, unless such device, or such component, part, or accessory, is in all respects in conformity with such performance standard; or

(2) if it is a banned device.

(f) If (1) it is a device, and (2) such devices, or any component, part, or accessory thereof, is deemed unsafe or ineffective within the meaning of section 514 with respect to its use or intended use.

(g) If it is a device and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, holding, or installation do not conform to, or are not operated or administered in conformity with, current good manufacturing practice, as determined by regulations of the Secretary promulgated under section 701(a) after consultation with all interested persons and after an opportunity for a hearing, to assure that such device is safe and effective.

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—

(a) * * *

* * * * * * *

(e) (1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (3)) [(2))] of the drug, if such there be, and (ii) in case it is fabricated from two or more ingredients, the

established name and quantity of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs; and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: and *Provided*, That to the extent that compliance with the requirements of clause (A)(ii) or clause (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(2) If it is a device, unless its label bears, to the exclusion of any other nonproprietary name, the established name (as defined in subparagraph (4)) of the device, if such there be, prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device: Provided, That to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(3) [(2)] As used in [this paragraph (e)] *subparagraph (1)*, the term "established name", with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 508, or (B) if there is no such name and such drug, or such ingredient, 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 the common or usual name, if any, of such drug or of such ingredient: *Provided further*, That where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homeopathic Pharmacopeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopeia shall apply.

(4) As used in subparagraph (2), the term "established name", with respect to a device, means (A) the applicable official name designated pursuant to section 508, or (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 the common or usual name of such device, if any.

* * * * * * *

(j) If it is dangerous to health when used in the dosage, *or manner* or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

* * * * * * *

(o) If it [is a drug and] was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered under section 510.

* * * * * * *

(q) If it is a device subject to a performance standard promulgated under section 513, unless (1) its labeling bears such instructions and warnings as may be prescribed in such performance standard; and (2) it complies with the requirements of section 513(i)(1).

(r) In the case of any device that is a prescription device, if its advertising is false or misleading in any particular.

(s) In the case of any prescription 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 a true statement of (1) the 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, (2) 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, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary after an opportunity for a hearing: Provided, That (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription device, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription devices, shall, with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 12 through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. 52–57). This paragraph shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m) of this Act.

AUTHORITY TO DESIGNATE OFFICIAL NAMES

SEC. 508. (a) The Secretary may designate an official name for any drug *or device* if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Any official name designated under this section for any *drug or device* shall be the only official name of that drug *or device* used in any official compendium published after such name has been prescribed or for any other purpose of this Act. In no event, however, shall the Secretary establish an official name so as to infringe a valid trademark.

(b) Within a reasonable time after the effective date of this section, and at such other times as he may deem necessary, the Secretary shall cause a review to be made of the official names by which drugs are identified in the official United States Pharmacopeia, the official Homeopathic Pharmacopeia of the United States, and the official National Formulary, and all supplements thereto, *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*, to determine whether revision of any of those names is necessary or desirable in the interest of usefulness and simplicity.

(c) Whenever he determines after any such review that (1) any such official name is unduly complex or is not useful for any other reason, (2) two or more official names have been applied to a single drug *or device*, or to two or more drugs which are identical in chemical structure and pharmacological action and which are substantially identical in strength, quality, and purity, *or two or more devices which are substantially similar in design and purpose*, or (3) no official name has been applied to a medically useful drug *or device*, he shall transmit in writing to the compiler of each official compendium in which that drug or drugs *or device* are identified and recognized his request for the recommendation of a single official name for such drug or drugs *or device* which will have usefulness and simplicity. Whenever such a single official name has not been recommended within one hundred and eighty days after such request, or the Secretary determines that any name so recommended is not useful for any reason, he shall designate a single official name for such drug or drugs *or device*. Whenever he determines that the name so recommended is useful, he shall designate that name as the official name of such drug or drugs *or device*. Such designation shall be made as a regulation upon public notice and in accordance with the procedure set forth in section 4 of the Administrative Procedure Act (5 U.S.C. 1003).

(d) After each such review, and at such other times as the Secretary may determine to be necessary or desirable, the Secretary shall cause to be compiled, published, and publicly distributed a list which shall list all revised official names of drugs *or devises* designated under this section and shall contain such descriptive and explanatory matter as the Secretary may determine to be required for the effective use of those names.

(e) Upon a request in writing by any complier of an official compendium that the Secretary exercise the authority granted to him under section 508(a), he shall upon public notice and in accordance with the procedure set forth in section 4 of the Administrative Procedure Act (5 U.S.C. 1003) designate the official name of the drug *or device* for which the request is made.

* * * * * * *

REGISTRATION OF PRODUCERS OF DRUGS *AND DEVICES*[1]

SEC. 510. (a) As used in this section—

(1) the term "manufacture, preparation, propagation, compounding, or processing" shall include repackaging or otherwise

[1] The Congress hereby finds and declares that in order to make regulation of interstate commerce in drugs *and devices* effective, it is necesary to provide for registration and inspection of all establishments in which drugs *or devices* are manufactured, prepared, propagated, compounded, or processed; that the products of all such establishments are likely to enter the channels of interstate commerce and directly affect such commerce; and that the regulation of interstate commerce in drugs *and devices* without provision for registration and inspection of establishments that may be engaged only in intrastate commerce in such drugs *or devices* would discriminate against and depress interstate commerce in such drugs *and devices*, and adversely burden, obstruct, and affect such interstate commerce.

changing the container, wrapper, or labeling of any drug package *or device package* in furtherance of the distribution of the drug *or device* from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer *or user*; and

(2) the term "name" shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

(b) On or before December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs *or a device or devices* shall register with the Secretary his name, places of business, and all such establishments.

(c) Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs *or a device or devices* in any establishment which he owns or operates in any State shall immediately register with the Secretary his name, place of business, and such establishment.

[(d) Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Secretary any additional establishment which he owns or operates in any State and in which he begins the manufacture, preparation, propagation, compounding, or processing of a drug or drugs.]

(d) (1) Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Secretary any additional establishment which he owns or operates in any State and in which he begins the manufacture, preparation, propagation, compounding, or processing of a drug or drugs, or of a device or devices.

(2) Every person who is registered with the Secretary pursuant to the first sentence of subsection (b) or (c) or paragraph (1) of this subsection shall, if any device is thereafter manufactured, prepared, propagated, compounded, or processed in any establishment with respect to which he is so registered, immediately file a supplement to such registration with the Secretary indicating such fact.

* * * * * * *

(g) The foregoing subsections of this section shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs *or devices*, upon prescriptions of practitioners licensed to administer such drugs *or devices* to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs *or devices* for sale other than in the regular course of their business of dispensing or selling drugs *or devices* at retail;

(2) practitioners licensed by law to prescribe or administer drugs *or devices* and who manufacture, prepare, propagate, compound, or process drugs *or devices* solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs *or devices* solely for use in research, teaching, or chemical analysis and not for sale;

(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

(h) Every establishment in any State registered with the Secretary pursuant to this section shall be subject to inspection pursuant to section 704 and shall be so inspected by one or more officers or employees duly designated by the Secretary at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter.

(i) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding or processing of a drug or drugs *or a device or devices* shall be permitted to register under this section pursuant to regulations promulgated by the Secretary. Such regulations *shall require such establishment to provide the information required by subsection (j) in the case of a device or devices and* shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by agreement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether drugs *or devices* manufactured, prepared, propagated, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a) of this Act.

(j)(1) Every person who registers with the Secretary under subsection (b), (c), or (d) shall, at the time of registration under any such subsection, file with the Secretary [a list of all drugs (by established name] *a list of all drugs and a list of all devices (in each case by established name* (as defined in section 502(e)) and by any proprietary name) which are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution and which he has not included in any list of drugs *or devices* filed by him with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

(A) in the case of a drug contained in [such] *the applicable list* [list] and subject to section 505, 506, 507, or 512, *or a device contained in the applicable list with respect to which a performance standard has been promulgated under section 513 or which is subject to section 514* a reference to the authority for the marketing of such drug *or device* and a copy of all labeling for such drug *or device;*

(B) in the case of any other drug *or device* contained in [such list —] *an applicable list—*

[(i) which is subject to section 503(b)(1), a copy of all labeling for such drug, a representative sampling of advertisements for such drug, and, upon request made by the Secretary for good cause, a copy of all advertisements for such drug, product, or]

(i) which drug is subject to section 503(b)(1), or which device, is a prescription 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;

[(ii) which is not subject to section 503(b)(1), the label and package insert for such drug and a representative sampling of any other labeling for such drug:]

(ii) which drug is not subject to section 503 (b)(1), or which device is not a prescription device, the label and package insert for such drug or device and a representative sampling of any other labeling for such drug or device;

(C) in the case of any drug contained in [such list] *an applicable list* which is described in subparagraph (B), a quantitative listing of its active ingredient or ingredients, except that with respect to a particular drug product the Secretary may require the submission of a quantitative listing of all ingredients if he finds that such submission is necessary to carry out the purposes of this Act: and

(D) if the registrant filing [the] *a* list has determined that a particular drug product contained in such list is not subject to section 505, 506, 507, or 512, *or the particular device contained in such a list is not subject to a performance standard promulgated under section 513, or is not a prescription device* a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular drug product [.] *or device.*

(2) Each person who registers with the Secretary under this subsection shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following information:

(A) A list of each drug *or device* introduced by the registrant for commercial distribution which has not been included in any list previously filed by him with the Secretary under this subparagraph or paragraph (1) of this subsection. A list under this subparagraph shall list a drug *or device* by its established name (as defined in section 502(e)) and by any proprietary name it may have and shall be accompanied by the other information required by paragraph (1).

(B) If since the date the registrant last made a report under this paragraph (or if he has not made a report under this paragraph, since the effective date of this subsection) he has discontinued the manufacture, preparation, propagation, compounding, or processing for commercial distribution of a drug *or device* included in a list filed by him under subparagraph (A) or paragraph (1) notice of such discontinuance, the date of such discontinuance, and the identity (by established name (as defined in section 502(e)) and by any proprietary name) of such drug *or device.*

(C) If since the date the registrant reported pursuant to subparagraph (B) a notice of discontinuance he has resumed the

manufacture, preparation, propagation, compounding, or processing for commercial distribution of the drug *or device* with respect to which such notice of discontinuance was reported; notice of such resumption, the date of such resumption, the identity of such drug *or device* (*each* by established name (as defined in section 502(e)) and by any proprietary name), and the other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary pursuant to this subparagraph.

(D) Any material change in any information previously submitted pursuant to this paragraph or paragraph (1).

(3) The Secretary may also require each registrant under this section to submit a list of each drug product which (A) the registrant is manufacturing, preparing, propagating, compounding, or processing for commercial distribution, and (B) contains a particular ingredient. The Secretary may not require the submission of such a list unless he has made a finding that the submission of such a list is necessary to carry out the purposes of this Act.

PRELIMINARY CLASSIFICATION OF DEVICES

SEC. 511. (a) Within sixty days after funds are first appropriated for the implementation of this section, the Secretary shall appoint and organize separate classification panels of experts, qualified by scientific training and experience, to review and classify devices intended for human use into appropriate categories based on the safety and effectiveness of such devices. Each panel shall review all devices intended for human use within its respective scientific field for purposes of appropriate classification and shall submit within one year of its appointment a report of its findings and conclusions to the Secretary. To the maximum extent practical the panel or panels shall provide an opportunity for any interested person to submit data and views on the classification of a device (or type or class of device). The Secretary may utilize any such panels which may have been formed for the purpose of such classification prior to enactment of this section and such panels may utilize information and findings developed prior to enactment of this section in making such reports. Such panels shall also serve as scientific review panels under section 514.

(b)(1) Panel members shall be qualified by training and experience to evaluate the safety and effectiveness of devices in the category or class of devices to be referred to such a panel and to the extent feasible shall possess skill in the use of or experience in the development, manufacture, perfection, or utilization of such devices. In addition to such experts, each panel shall include as nonvoting members a representative of consumer interests and a representative of industry interests. Panel members may be nominated by appropriate scientific, trade, and consumer organizations.

(2) The panels shall be organized according to the various fields of clinical medicine and the fundamental sciences which utilize medical devices, and shall consist of members with diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, or other related professions. The Secretary shall designate one of the members of each panel to serve as chairman

thereof. Panel members shall, while attending meetings or conferences of the panel or otherwise engaged on its business, be compensated at per diem rates fixed by the Secretary but not in excess of the rate for grade GS–18 of the General Schedule at the time of such service, including travel-time, and while so serving away from their homes or regular places of business they may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by title 5, United States Code, section 5703, for persons in the Government service employed intermittently. The Secretary shall furnish each panel with adequate clerical and other necessary assistance, and shall prescribe by regulation the procedures to be followed by each panel.

(c) Panels appointed pursuant to subsection (a) shall submit (in the final report of the panel or such interim reports as may be appropriate) recommendations for the classification of devices for purposes of and in accordance with sections 513 and 514 into one of the three following classes and shall, to the extent practicable, assign priorities within such classes:

(1) Those devices (A) for which insufficient information exists to—

(i) assure effectiveness, or

(ii) assure that exposure to such devices will not cause unreasonable risk of illness or injury, and

(B) for which standards or other means may not be appropriate to reduce or eliminate such risk of illness or injury and which therefore should be subject to premarket scientific review pursuant to section 514. Such review, either initial or continuing, shall be required if the panels determine that such device purports or is represented to be for a use which is life sustaining or life supporting.

(2) Those devices for which in order to assure effectiveness or to reduce or eliminate unreasonable risk of illness or injury it is appropriate to establish reasonable performance standards pursuant to section 513 relating to safety and effectiveness and for which other means may not be appropriate to reduce or eliminate such risk of illness or injury.

(3) Those devices which are safe and effective when used in conjunction with instructions for usage and warnings of limitation, which are adequate for the persons by whom the device is represented or intended for use, which present a minimum risk, and which should be exempt from requirements for scientific review or performance standards.

(d) As soon as possible after filing of the report required for compliance with subsection (a), the Secretary shall publish such report in the Federal Register and provide interested persons an opportunity to comment thereon. After reviewing such comments the Secretary shall by regulation provide for preliminary classification of such devices. The Secretary may establish priorities for implementing the action warranted by such classification under sections 513 and 514 and may defer such action for any device until an appropriate time, consistent with expeditious implementation of these provisions.

(e) The Secretary, with the advice of the appropriate panel and after making a specific finding and publishing such finding in the Federal Register and providing interested persons an opportunity for comment thereon may by regulation change the preliminary classification of a device or group of devices from one category to another.

(f) The preliminary classification of a device shall constitute public notice that, as expeditiously as is feasible, the Secretary will issue a final classification in the form of a determination of a need for a performance standard pursuant to section 513 or a determination of the need for scientific review pursuant to section 514. The preliminary classification shall not relieve the Secretary of any obligation to provide notice as required by sections 513 and 514. Any interested person will have an opportunity, pending such final classification, to undertake studies and other work appropriate to develop a performance standard or to demonstrate the safety and effectiveness of a device.

(g) After the promulgation of regulations under subsection (d) of this section and commensurate with the effective date of section 501(f) a manufacturer of a medical device which has not been classified in accordance with this section shall file an application for the classification of the device and must receive from the Secretary notification of the classification of such device. The Secretary shall act on the application within sixty days unless the Secretary and the manufacturer agree to an additional period of time. The Secretary shall classify the devices in accordance with the criteria and procedures listed in 511, 513, and 514 including the requirement for consultation with the appropriate panel or panels. The appeal provisions of sections 513 and 514 shall apply.

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PERFORMANCE STANDARDS FOR MEDICAL DEVICES

Authority To Set Standards

SEC. 513. (a)(1) Whenever in the judgment of the Secretary such action is appropriate to assure effectiveness or to reduce or eliminate unreasonable risk of illness or injury associated with exposure to or use of a device (including the need for uniformity and compatibility with systems or environments in which it is intended to be used) and for which other means may not be appropriate to reduce or eliminate such risk of illness or injury he shall by order issued in accordance with subsection (c) of this section promulgate for any device, or type or class of device, for which a performance standard has been determined to be appropriate pursuant to section 511(d), a performance standard relating to safety and effectiveness, (including effectiveness over time), and including where necessary: the composition, the construction, the compatibility with power systems and connections, and the properties, and including where appropriate the uniform identification of such device. Such performance standard shall where appropriate include provisions for the testing of the device and the measurement of its characteristics (including individual lot testing by or at the direction of the Secretary where necessary to assure the accuracy and reliability of results when it is determined that no other more practicable means to assure accuracy and reliability are available to the Secretary) and shall where appropriate require the use and prescribe the form and content of instructions or warnings necessary for the proper installation, maintenance, operation, and use of the device.

(2) A performance standard may require that the device or any component thereof be marked, tagged, or accompanied by clear and

adequate warnings or instructions reasonably necessary for the protection of health or safety.

(3) The Secretary shall provide for a periodic evaluation of the adequacy of all performance standards promulgated under this section in order to reflect changes in the state of the art of the development of devices and in applicable medical, scientific, and other technological data.

(4) For the purposes of this section, when a device is intended for use by a physician, surgeon, or other person licensed or otherwise specially qualified therefor, its safety and effectiveness shall be determined with regard to such intended use.

Consultation with Other Federal Agencies and Interested Groups; Use of Other Federal Agencies

(b)(1) Prior to (A) initiating a proceeding under subsection (c) to promulgate a performance standard under this section, (B) initiating the development of a proposed performance standard under subsection (f) of this section, or (C) the taking of any action under subsection (g) of this section, the Secretary shall to the maximum practicable extent consult with, and give appropriate weight to relevant standards published by, other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting agencies or organizations. In considering proposals for the development of performance standards, the Secretary shall to the maximum extent practicable invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, and consumer organizations which in his judgment can make a significant contribution to such development.

(2) In carrying out his duties under this section, the Secretary shall utilize to the maximum practicable extent the personnel, facilities, and other technical support available in other Federal agencies.

Initiation of Proceeding for Performance Standards—Development by Interested Parties

(c)(1) A proceeding to promulgate a performance standard under this section shall be initiated by the Secretary by publication of notice in the Federal Register. Such notice shall advise of the opportunity for comment on the need to initiate such proceeding and shall include—

(A) a description or other designation of the device (or type or class of device) to which the proceeding relates;

(B) the nature of the risk or risks intended to be controlled;

(C) a summary of the data on which the Secretary has found a need for initiation of the proceeding;

(D) identification of any existing performance standard (if known to the Secretary) which may be relevant to the proceeding; and

(E) an invitation to any person, including any Federal agency, which has developed or is willing to develop a proposed performance standard to submit to the Secretary, within sixty days after the date of such notice (i) such a performance standard; or (ii)

an offer to develop a proposed performance standard in accordance with procedures prescribed by regulations of the Secretary. Such invitation shall specify a period of time, during which the performance standard is to be developed, which shall be a period ending one hundred and eighty days after the publication of the notice, unless the Secretary for good cause finds (and includes such funding in a notice published in the Federal Register) that a different period is appropriate.

(2) Prior to his issuance of an order to promulgate a performance standard, the Secretary shall consider—

(A) the degree of risk of illness or injury associated with those aspects of the devices subject to the order;

(B) the approximate number of devices, or types or classes thereof, subject to the order;

(C) the benefit to the public from the devices subject to the order, and the probable effect of the order upon the utility cost or availability of the devices to meet that need;

(D) means of achieving the objective of the order with a minimal disruption or dislocation of competition and of reasonable manufacturing and other commercial practices consistent with the public health and safety; and

(E) data and comments submitted pursuant to subsection (c) relevant to such order.

(3) Before taking action pursuant to subsections (d), (e), and (f) concerning the use of an existing performance standard or the designation of a person or governmental body to formulate a proposed performance standard, or simultaneous with such action, the Secretary shall publish a notice in the Federal Register containing his findings pursuant to paragraph (2) on the need to establish a standard. Such findings shall be made only after consideration of the report, comments, and regulation provided for in section 511(d) and the comments received under the notice described in subsection (a)(1), and may be appealed to the courts pursuant to subsection (g)(5) within thirty days after publication in the Federal Register.

Use of Existing Performance Standards

(d) If the Secretary (1) finds that there exists a standard which has been published by any Federal agency or other qualified agency, organization, or institution, (2) has made reference to such standard (unless it is a standard submitted under subsection (c)(1)(E)) in his notice pursuant to subsection (c)(1)(D), and (3) determines that such performance standard may be substantially acceptable to him as a device standard, then he may, in lieu of accepting an offer under this section, publish such performance standard as a proposed device performance standard in accordance with subsection (g).

Acceptance of Offers To Develop Performance Standards

(e)(1) Except as otherwise provided by subsection (d), the Secretary may accept one or more offers to develop a proposed performance standard pursuant to the invitation prescribed by subsection (c)(1)

(E) if he determines that (A) the offeror is technically competent to undertake and complete the development of an appropriate performance standard within the period specified in the invitation under subsection (c)(1)(E) and (B) the offeror has the capacity to comply with procedures prescribed by regulations of the Secretary under paragraph (4) of this subsection. Where more than one offer is received and the Secretary determines that the requirements of subparagraphs (A) and (B) have been met, the Secretary shall, wherever practicable, give priority to offerors who have no proprietary interest in the device for which the standard is to be developed. The Secretary shall require, by regulation, that in making an offer, each offeror and appropriate individual directors, officers, consultants, and employees of each offeror company, disclose the following information:

(i) all current industrial or commercial affiliations;

(ii) sources of research support other than the offeror;

(iii) companies in which offerors have financial interests;

(iv) such additional information as the Secretary deems pertinent to reveal potential conflicts of interest with regard to the offer.

The information received by the Secretary from an offeror whose offer has been accepted shall be made public by the Secretary at the time that an offer is a accepted.

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

(3) When an offer is accepted under this subsection the Secretary may agree to contribute to the offeror's cost in developing a proposed performance standard, if the Secretary determines that such contribution is likely to result in a more satisfactory performance standard than would be developed without such contribution, and that the offeror is financially responsible. Regulations of the Secretary, shall set forth the items of cost in which he may participate, except that such items may not include construction (except minor remodeling), or the acquisition of land or buildings.

(4) The Secretary shall prescribe regulations governing the development of proposed performance standards under this subsection and subsection (f). Such regulation shall include requirements—

(A) that performance standards recommended for promulgation be supported by test data or such other documents or materials as the Secretary may reasonably require to be developed, and be suitable for promulgation under subsection (g);

(B) that performance standards recommended for promulgation contain such test methods as may be appropriate for measurement of compliance with such performance standards;

(C) for notice and opportunity by interested persons, including representatives of consumers or consumer organizations, to participate in the development of such performance standards;

(D) for the maintenance of such records as the Secretary prescribes in such regulations to disclose the course of the development of performance standards recommended for promulgation, 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 recommended performance standards, and such other matters as may be relevant to the evaluation of such recommended performance standards; and

(E) that the Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, have access for the purpose of audit and examination to any books, documents, papers, and records, relevant to the expenditure of any contribution of the Secretary, under paragraph (3).

Development of Performance Standards by the Secretary

(f) If the Secretary has published a notice as provided by subsection (c), and—

(1) no person accepts the invitation prescribed by subsection (c)(1)(E);

(2) the Secretary has accepted neither an existing performance standard pursuant to subsection (d) nor an offer to develop a proposed performance standard pursuant to subsection (e); or

(3) the Secretary has accepted an offer pursuant to subsection (e) but determines that the offeror is unwilling or unable to continue the development of the performance standard which was the subject of the offer or the performance standard which has been developed is not satisfactory;

then the Secretary shall proceed to develop a proposed performance standard pursuant to procedures prescribed by subsection (g).

Procedure for Promulgation, Amendment, or Revocation of Performance Standards

(g)(1)(A) Within one year after expiration of the period provided for persons to submit a proposed performance standard or offer to develop a proposed performance standard (which time may be extended by the Secretary by a notice published in the Federal Register stating the good cause therefor) and after review of any proposal submitted under subsection (e), the Secretary shall publish in the Federal Register either a proposal to promulgate a performance standard applicable to the device (or type or class of device) subject to the proceeding, or a notice that the proceeding is terminated. The proposal to promulgate a performance standard shall set forth the performance standard, the manner in which interested persons may examine data and other information on which the performance standard is based, and the period within which interested persons may present their comments on the standard (including the need therefor) orally or in writing. Such period for comment shall be at least sixty days, but not to exceed ninety days which time may be extended by the Secretary by a notice published in the Federal Register stating the cause therefor.

(B) Within ninety days after the expiration of the period for comments pursuant to paragraph (A), the Secretary shall, by order published in the Federal Register, act upon the proposed performance standard or terminate the proceeding. The order shall set forth the performance standard, if any, the reasons for the Secretary's action, and the date or dates upon which the performance standard, or por-

tions thereof, will become effective. 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. If any performance standards set forth in the order is substantially different from that set forth in the proposal an additional period of thirty days shall be permitted for comment on such performance standard.

(C) The Secretary may include in the order promulgating a performance standard such findings in addition to those made pursuant to subsection (c) (3) as he may determine to be necessary to support the judgment required by subsection (a) (1).

(2) The Secretary may revoke any performance standard, in whole or in part, upon the ground that there no longer exists a need therefor or that such performance standard (or part thereof) is no longer in the public interest. Such revocation shall be published as a proposal in the Federal Register and shall set forth such performance standard or portion thereof to be revoked, a summary of the reasons for his determination that there may no longer be a need therefor or that such standard (or any part thereof) may no longer be in the public interest, the manner in which interested persons may examine data and other information relevant to the Secretary's determination, and the period within which any interested person may present his views, orally or in writing, with respect to such revocation. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall publish such order in the Federal Register. The order shall include the reasons for the Secretary's action and the date or dates upon which such revocation shall become effective.

(3) The Secretary may propose an amendment of a performance standard on his own initiative or on the petition of any interested person by publishing such proposal in the Federal Register. Such proposal shall be subject to paragraphs (4) and (5) of this subsection and subsection (h).

(4) To the extent not inconsistent with this section, the provisions of section 553 of title 5 of the United States Code, shall govern proceedings under this section to promulgate, amend, or revoke a performance standard.

(5) (A) In a case of actual controversy as to the validity of any order promulgating, amending, or revoking a performance standard or findings that a standard is needed or a regulation banning a device, any person who will be adversely affected by such order if placed in effect may at any time prior to the thirtieth day after such order is issued 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 a judicial review of such 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 thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28, United States Code.

(B) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary the court may order such additional evidence (and evidence in rebuttal thereof) to be presented to the Secretary. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence, so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(C) Upon the filing of the petition referred to in subparagraph (A) of this paragraph, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily, or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(D) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(E) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(F) A certified copy of the transcript of the record of the proceedings before the Secretary shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal libel for condemnation, exclusion of imports, or other proceeding arising under or in respect of this Act, notwithstanding proceedings with respect to the order have been previously instituted or become final under this subsection.

(6) The Secretary may by regulations prohibit a manufacturer of a device from stockpiling any device to which a performance standard applies, so as to prevent such manufacturer from circumventing the purpose of such performance standard. For purposes of this paragraph, the term 'stockpiling' means manufacturing or importing a device between the date of promulgation of such performance standard and its effective date at a rate which is significantly greater (as determined under the regulations under this paragraph) than the rate at which such device was produced or imported during a base period (prescribed in the regulations under this paragraph) ending before the date of promulgation of the performance standard.

Referral to Independent Advisory Committee

(h) (1) The Secretary may refer a proposal under subsection (g) to an advisory committee of experts for a report and recommendation with respect to any matter involved in such proposal which requires the exercise of scientific judgment. Such referral shall be prior to or after publication under such subsection, and shall be so referred upon a request, within the time for comment specified in the proposal, of

any interested person (unless the Secretary finds the request to be without good cause). For the purpose of any such referral, the Secretary shall appoint an advisory committee (which may be a standing advisory scientific review panel established under section 514(b)) and shall refer to it, together with all the data before him, the matter so involved for study, and for a report and recommendation. The advisory committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of such report shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. After giving consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order conform or modify any prior order, or, if no such prior order has been issued, shall by order act upon the proposal. Any interested person shall have the right to consult with such advisory committee, and such advisory committee is authorized to consult with any person, in connection with the matter referred to it.

(2) 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. Members of an advisory committee who are not in the regular full-time employ 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 but not at rates exceeding the daily equivalent 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 they 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 furnish the committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by the committee.

Testing or Manufacture of Devices To Assure Compliance With Standards

(i)(1) Every manufacturer of a device subject to a standard under this section shall assure the Secretary, at such times and in such form and manner as the Secretary shall by regulation prescribe, that testing methods prescribed by the performance standard show the device to comply therewith, or that the device has been manufactured under a program of quality control which is in accord with current good manufacturing practice (as may be determined by regulations of the Secretary) designed to assure such compliance.

(2) To assure that devices conform to performance standards under this section, the Secretary shall review and evaluate on a continuing basis testing and other quality control programs carried out by manufacturers of devices subject to such performance standards.

Exemption

(j) This section shall not apply to any device (1) intended solely (A) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals other than man or (B) to affect the structure or any function of the body of such animals; or (2) subject to section 514 except for those characteristics of the device made subject to provisions of existing performance standards by an application approved pursuant to that section; or (3) any device of a particular manufacturer which the Secretary finds pursuant to regulations issued after an opportunity for a hearing may notwithstanding any standard promulgated under this section be marketed pursuant to an approval under section 514.

Temporary Permits

(k) The Secretary shall issue regulations permitting the interstate shipment of devices varying from an applicable performance standard for the purpose of investigation or other testing prior to amendment of the standard. Such regulations may include reasonable conditions related to the safety and effectiveness of the devices.

Custom Devices

(l) This section shall not apply to any custom device to the extent that it is ordered by a physician (or other specially qualified persons, authorized by regulations promulgated by the Secretary, after an opportunity for a hearing) to be made in a special way for individual patients. Any such device shall comply with all aspects of any applicable performance standard except those specifically ordered by a physician or such other authorized person to be changed. This subsection shall apply only to devices ordered for individual patients, and shall not otherwise exempt a device from subsection (k). Custom devices shall not be used as a course of conduct and shall not be generally available in finished form for purchase or for dispensing upon prescription, and whether in finished form or otherwise, shall not be made available through commercial channels by the maker or processor thereof.

Banned Device

(m)(1) Whenever the Secretary finds after consultation with the appropriate panel or panels established under section 514(b) and after affording all interested persons an opportunity for an informal hearing, that—

(A) a device presents an unreasonable risk of illness or injury or deception; and

(B) no feasible performance standard or approved application under section 514 would adequately protect the public from the unreasonable risk of illness or injury or deception associated with such device,

he may propose and, in accordance with subsection (g), promulgate a regulation declaring such product a banned device.

(2) The Secretary may declare a proposed regulation banning a device to be effective on an interim basis after publication in the

Federal Register, pending completion of the procedures established in subsection (g)(3), if he determines, after affording all interested persons an opportunity for an informal hearing, that such banning will expeditiously reduce or eliminate a hazard to the public health or safety, fraud, or gross deception associated with such device.

Expedited Amendment

(n) The Secretary may declare a proposed amendment of a performance standard to be effective on an interim basis after publication in the Federal Register, pending completion of the procedures established in subsection (g)(3), if he determines, after affording all interested persons an opportunity for an informal hearing, that such amendment will permit rapid implementation of desirable changes or will expeditiously reduce or eliminate a hazard to the public health or safety without prohibiting devices permitted by the existing performance standard and that to do so is in the public interest.

SCIENTIFIC REVIEW OF CERTAIN MEDICAL DEVICES

When Scientific Review Is Required

SEC. 514. (a)(1) The Secretary may declare that a device (or type or class of device) for which scientific review has been determined to be appropriate pursuant to section 511(d) shall be subject to scientific review under this section with respect to any particular use or intended use thereof if, after consultation with the appropriate panel or panels specified in subsection (b), he finds that (A) such review is appropriate to assure effectiveness or is appropriate to reduce or eliminate unreasonable risk of illness or injury associated with exposure to or use of a device and (B) other means available to the Secretary may not be appropriate to reduce or eliminate such risk of illness or injury. (2) The Secretary may declare that a device (or type or class of device) shall be subject to scientific review under this section with respect to any particular use or intended use thereof if he (A) determines that scientific review for any device is appropriate to protect the public health and safety and (B) finds that other means available to the Secretary may not be appropriate to reduce or eliminate such risk of illness or injury. To the maximum extent practicable the panel or panels shall provide an opportunity for any interested person to submit data and views on the appropriateness of applying scientific review to a device (or type or class of device) or any particular use of a device. The declaration shall be by regulation (which may be rescinded by the Secretary) which shall not set forth and be based upon the report, comments, and regulations provided for in section 511(d), the findings prescribed in this subsection, and findings as described in section 513(c)(2). The promulgation of such regulation may be appealed to the courts pursuant to the provisions of section 513(g)(5) within thirty days after publication in the Federal Register. A device (or type or class of device) declared to be subject to scientific review shall be deemed unsafe or ineffective for the purpose of the application of section 501(f) unless either—

(i) there is in effect an approval of an application with respect to such device under this section,

(ii) such device is exempted by or pursuant to subsections (k), (l), or (m) of this section, or

(iii) such device is intended solely (I) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals other than man or (II) to affect the structure or any function of the body of such animals.

Standing Advisory Scientific Review Panels

(b) For the purpose of reviewing applications filed under subsection (c), and of reviewing plans and protocols submitted under subsection (k)(4), and of reviewing product development protocol under subsection (m)(2) the Secretary shall utilize the standing advisory panels established under section 511. The selection, payment, and administration of these panels shall be governed by section 511.

Application for Scientific Review

(c)(1) Scientific review of a device (or type or class of device) which has been declared subject to such review in accordance with subsection (a) may be obtained by submitting to the Secretary an application for his determination of the safety and effectiveness of the device. The application 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 for use; (B) a full statement of the composition, properties, and construction, 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, applicable to such device, or component of such device, which is in effect pursuant to section 513, and either adequate information to show that 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 the articles used as components thereof as the Secretary may require; (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, upon advice of the appropriate panel or panels established pursuant to subsection (b), 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 or panels (established pursuant to subsection (b)) for study and for submission (within such period, if any, as he may establish) of a report and recommendations, together with all underlying data and the reasons or basis for the recommendations. The provisions of section 706(d)(2) shall apply with respect to the material so submitted.

Consideration of an Initial Action on Application

(d) As promptly as possible, but in no event later than one hundred and twenty days after the receipt of an application under subsection (c), unless an additional period is agreed upon by the Secretary and the applicant, the Secretary, after considering the report and recommendations referred to in paragraph (2) of such subsection, shall—

(1) approve the application if he finds that none of the grounds for denying approval specified in subsection (e) applies,

(2) advise the applicant that the application is not in approvable form; and inform the applicant, insofar as the Secretary determines to be practicable, 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); or

(3) deny approval of the application if he finds (and sets forth the basis of such findings as part of or accompanying such denial) that one or more grounds for denial specified in subsection (e) applies.

Basis for Approval or Disapproval; Opportunity for Review

(e)(1) 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, after opportunity to the applicant for the review prescribed by paragraph (4), that—

(A) such device is not shown to be safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof;

(B) 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 501(g);

(C) there is a lack of adequate scientific evidence 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 proposed labeling thereof;

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

(E) such device is not shown to conform in all applicable respects to a currently effective performance standard promulgated under section 513;

he shall issue an order denying approval of the application and stating the findings upon which the order is based. In determining if a device is shown to be safe for purposes of this paragraph, the Secretary shall weigh any benefit to the public health probably resulting from the use of the device against any hazard to the public health probably resulting from such use.

(2) As used in this subsection and subsection (f), the term 'adequate scientific evidence' means evidence consisting of sufficient well-controlled investigations, including clinical investigations where approprate, by experts qualified by scientific training and experience to evaluate the effectiveness of the device involved, on the basis of which

it could fairly and responsibly be concluded by such 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 or proposed labeling thereof, unless the Secretary determines that other valid scientific evidence is sufficient to establish the effectiveness of the device.

(3) For the purposes of this section, when a device is intended for use by a physician, surgeon, or other person licensed or otherwise specially qualified therefor, its safety and effectiveness shall be determined in the light of such intended use.

(4)(A) 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 subsection (i). The Secretary shall consider and give appropriate weight to the report and recommendations received from the advisory committee conducting such review under such subsection.

(B) In lieu of the review provided by subparagraph (A), such applicant may petition to obtain a hearing in accordance with section 554 of title 5 of the United States Code.

Withdrawal of Approval

(f)(1) The Secretary may, upon obtaining where appropriate, advice on scientific matters from a panel or panels established pursuant to subsection (b), and after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application with respect to a device under this section if the Secretary finds—

(A)(i) that clinical or other experience, tests, or other scientific data show that such device is unsafe for use under the conditions of use for which the application was approved; or (ii) on the basis of evidence of clinical experience, not included in or accompanying such application and not available to the Secretary until after the application was approved, or of tests by new methods or by methods not reasonably applicable when the application was approved, evaluated together with the evidence available to the Secretary when the application was approved, that such device is not shown to be safe for use under the conditions of use on the basis of which the application was approved;

(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 adequate scientific evidence that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or sugested in the labeling thereof;

(C) that the application filed pursuant to subsection (c) contains or was accompanied by an untrue statement of a material fact;

(D) that the applicant 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 or order under subsection (a) of section 516, or that the applicant has refused to permit access to, or copying or verifica-

tion of such records as required by paragraph (2) of such subsection;

(E) on the basis of new information before him, 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 to the requirements of section 501(g) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary; or

(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; 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 an applicable performance standard promulgated pursuant to section 513.

(2) If the Secretary (or in his absence the officer acting as Secretary) finds that an imminent health or safety hazard is involved, he may by order suspend the approval of such application immedinately and give the applicant prompt notice of his action and afford the applicant an opportunity for an expedited hearing under this subsection. Such authority to suspend the approval of an application may not be delegated.

(3) Any order under this subsection shall state the findings upon which it is based.

Authority To Revoke Adverse Orders

(g) Whenever the Secretary finds that the facts so require, he shall revoke an order under subsection (e) or (f) denying, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

Service of Secretary's 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.

Referral to Independent Advisory Committee

(i)(1) A person who has filed an application under subsection (c) may petition the Secretary, in accordance with subparagraph (A) of subsection (e)(4), to refer such application, or the Secretary's action thereon, to an advisory committee of experts for a report and recommendations with respect to any question therein involved which requires the exercise of scientific judgment. Upon such petition, or if the Secretary on his own initiative deems such a referral necessary, the Secretary shall appoint an advisory committee and shall refer to it, together with all the data before him, the question so involved for study thereof and a report and recommendations thereon. The committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the foregoing shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. After giving consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order conform or modify any prior order or, if no such prior order has been issued, shall by order act upon the application. The applicant, as well as representatives of the Secretary, shall have the right to consult with such advisory committee, and such advisory committee is authorized to consult with any person in connection with the question referred to it.

(2) Section 513(h)(2) shall apply to the appointment, compensation, staffing, and procedure of any such advisory committee.

Judicial Review

(j) The applicant may, by appeal taken in accordance with section 505(h), obtain judicial review of a final order of the Secretary denying or withdrawing approval of an application filed under subsection (c) of this section or a final order under subsection (m) revoking an exemption in effect under that subsection. Judicial review of such final order shall not be denied upon the ground that the petitioner has failed to avail himself of the review or hearing provided by subsection (e)(4) or the hearing provided by subsection (m).

Exemption for Investigational Use

(k)(1) It is the purpose of this subsection to encourage, to the maximum extent consistent with the protection of the public health and safety and with professional ethics, the discovery and development of useful devices and to that end to maintain optimum freedom for individual scientific investigators in their pursuit of that objective. All information required under this section to be submitted to the Secretary or to an institutional review committee shall be concise and no more burdensome than is necessary to permit adequate review.

(2) Subject to the succeeding paragraphs of this subsection, there shall be exempt from the requirement of approval of an application under the foregoing provisions of this section any device which is intended solely for investigational use (in an appropriate scientific environment) by an expert or experts qualified by scientific training and experience to investigate the safety and effectiveness of such device.

(3) The Secretary shall promulgate regulations after an opportunity for a hearing, relating to the application of the exemption re-

ferred to to in paragraph (2) to any device which is intended for use in the clinical testing thereof upon humans, in developing data required to support an application under subsection (c).

(4) Such regulations may provide for conditioning the exemption, in the case of a device intended for such clinical use, upon—

(A) the submission, by the manufacturer of the device or the sponsor of the investigation, of an outline of the plan of initial clinical testing—

(i) to a local institutional review committee which has been established to supervise clinical testing in the facility where the initial clinical testing is to be conducted, the composition and procedures of which comply with regulations of the Secretary, for review as being adequate to justify the commencement of such testing, or

(ii) if no such committee exists or if the Secretary finds that the process of review by such committee is inadequate or that protection of health and safety so requires (whether or not the plan has been approved by such committee), to the Secretary for review by the appropriate panel or panels established pursuant to subsection (b) as being adequate to justify the commencement of such testing;

(B) prompt notification to the Secretary by such manufacturer or sponsor (under such circumstances and in such manner as the Secretary prescribes) of approval of any plan pursuant to clause (A)(i);

(C) the submission, by the manufacturer of the device or the sponsor of the investigation, of an adequate protocol for clinical testing to be conducted by separate groups of investigators under essentially the same protocol, together with a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed testing, either (i) to a local institutional review committee for review in accordance with the provisions of clauses (A)(i) and (B), or (ii) to the Secretary for review in accordance with the provisions of clause (A)(ii) if such testing involves facilities in which no such committee exists, or facilities served by more than one local institutional review committee if such committees are unable to agree on the adequacy of the submission;

(D) the obtaining, by the manufacturer of the device or the sponsor of the investigation, if the device is to be distributed to investigators for testing, of a signed agreement from each of such investigators that humans upon whom the device is to be used will be under such investigator's personal supervision or under the supervision of investigators responsible to him;

(E) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer of the device or the sponsor of the investigation, of data (including but not limited to analytical reports by investigators) obtained as a result of such investigational use of the device, as the Secretary finds will enable him to evaluate the safety and effectiveness of the device in the event of the filing of an application pursuant to subsection (c); and

(F) such other conditions relating to the protection of the public health and safety as the Secretary may determine to be necessary.

Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of devices. The Secretary shall within thirty days of the receipt of a notification or submission pursuant to this paragraph, determine whether the proposed investigation conforms to the requirements of this section. An investigation shall not begin until the sponsor receives notice from the Secretary that the proposed investigation conforms with the requirements of this section. The Secretary may not delay the beginning of an investigation pursuant to this paragraph unless he finds that the investigation does not conform to the requirements of this section and he has notified the sponsor of such findings. The Secretary may exempt investigations from part or all the requirements of this subsection when he determines that to do so is in the public interest.

(5) Such regulations shall assure that the rights and welfare of the subjects involved are adequately protected, that the risks to an individual are outweighed by the potential benefits to him or by the importance of the knowledge to be gained and that informed consent is to be attained by methods that are adequate. Such informed consent shall be obtained in all but exceptional cases.

(A) For the purposes of this section, only the term "informed consent" shall mean the consent of a person, or his legal representative, so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, or other form of constraint or coercion. Such consent shall be evidenced by an agreement signed by such person, or his legal representative. The information to be given to the subject in such written agreement shall include the following basic elements:

(1) a fair explanation of the procedures to be followed, including an identification of any which are experimental;

(2) a description of any attendant discomforts and risks reasonably to be expected;

(3) a fair explanation of the likely results should the experimental procedure fail;

(4) a description of any benefits reasonably to be expected;

(5) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;

(6) an offer to answer any inquiries concerning the procedures; and

(7) an instruction that the subject is free to either decline entrance into a project or to withdraw his consent and to discontinue participation in the project or activity at any time without prejudicing his future care.

In addition, the agreement entered into by such person or his legal representative, shall include no exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal rights, or to release the institution or its agents from liability for negligence. Any organization which initiates, directs, or engages in programs of research, development, or demonstration which require informed consent shall keep a permanent record of such consent and

the information provided the subject and develop appropriate documentation and reporting procedures as an essential administrative function.

(B) The term "exceptional cases" as used in paragraph (5) shall be strictly construed; shall permit the waiver only of those elements of consent listed in subparagraph (A) as may be justified by the circumstances of each case; and shall require the written concurrence in the acting physician's decision by at least two other licensed physicians not involved in the research project, unless in a life threatening situation, it is not feasible to obtain such concurrence.

(6) Whenever the Secretary determines that a device is being or has been shipped or delivered for shipment in interstate commerce for investigational testing upon humans, and that such device is subject to the preceding subsections of this section and fails to meet the conditions for exemption therefrom for investigational use, he shall notify the sponsor of his determination and the reasons therefor, and the exemption will not thereafter apply with respect to such investigational use until such failure is corrected.

(7) In determining whether this subsection is applicable to any device and, if so, whether there has been compliance with the conditions of exemption, or upon application for reconsideration of any such determination, the Secretary shall, if so requested by the sponsor of the investigation, or may on his own initiative, obtain the advice of an appropriate expert or experts who are not otherwise, except as consultants, engaged in the carrying out of this Act.

Custom Devices

(l) This section shall not apply to any custom device to the extent that it is ordered by a physician (or other specially qualified persons authorized by regulations promulgated by the Secretary after an opportunity for a hearing) to be made in a special way for individual patients. Any such device shall comply with all aspects of any applicable performance standard except those specifically ordered by a physician or such other authorized person to be changed. This subsection shall apply only to devices ordered for individual patients, and shall not otherwise exempt a device from subsection (k). Custom devices shall not be used as a course of conduct and shall not be generally available in finished form for purchase or for dispensing upon prescription, and, whether in finished form or otherwise, shall not be made available through commercial channels by the maker or processor thereof.

Product Development Protocol

(m)(1) Any device (or type or class of device), manufactured or distributed by a particular person, which has been made subject to this section by a regulation promulgated by the Secretary, may be exempted by the Secretary from the requirement of approval of an application under the foregoing provisions of this section if—

(A) the nature of the device (or type or class of device) is such that it is likely that it will be subject to frequent modification or rapid obsolescence or will not be produced in substantial volume; and

(B) it is intended solely for use by or under the direction or supervision of a practitioner licensed by law to use or to prescribe the use thereof; and

(C) it is, or will be, investigated in accordance with an approved product development protocol established pursuant to paragraph (2) of this subsection, or it is subject to an effective notice of completion of the requirements of such protocol.

(2) Any person may submit a petition to the Secretary to establish a product development protocol with respect to a particular device (or type or class of device) meeting the requirements set forth in subparagraphs (A) and (B) of paragraph (1) of this subsection. Such petition shall include supporting data and a proposed protocol. The Secretary shall, within thirty days, refer any such petition to the appropriate panel of experts appointed pursuant to subsection (b) of this section. Such panel may, within sixty days, or such other time as may be agreed upon by the panel and the petitioner, approve with or without modification the proposed protocol. The protocol, if approved, shall provide—

(A) the investigational and testing procedures required prior to the commencement of clinical trials of such device and subsequent significant modifications thereto;

(B) a requirement that an institutional review committee similar to that described in clause (i) of subparagraph (A) of paragraph (4) of subsection (k) of this section shall make a written finding that the predicted risk-to-benefit ratio applicable to the use of the device justifies clinical trials and that one or more such committees will continually monitor and make periodic written records on all clinical trials conducted in connection with the institution in which such committee operates;

(C) the type and quantity of clinical trials and findings therefrom required prior to the filing of a notice of completion of a product development protocol;

(D) a requirement for complete records of the investigation to be maintained which are adequate to show compliance with the product development protocol;

(E) a requirement that consent, as described in paragraph (5) of subsection (k) of this section, be obtained from all subjects of the investigation; and

(F) a requirement that copies of all records which are to be maintained pursuant to this paragraph be made available to the Secretary upon request.

(3) If the panel to which such petition has been referred does not approve the proposed protocol within sixty days (or within such other time as may be agreed upon), the Secretary may consider and approve with or without modification the proposed protocol within sixty days after the date he is notified that the panel has concluded not to approve a protocol. If neither the panel nor the Secretary approves a proposed protocol, the Secretary shall issue a final order denying the petition and stating the grounds therefor.

(4) At any time after a product development protocol for a particular device (or type or class of device) has been approved pursuant to this section, the petitioner may submit a notice of completion stating

that the requirements of the protocol have been fulfilled and that, to the best of his knowledge, there is no reason bearing on safety, effectiveness, or other public health considerations why the device should not be marketed. Such notice shall contain all the data and information from which the petitioner made this determination. The Secretary shall approve or disapprove the notice of completion within ninety days after receipt of such notice.

(5) The Secretary may, after providing the petitioner an opportunity for an informal hearing, at any time prior to approving a notice of completion, issue a final order to revoke a product development protocol or disapprove a notice of completion if he finds that—

(A) the petitioner has failed substantially to comply with the requirements of the protocol; or

(B) the results of the clinical trials conducted differ so substantially from the results required in the protocol that further trials cannot be justified; or

(C) such device is not shown to be safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or

(D) there is a lack of adequate scientific evidence 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 thereof.

A final order issued under this paragraph shall be in writing and shall contain the reasons to support the conclusions thereof.

(6) The Secretary (or in his absence the officer acting as Secretary) may at any time, by an order in writing stating the findings on which it is based, immediately revoke an exemption from the requirement of approval of an application under the foregoing provisions of this section, if he finds that there is an imminent hazard to the public health or safety caused by the existence of the exemption. In taking such action the Secretary shall give prompt notice to the person following the protocol or having filed the notice of completion, and afford such person an opportunity for an expedited hearing under this paragraph.

(7) At any time after a notice of completion has been approved, the Secretary may issue an order revoking an exemption of the device (or type or class of device) from the requirement of approval of an application under the foregoing provisions of this section if he finds that any of the grounds listed in subparagraphs (A) through (F) of paragraph (1) of subsection (f) of this section apply. The provisions of paragraphs (1) and (3) of subsection (f) and subsections (g) through (j) of this section shall apply.

(8) Whenever the Secretary finds that the facts so justify, he may reconsider an order under this subsection revoking the exemption granted by this subsection and reinstate the exemption.

Transitional Provisions

(n) (1) If, on the day immediately prior to the date upon which a device is declared to be subject to scientific review under this section, the device was in use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, or for the purpose of affectng the structure or any function of the body of man, section 501(f) shall become effective with respect to such preexisting use or uses of such device on the closing date (as defined in paragraph (2) of this subsection) or, if sooner, with respect to any person who has filed an application, on the effective date of an order of the Secretary approving or denying approval of such application with respect to such use of the device under this section.

(2) For the purposes of this subsection, the term "closing date" means, with respect to a device, the first day of the thirty-first calendar month which begins after the month in which the device is declared to be subject to scientific review under this section, except that, if in the opinion of the Secretary it would not involve any undue risk to the public health, he may on application or on his own initiative postpone such closing date with respect to any particular use or uses of a device until such later date (but not beyond the close of the sixtieth month after the month of such declaration) as he determines is necessary to permit completion, in good faith and as soon as practicable, of the scientific investigations necessary to establish the safety and effectiveness of such use or uses. The Secretary may terminate any such postponement at any time if he finds that such postponement should not have been granted or that, by reason of a change in circumstances, the basis for such postponement no longer exists or that there has been a failure to comply with a requirement of the Secretary for submission of progress reports or with other conditions attached by him to such postponement.

NOTIFICATION OF DEFECTS IN, AND REPAIR OR REPLACEMENT OF, DEVICES

SEC. 515. (a) (1) Every person who acquires information which reasonably supports the conclusion that a device intended for human use, which has been produced, assembled, distributed, or imported by him (A) contains a defect which could create a substantial risk to the public health or safety, or (B) on or after the effective date of an applicable performance standard promulgated pursuant to section 513 fails to comply with such standard, shall immediately notify the Secretary of such defect or failure to comply if such device has left the control of the manufacturer. No information or statements exclusively derived from the notification required by this subsection (except for information contained in records required to be maintained under any provision of this Act) shall be used as evidence in any proceeding brought against a natural person pursuant to section 303 of this Act with respect to a violation of law occurring prior to or concurrently with the notification.

(2) The notifications required by paragraph (1) of this subsection shall contain a clear description of such defect or failure to comply, and evaluation of the hazard related thereto, and a statement of the measures to be taken to correct such defect or failure or to effect protection against the hazard created by the defect or failure.

(3) For purposes of this section, the term "defect" means a deficiency in design, materials, or workmanship, and does not include any deficiency resulting from use of improper accessories or from improper installation, maintenance, repair, or use of the device or any deficiency

resulting from normal use of the device after the lifetime represented by the manufacturer has expired.

(b) (1) If the Secretary determines that a device intended for human use distributed in commerce presents a substantial hazard to the public health or safety and that notification is required in order adequately to protect the public from such hazard, he shall immediately make certain that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved to all persons (including manufacturers, distributors, retailers, health professionals, and users) who should properly receive such notification in order to reduce or eliminate the effects of such hazard.

(2) Where the Secretary determines that users shall not be notified under paragraph (1), he shall provide those health professionals who receive notification an opportunity to comment on the advisability of notifying the general public of the hazard. Within 30 days after such notification the Secretary shall notify the general public of the hazard, if after reviewing such comments, he determines that such notification will not endanger the public health.

(c) If the Secretary determines (after affording interested parties, including consumers and consumer organizations, an opportunity for a hearing in accordance with subsection (e)) that a device intended for human use distributed in commerce presents a substantial hazard to the public health or safety and that action under this subsection is in the public interest, it may order the manufacturer or any distributor or retailer of such device to take whichever of the following actions the person to whom the order is directed elects to the extent that the consent of the purchaser and, where appropriate, his physician, is obtained:

(1) bring such device into conformity with the requirements of the applicable performance standard or repair the defect in such device;

(2) replace such device with a like or equivalent device which complies with the applicable performance standard or which does not contain the defect; or

(3) refund the purchase price of such device (less a reasonable allowance for use, if such device has been in the possession of a user for one year or more (A) at the time of public notice under subsection (c), or (B) at the time the user receives actual notice of the defect or noncompliance, whichever first occurs.

An order under this subsection may also require the person to whom it applies to submit a plan, satisfactory to the Secretary for taking action under whichever of the preceding paragraphs of this subsection such person has elected to act. The Secretary shall specify in the order the persons to whom refunds must be made if the person to whom the order is directed elects to take the action described in paragraph (3). If an order under this subsection is directed to more than one person, the Secretary shall specify which person has the election under this subsection.

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

(2) An order issued under subsection (b) or (c) with respect to a device may require any person who is a manufacturer, distributor, or retailer of the device to reimburse any other person who is a manufacturer, distributor, or retailer of such device for such other person's expenses in connection with carrying out the order, if the Secretary determines such reimbursement to be in the public interest.

(3) An order under subsection (c) may be issued only after an opportunity for an informal hearing. If the Secretary determines that any person who wishes to participate in such hearing is a part of a class of participants who share an identity of interest, the Secretary may limit such person's participation in such hearing to participation through a single representative designated by such class (or by the Secretary if such class fails to designate such a representative).

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

RECORDS AND REPORTS ON DEVICES

SEC. 516. (a) (1) Every person engaged in manufacturing, processing, or distributing, or selling a device that is subject to a performance standard promulgated under section 513, or with respect to which there is in effect an approval under section 514 of an application filed under subsection (c) thereof, shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such person with respect to such device, and bearing on the safety or effectiveness of such device, or on whether such device may be adulterated or misbranded, as the Secretary may by general regulation, or by special regulation or order applicable to such device, require. In prescribing such regulations or issuing such orders the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, wherever he deems it appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, 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 copy and verify such records.

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

(1) practitioners licensed by law to prescribe or administer drugs and devices and who manufacture or process devices solely for use in the course of their professional practice;

(2) persons who manufacture or process devices solely for use in research or teaching and not for sale; and

(3) such other classes of persons as the Secretary may by or pursuant to regulation exempt from the application of this subsection upon a finding that such application is not necessary to accomplish the purposes of this subsection.

(c) Every person engaged in manufacturing a device subject to this Act shall provide to the Secretary upon his request such technical data and other data or information with respect to such device as may be reasonably required to carry out this Act.

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

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FACTORY INSPECTION

SEC. 704. (a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle, being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs *or prescription devices* are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs *or prescription devices* which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized [for prescription drugs] by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data, relating to new drugs, *antibiotic drugs, and devices*, [and antibiotic drugs.] subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j), *section 507 (d) or (g), section 514 (k), or section 516* [or section 507 (d) or (g)] of this Act, and data, relating to other drugs *or devices*, which in the case of a new drug *or of a device subject to section 514* would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) *or section 516* of this Act). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this subsection shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs *or devices*, upon prescriptions of practitioners licensed to administer such drugs *or devices* to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs *or devices* for sale other than in the regular course of their business of dispensing or selling drugs *or devices* at retail;

(2) practitioners licensed by law to prescribe or administer drugs *or prescribe or use devices, as the case may be*, and who manufacture, prepare, propagate, compound, or process drugs *or manufacture or process devices* solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs *or manufacture or process devices* solely for use in research, teaching, or chemical analysis and not for sale;

(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

(c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

(d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

PUBLICITY

SEC. 705. (a) * * *

* * * * * * *

(c) To assist in carrying out the provisions of this Act, the Secretary may cause to be disseminated information regarding standards, testing

facilities, and testing methods promulgated, established, or approved under this Act and other information relating to the nature and extent of hazards subject to this Act. Subject to the provisions of section 301 (j), the Secretary may also cause to be published reports summarizing clinical data relevant to marketed products approved under this Act.

* * * * * * *

ADVISORY COUNCIL ON DEVICES, AND OTHER ADVISORY COMMITTEES

SEC. 708. (a) For the purpose of advising the Secretary with respect to matters of policy in carrying out the provisions of this Act relating to devices, there is established in the Department an Advisory Council on Devices appointed by the Secretary without regard to the civil service and classification laws. The persons so appointed shall be manufacturers and other persons with special knowledge of the problems involved in the regulation of various kinds of devices under this Act, members of the professions using such devices, scientists expert in the investigational use of devices, engineers expert in the development of devices, and members of the general public representing consumers of devices.

(b) The Secretary may also from time to time appoint, without regard to the civil service or classification laws, in addition to the advisory councils and committees otherwise authorized under this Act, such other advisory committees or councils as he deems desirable.

(c) Members of an advisory council or committee appointed pursuant to subsection (a) or (b) who are not in the regular full-time employ of the United States shall, while attending meetings or conferences of the council or committee or otherwise engaged on its business, be compensated at per diem rates fixed by the Secretary but not in excess of the rate for grade GS-18 of the General Schedule at the time of such service, including traveltime, and while so serving away from their homes or regular places of business they may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by title 5, United States Code, section 5703, for persons in the Government service employed intermittently.

RESEARCH AND STUDIES RELATING TO DEVICES

SEC. 709. (a) The Secretary is authorized, directly or through contracts with public or private agencies, institutions, and organizations and with individuals, to plan, conduct, coordinate, and support—

(1) research and investigation into the safety and effectiveness of devices, and into the causes and prevention of injuries or other health impairments associated with exposure to or use of devices;

(2) studies relating to the development and improvement of device performance standards, and device testing methods and procedures; and

(3) education and training with respect to the proper installation, maintenance, operation, and use of devices.

(b) In carrying out the purposes of subsection (a), the Secretary, in addition to or in aid of the foregoing—

(1) shall, to the maximum practicable extent, cooperate with and invite the participation of other Federal or State departments and agencies having related interests, and interested professional or industrial organizations;

(2) shall collect and make available, through publications and by other appropriate means, the results of, and other information concerning, research and other activities undertaken pursuant to subsection (a); and

(3) may procure (by negotiation or otherwise) devices for research and testing purposes, and sell or otherwise dispose of such products.

CHAPTER VIII—IMPORTS AND EXPORTS

SEC. 801. (a) The Secretary of the Treasury shall deliver to the Secretary of Health, Education, and Welfare, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health, Education, and Welfare and have the right to introduce testimony. The Secretary of Health, Education, and Welfare shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 510 and shall request that if any drugs *or devices* manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs *or devices* be delivered to the Secretary of Health, Education, and Welfare with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health, Education, and Welfare and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. Clause (2) of the third sentence of this paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act.

(b) Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health, Education, and Welfare that an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with the Act or rendered other than a food, drug, device, or

cosmetic, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary may, in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Department of Health, Education, and Welfare designated by the Secretary, or an officer or employee of the Department of the Treasury designated by the Secretary of the Treasury.

(c) All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any article refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any future importations made by such owner or consignee.

(d) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it (1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show that it is intended for export. But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this Act. Nothing in this subsection shall authorize the exportation of any new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 512 of this Act.], *or to authorize the exportation of any device which does not comply with section 513 or 514 of this Act. The Secretary may permit exportation of any article if he determines that such exportation is in the interest of public health and safety, and has the approval, of the country to which it is intended for export.*

CHAPTER IX—MISCELLANEOUS

* * * * * * *

EFFECT ON STATE REQUIREMENTS

SEC. 903. (a) Whenever a performance standard pursuant to section 513 or scientific review pursuant to section 514 under this Act is in effect, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the

same device unless such requirements are identical to the requirements of the Federal requirements.

(b) Nothing in this section shall be construed to prevent the Federal Government or the government of any State or political subdivision thereof from establishing a safety requirement applicable to a device for its own use if such requirement imposes a higher standard of performance than that required to comply with the otherwise applicable Federal requirements.

(c) Upon application of a State or political subdivision thereof, the Secretary may by rule, after notice and opportunity for oral presentation of views, exempt from the provisions of subsection (a) (under such conditions as he may impose) a proposed safety requirement described in such application, where the proposed requirement—

(1) imposes a higher level of performance than the Federal standard,

(2) is required by compelling local conditions, and

(3) does not unduly burden interstate commerce.

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94TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
2d Session } { No. 94–1090

MEDICAL DEVICE AMENDMENTS OF 1976

MAY 6, 1976.—Ordered to be printed

Mr. STAGGERS, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany S. 510]

The committee of conference on the disagreeing votes of the two Houses on the amendments of the House to the 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, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House to the text of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment to the text of the bill insert the following:

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 (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 in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human 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 in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human 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 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, 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. 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 pararaph (1) to a panel, and which—

"(i) is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life, 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. A regulation which makes a requirement of section 510, 519, or 520(f) inapplicable to a device shall be accompanied by a statement of the reasons of the Secretary for making such requirement inapplicable.

"(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 full statement of the reasons of the Secretary (and supporting documentation and data) for not classifying such device in such class and an identification of the risks to health (if any) presented by such device.

"(3) In the case of devices classified 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) the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

A device 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.

"(2)(A) 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.

"(B)(i) Upon determining that a petition does not contain any deficiency which prevents the Secretary from making a decision on the petition, the Secretary shall refer the petition to an appropriate panel established or authorized to be used under subsection (b). A panel to which such a petition has been referred shall not later than ninety days after the referral of the petition make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall 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 petition was filed. In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the panel shall recommend that the petition be denied unless the panel determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. If the panel recommends that such petition be approved, it shall in its recommendation to the Secretary set forth its reasons for such recommendation.

"(ii) The requirements of paragraphs (1) and (2) of subsection (c) (relating to opportunities for submission of data and views and recommendations respecting priorities and exemptions from sections 510, 519, and 520(f)) shall apply with respect to consideration by panels of petitions submitted under subparagraph (A).

"(C)(i) Within ninety days from the date the Secretary receives the recommendation of a panel respecting a petition (but not later than 210 days after the filing of such petition) the Secretary shall by order deny or approve the petition. If the Secretary approves the petition, the Secretary shall order the classification of the device into class I or class II in accordance with the criteria prescribed by subsection (a)(1)(A) or (a)(1)(B). In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented be for a use in supporting or sustaining human life, the Secretary shall deny the petition unless the Secretary determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. An order approving such petition shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for approving the petition and an identification of the risks to health (if any) presented by the device to which such order applies.

"(ii) The requirements of paragraphs (1) and (2)(A) of subsection (d) (relating to publication of recommendations, opportunity for submission of comments, and exemption from sections 510, 519, and 520(f)) shall apply with respect to action by the Secretary on petitions submitted under subparagraph (A).

"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 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.

"(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 (and if the offeror is a business entity, require that appropriate directors, officers, and employees of, and consultants to, the business entity 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, current industrial or commercial affiliates of the offeror, current sources of financial support for research, and business entities in which the offeror has a financial interest, 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, except that in the case of information submitted by an offeror whose offer has been accepted, the Secretary shall make such information (other than information which because of subsection (b)(4) of section 552, title 5, United States Code, is exempt from disclosure pursuant to subsection (a) of such section) public at the time the offer is accepted.

"(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 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 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) and other information submitted pursuant to subsection (c)(3), 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 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 fact 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 provided 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 reason 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, within fifteen days after publication of a notice under subparagraph (A), the Secretary receives a request for a change in the classification of a device, 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).

"(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 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 as 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, or the facilities or controls used for, the manufacture, processing, packing, or 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 applications 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 approprite 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 protcol 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 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 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 backgrounds, 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. 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 reclassifying a device or denying a petition for reclassification 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 subject 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 provide for the notification of 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 exists 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 pro-

tection 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) 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 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 for such a device records respecting information not in the possession of the manufacture, 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 adulterrated 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*) *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, 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 an individual 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 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 an individual patient named in such order of such physician or dentist (or other specially qualified person so designated) and is to be made in a specific form for such patient, or*

"(*ii*) *in intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) 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 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, distribution, or use—*

"(*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 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. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

"(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) 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 nine 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 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 ap-

plication 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 befor 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 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 summary shall include information respecting any adverse effect 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 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, and (B) shall be made available subject to subsection (c) of this section.

"Proceedings of Advisory Panels and Committees

"(i) Each panel under section 513 and each advisory committee established under section 514(g)(5)(B) or 515(g) or under subsection (f) of this section 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 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 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 en-

forces 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 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 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 clauses (ii) and (iii), a device which is described in subparagraph (D), (E), or (F) of paragraph (1) and which is in class III is required, unless exempt under subsection (g) of this section, to have on and after sixty days 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 beginmay agree upon), the Secretary shall act on such petition or applicaor 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.

"(iii) In the case of a device which is described in subparagraph (E) of paragraph (1), which the Secretary in a notice published in the Federal Register after March 31, 1976, declared to be a new drug subject to section 505, and which is in class III—

"(I) the device shall, after eighteen months after the enactment date, have in effect an approved application under section 515 unless exempt under subsection (g) of this section, and

"(II) the Secretary may, during the period beginning one hundred and eighty days after the enactment date and ending eighteen months after such date, restrict the use of the device to investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of such device, and to investigational use in accordance with the requirements applicable under regulations under subsection (g) of this section to investigational use of devices granted an exemption under such subsection.

If the requirements under subsection (g) of this section are made applicable to the investigational use of such a device, they shall be made applicable in such a manner that the device shall be made reasonably available to physicians meeting appropriate qualifications prescribed by the Secretary.

"(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 section 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.".

(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 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 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, distributed, or used 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 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 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.

This paragraph does not authorize the exportation of any new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 512.

"(2) Paragraph (1) does not apply to any device—

"(A) which does not comply with an applicable requirement of section 514 or 515,

"(B) which under section 520(g) is exempt from either such section, or

"(C) which is a banned device under section 516,

unless, in addition to the requirements of paragraph (1), the Secretary has determined that the exportation of the device is not contrary to public health and safety and has the approval of the country to which it is intended for export.".

(2) Section 801(a)(1) is amended by inserting after "conditions" the following: "or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or 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 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 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 nonproprietary name, its established name (as defined in subparagraph (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: "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 "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 qualification 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 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:

"(r) 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. 708. 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. 709. 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".

ASSISTACE 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 Federal Food, Drug, and Cosmetic Act, as amended by this Act.

And the House agree to the same.

That the Senate recede from its disagreement to the House amendment to the title of the bill.

HARLEY O. STAGGERS,
PAUL G. ROGERS,
RICHARDSON PREYER,
JIM SYMINGTON,
J. SCHEUER,
HENRY A. WAXMAN,
W. G. HEFNER,
J. J. FLORIO,
CHARLES J. CARNEY,
ANDREW MAGUIRE,
TIM LEE CARTER,
JAMES T. BROYHILL,
H. JOHN HEINZ III,
EDWARD MADIGAN,

Managers on the Part of the House.

EDWARD M. KENNEDY,
HARRISON A. WILLIAMS, Jr.,
GAYLORD NELSON,
THOMAS F. EAGLETON,
ALAN CRANSTON,
CLAIBORNE PELL,
WALTER F. MONDALE,
WILLIAM D. HATHAWAY,
JOHN A. DURKIN,
RICHARD S. SCHWEIKER,
J. JAVITS,
J. GLENN BEALL, Jr.,
BOB TAFT, Jr.,
ROBERT T. STAFFORD,
PAUL LAXALT,

Managers on the Part of the Senate.

JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and Senate at the conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 510) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act (hereinafter "the Act") to assure the safety and effectiveness of medical devices submit the following joint statement to the House and the Senate in explanation of the effect of the action agreed upon by the managers and recommended in the accompanying conference report:

The House amendment struck out all of the Senate bill after the enacting clause and inserted a substitute text.

The Senate recedes from its disagreement to the amendment of the House with an amendment which is a substitute for the Senate bill and the House amendment.

The Senate bill and the House amendment were similar in scope and identical in purpose: to assure the reasonable safety and effectiveness of medical devices intended for human use.

Because a more extensive legislative history accompanied the House amendment, the conferees agreed to use the House amendment as the basis for the conference substitute with changes to reflect certain policies embodied in the Senate bill. Thus, except as specifically set forth below, the conference substitute conforms to the House amendment.

CLASSIFICATION OF MEDICAL DEVICES

Both the Senate bill and the House amendment provided for the classification of all medical devices intended for human use into one of three categories based on the extent of regulation necessary to assure safety and effectiveness. Both measures mandated the establishment of panels of experts to make recommendations to the Secretary of Health, Education, and Welfare with respect to the classification of devices. However, there were significant differences between the two measures with respect to criteria for classification and classification procedures.

SENATE BILL

Under the Senate bill all medical devices were subject to regulation following their classification into one of three categories based on the safety and effectiveness of such devices.

The categories were (1) devices subject to scientific review, (2) devices subject to performance standards, and (3) devices exempted from scientific review and performance standards.

Under the Senate bill, classification panels were to recommend classification of all medical devices—those on the market on or before the date of enactment as well as those marketed after enactment—based upon certain statutory criteria.

The panels, in making their recommendations respecting the classification of devices, were, to the extent practicable, to assign priorities for the implementation of regulations applicable to devices classified into the scientific review and performance standards categories.

After receipt of the recommendations the Secretary was to provide for the preliminary classification of devices, and was authorized to establish priorities for implementing the action warranted by such classification. Following such preliminary classification, the Secretary was to require that certain devices undergo scientific review or conform to performance standards.

Scientific Review

Under the Senate bill, classification panels were to recommend that devices (1) for which insufficient information existed to assure effectiveness or assure that exposure to them would not cause unreasonable risk of illness or injury and (2) for which standards or other means might not be appropriate to reduce or eliminate such risk of illness or injury be subject to scientific review.

In addition, the Senate bill authorized the Secretary to require that a device undergo scientific review in two instances. First, he was authorized to require such review of a device which he had initially classified into the scientific review category if he found that (1) such review would be appropriate to assure effectiveness or be appropriate to reduce or eliminate unreasonable risk of illness or injury associated with exposure to or use of the device and (2) other means available to him might not be appropriate to reduce or eliminate such risk of illness or injury. Second, the Secretary was authorized to declare that a device be subject to scientific review (irrespective of its preliminary classification) if (1) he determined that such review was appropriate to protect the public health and safety and (2) he found that no other means available to him would be appropriate to reduce or eliminate such risk of illness or injury.

Life Supporting, Life Sustaining and Implantable Devices

The Senate bill contained special provisions with respect to devices which are life sustaining or life supporting or are intended to be implanted in the human body. The Senate bill required that classification panels classify into the scientific review category medical devices which met the two general criteria described above and which the panels determined were purported or represented to be for a use which is life sustaining or life supporting, or are intended to be implanted into human beings, except that implanted devices were required to be classified into such category unless the Secretary determined on the basis of specific recommendations by the appropriate classification panels that the use of such devices did not pose a health hazard.

Performance Standards

Under the Senate bill, classification panels were to recommend that those devices for which in order to assure effectiveness or to reduce or eliminate unreasonable risk of illness or injury it would be appropriate to establish reasonable performance standards relating to safety and effectiveness and for which other means might not be appropriate to reduce or eliminate such risk of illness or injury be subject to performance standards.

The Senate bill authorized the Secretary to promulgate a performance standard for any device which was initially classified into the performance standard category if he found that (1) such action would be appropriate to assure effectiveness or to reduce or eliminate unreasonable risk of illness or injury associated with exposure to or use of the device and (2) other means available to him might not be appropriate to reduce such risk of illness or injury.

Exempt Devices

Finally, those devices which were determined to be safe and effective when used in conjunction with instructions for usage and warnings of limitation, which were adequate for the persons for whom the device was represented or intended for use, and which presented a minimum risk were to be exempt from requirements for scientific review or performance standards.

Such devices would, however, be subject to existing requirements prohibiting devices which are adulterated or misbranded as well as new requirements relating to provision of certain information to the Secretary upon request; registration; banned devices; notification; repair, replacement, or refund; and good manufacturing practices.

HOUSE AMENDMENT

Under the House amendment all medical devices were subject to regulation based upon their classification into one of three categories in accordance with statutory criteria. The classes were class I, general controls; class II, performance standards; and class III, premarket approval.

General Controls

Under the House amendment, devices for which controls relating to adulteration; misbranding; registration; misbranding; notification and repair replacement or refund; records and reports; and good manufacturing practices were sufficient to provide reasonable assurance of safety and effectiveness or for which insufficient information existed to determine that general controls were sufficient but which are not represented to be for a use of substantial importance in supporting, sustaining, or preventing impairment of human life or health and which do not present a potential unreasonable risk of illness or injury were to be classified into class I and subject to general controls. Class I devices were, with the exception noted below, to be subject to existing requirements prohibiting devices which are adulterated or misbranded as well as new requirements respecting registration; banned devices; records and reports; notification; repair, replacement, or refund; and good manufacturing practices. The House amendment required that the recommendation of a classification panel for the classification of a device in class I include a recommendation as to whether the device should be exempted from requirements relating to registration, records and reports, or good manufacturing practices. Further, the House amendment required that a regulation classifying a device into class I prescribe which, if any, of such requirements would not apply to the device.

Performance Standards

A device for which general controls were determined to be insufficient to provide reasonable assurance of safety and effectiveness and for which there was determined to be sufficient information to establish a performance standard to provide reasonable assurance of safety and effectiveness was to be classified into class II and made subject to performance standards.

Premarket Approval

Under the House amendment, two criteria were to be applied in determining whether a device should be subject to premarket approval.

First, classification into class III, premarket approval, was to be required for a device if it could not be classified into class I or II because insufficient information existed to determine the adequacy of general controls or performance standards to provide reasonable assurance of safety and effectiveness. The second criterion provided that premarket approval was to be required only for devices which either were for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health, or which presented a potential unreasonable risk of illness or injury.

"Old" Devices

All devices on the market prior to the date of enactment were to be reviewed by classification panels. Upon completion of a panel's review of a device, the panel was to submit to the Secretary its recommendation for the classification of the device which was to include a summary of the reasons for the recommendation, a summary of the data upon which the recommendation was based, an identification of the risks to health, if any, presented by the device, and to the extent practicable a recommendation for the assignment of a priority for the application of performance standards or premarket approval requirements to a device recommended to be classified in class II or class III. Following receipt of the recommendations, the Secretary was to classify such devices. After such classification, the Secretary was to provide for the regulation of class II and class III devices through requiring conformance to performance standards or submission of premarket approval applications.

"New" Devices

The House amendment contained special provisions with respect to devices which were not on the market prior to the date of enactment and not substantially equivalent to a device so marketed or not substantially equivalent to a device not on the market prior to the date of enactment but which had subsequently been classified into class I or II. Under the House amendment, these so-called "new" devices were to be automatically classified into class III and thus could not be marketed until they had in effect an approved application for premarket approval or had been reclassified into class I or II by the Secretary. Reclassification was authorized through petition to the Secretary who, after consultation with the appropriate classification panel and opportunity for an informal hearing, was to affirm or deny the petition within 180 days after it was submitted.

Implantable Devices

The House amendment contained special provisions for the regulation of devices intended to be implanted in the human body.

It required that with respect to an implantable device which had been introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of the bill, or which was substantially equivalent to a device so introduced or delivered, classification panels were to recommend classification into class III unless they determined that such classification was not necessary to provide reasonable assurance of safety and effectiveness of the device. In addition, the House amendment required that if panels did not recommend that such devices be classified into class III, their recommendations were to set forth the reasons for not so recommending. Further, the House amendment instructed the Secretary to classify such devices into class III unless he determined that such classification was not necessary to provide reaonable assurance of safety and effectiveness. A proposed regulation classifying such a device into class I or class II was to be accompanied by a statement of the Secretary's reasons for not classifying the device into class III. Reclassification was not available to a "new" implantable device before the device had in effect an approved application for premarket approval.

CONFERENCE SUBSTITUTE

Under the conference substitute, three classes of devices intended for human use are established. The extent of regulation under each class to provide reasonable assurance of safety and effectiveness varies with each class as follows:

Class I, General Controls

This class consists of devices for which general controls (that is, controls relating to adulteration; misbranding; registration; banned devices; notification and repair, replacement or refund; records and reports; and good manufacturing practices) are sufficient to provide reasonable assurance of safety and effectiveness or for which insufficient information exists to determine that general controls are sufficient for such purpose but which are not represented to be for a use in supporting or sustaining life or preventing impairment of health, and which do not present a potential unreasonable risk of illness or injury.

Class II, Performance Standards

This class consists of devices for which general controls are determined to be insufficient to provide reasonable assurance of safety and effectiveness and for which there is determined to be sufficient information to establish a performance standard to provide reasonable assurance of safety and effectiveness is to be classified into class II and made subject to performance standards.

Class III, Premarket Approval

This class consists of devices which cannot be classified as a class I or II device because insufficient information exists with which to determine the adequacy of general controls or standards to provide reason-

able assurance of safety and effectiveness, and which are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health or which present a potential unreasonable risk of illness or injury.

Classification of "Old" Devices

Under the conference substitute, classification panels are to submit recommendations to the Secretary respecting the classification of all "old" devices (e.g., devices of a type introduced or delivered for introduction into interstate commerce for commerce distribution before the date of enactment of the conference report). Interested persons are to be afforded opportunity to submit data on views on the classification of devices. A panel's recommendation for the classification of a device is to include a summary of the reasons for the recommendation, a summary of the data upon which the recommendation is based, an identification of the risks to health (if any) presented by the device, and, to the extent practicable, a recommendation for the assignment of a priority for the application of performance standards or premarket approval requirements to a device recommended to be classified in class II or class III. The recommendation of a classification panel for the classification of a device in class I is to include a recommendation as to whether the device should be exempted from the requirements relating to registration, records and reports, or good manufacturing practices. A regulation classifying a device into class I should prescribe which, if any of the requirements of such subsections shall not apply to the device.

Following receipt of a panel's recommendation with respect to the classification of an "old" device, the Secretary is to promulgate a regulation classifying the device. In the case of a device classified into class II or class III, the Secretary is required to establish priorities which he may use in applying requirements with respect to performance standards and premarket clearance. Any regulation which makes a requirement with respect to registration, records and reports, and good manufacturing practices inapplicable to a class I device must be accompanied by a statement of the reasons of the Secretary for making such a requirement inapplicable.

Classification of "New" Devices

Under the conference substitute, all "new" devices (e.g., devices not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of the conference report and not substantially equivalent to a device so introduced or delivered, or not substantially equivalent to a device so introduced or delivered but which has subsequently been classified into class I or II) are automatically classified into class III and are to remain in that class until they have been reclassified by the Secretary. Reclassification may be accomplished by petition to the Secretary, who is to refer the petition to the appropriate classification panel for a classification recommendation.

A panel to which a petition for reclassification is referred is required to make a recommendation to the Secretary respecting approval or denial of a petition within 90 days after its referral. Interested persons are to be afforded opportunity to submit data and views on the petition.

A panel recommendation must contain a summary of reasons for the recommendation, a summary of the data on which the recommendation is based, an identification of the risks to health (if any) presented by the "new" device and, to the extent practicable, a recommendation for the assignment of a priority for the application of performance standards or premarket approval requirements to a device recommended to be classified in class II or class III. The recommendation of a classification panel for the classification of a device in class I is to include a recommendation as to whether the device should be exempted from the requirements relating to registration, records and reports, or good manufacturing practices.

Following receipt of a panel's recommendation with respect to a "new" device, the Secretary is required to by order approve or deny the petition within 90 days from the date he receives the panel's recommendation. An order classifying a device into class I shall prescribe which, if any, of the requirements with respect to registration, records and reports, and good manufacturing practices shall not apply to the device. Any order which makes any such requirement inapplicable to a class I device must be accompanied by a statement of the reasons of the Secretary for making such a requirement inapplicable.

Special Requirements for Devices Which are Intended to be Implanted or are Life Supporting or Life Sustaining

Under the conference substitute, a classification panel is to recommend that any "old" device which is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life be classified into class III unless the panel determines that classification in class III is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If a panel does not recommend that such device be classified into class III, its recommendation is to set forth the reasons for not so recommending. A proposed regulation classifying such device into class I or class II is to be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for not classifying the device into class III, and an identification of the risks to health (if any) presented by the device.

In the case of a petition for reclassification of a "new" device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, a classification panel is to recommend that the petition be denied unless the panel determines that classification in class III is not necessary to provide reasonable assurance of the device's safety and effectiveness and sets forth its reasons for not so recommending. If the Secretary approves such a petition and orders the classification of such a device into class I or class II, any such order shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for approving the petition and an identification of the risks to health (if any) presented by the device to which such order applies.

Intent of the Conferees

The conferees expressed their intention with respect to three aspects of the conference substitute as it relates to the classification of devices. First, the conferees intend that only in highly unusual circumstances

should the membership of classification panels include employees of the Federal Government. Second, as a general rule, and consistent with the need to protect human health, devices which do not remain in the human body for a period of 30 days or more should not be considered to be devices intended to be implanted in the human body. Third, although the conferees recognize that many considerations must be taken into account in determining whether a device is purported or represented to be for a use in supporting or sustaining human life, the conferees expect the panels and the Secretary to consider devices which are essential to the restoration or continuation of a bodily function important to life to be life supporting or life sustaining.

Restrictions on Content of Performance Standards

The House amendment included a requirement, not contained in the Senate bill, that specified that performance standards could not include provisions not required or authorized under the House amendment.

The conference substitute does not contain this provision.

Requirements With Respect to Submission of Information by Offerors To Develop Performance Standards and Disclosure of Such Information

The House amendment required the Secretary to promulgate regulations requiring that an offeror of an offer to develop a performance standard submit to the Secretary relevant information with respect to the offeror's qualifications, including information respecting the offeror's financial stability, expertise, and any potential conflicts of interest, including financial interest in the device for which the proposed standard was to be developed. Further, the House amendment required that such information could not be made public by the Secretary unless required by section 552 of title 5, United States Code.

The Senate bill required the Secretary to promulgate regulations requiring that an offeror and appropriate directors, consultants and employees of the offeror disclose (1) all current industrial or commercial affiliations (2) sources of research support (3) companies in which they have financial interests and (4) such additional information as would be pertinent to reveal potential conflicts of interests. Further, the Senate bill required that such information with respect to the offeror whose offer was accepted was to be made public by the Secretary at the time the offer was accepted.

The conference substitute combines the provisions of the House amendment and the Senate bill with respect to the submission of information by offerors. Further, it requires that information submitted by an offeror not be made public by the Secretary unless required by section 552 of title 5, United States Code, except that the Secretary is required to make public information with respect to an offeror whose offer is accepted at the time the offer is accepted unless it is exempt from disclosure under section 552(b)(4) of title 5, United States Code (relating to trade secrets and privileged or commercial or financial information).

Opportunity To Request Reclassification of a Device After Publication of a Notice of Proposed Rulemaking Requiring Premarket Approval

The House amendment included a provision, for which there was no comparable provision in the Senate bill, which required that a notice of proposed rulemaking requiring premarket approval of a class III device contain an opportunity to request a change in the classification of the device based on new information relevant to such classification.

The conference substitute adopts the House provision, except that it requires that any request for a change in classification must be submitted within 15 days of the publication of the notice and acted upon within 60 days of such publication.

Nonvoting Representatives of Consumer and Industry Interests as Members of Advisory Committee to Review Actions of the Secretary

Both the Senate bill and the House amendment contained provisions authorizing administrative review of decisions of the Secretary with respect to premarket approval or scientific review, and product development protocols. Both authorized review of such decisions by expert advisory committees as an option to review under the provisions of section 554 of title 5, United States Code.

Under the House amendment, each such committee was to include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry.

The Senate bill contained no comparable provision.

Under the conference agreement, the membership of such advisory committees is not required to include such representatives.

Requirements for Notification of Patients of Risks or Hazards Presented by Devices

Both the Senate bill and the House amendment included provisions requiring notification to persons of risks or hazards presented by devices.

Under the House amendment, if the Secretary determined that (1) a device intended for human use which was introduced into interstate commerce presented an unreasonable risk of substantial harm to the public health, and (2) notification was necessary to eliminate the risk and no more practicable means was available under the Act to eliminate the risk, he was authorized to issue an order requiring adequate notification to all persons who should receive notification in order to eliminate the risk.

Notification was to be provided only after the Secretary consulted with the persons who were to give notice. All health professionals who prescribed or used the device presenting the risk were required to be notified, and all persons exposed to the risk were to be notified unless the Secretary determined that notification by the Secretary or by a manufacturer, importer, distributor, or retailer presented a greater danger to the health of such persons than no such notice. In such instances, the Secretary was to require health professionals who pre-

scribed or used the device to notify the persons whom they treated with the device of the risk it presented and of action which could be taken to reduce or eliminate such risk.

Under the Senate bill, if the Secretary determined that (1) a device intended for human use which was distributed in commerce presented a substantial hazard to the public health and safety and (2) notification was required in order to adequately protect the public from the hazard, he was required immediately to make certain that adequate notification was provided to all persons who should receive notification in order to eliminate the effects of the hazard. In instances in which the Secretary determined that device users should not be notified, he was required to provide health professionals who received notification an opportunity to comment on the advisability of notifying the general public of the hazard. Within 30 days after the notification to health professionals, the Secretary was to notify the general public of the hazard if, after reviewing the comments, he determined that notification would not endanger the public health.

The conference substitute conforms to the House amendment, with two exceptions.

First, the provision with respect to notification of device users is modified to require notification of persons *subject* to the risk in lieu of the requirement that persons *exposed* to the risk be so notified. This modification was adopted because of the recognition that exposure to a risk does not necessarily mean that there exists a continuing risk to health after exposure for which notification would serve a useful purpose. A patient could, for example, be treated by a structurally defective device and yet suffer no adverse consequences. Exposure to an X-ray machine with a structurally defective arm which could have collapsed but did not is one such example. Notification of persons exposed to the risk in such instances would be of no value and is not intended by the conferees. If, however, an X-ray machine was found to have emitted excessive radiation, all persons who used or were treated by that machine should be notified under the Secretary's order so that appropriate treatment could be undertaken. It was these considerations which prompted the conferees to narrow the language in the House bill to require device users to be notified by the Secretary should they be subject to a risk to their health.

Secondly, the provision requiring notification by health professionals in instances in which persons exposed to the risk are not to be notified is modified to require that health professionals *provide for* the notification of individuals they treated with the device in lieu of the requirement that such professionals *notify* such individuals. This modification was adopted by the conferees in recognition of the fact that there are instances in which notification would be more appropriately provided by persons other than health professionals, such as close family members.

Exemptions for Custom Devices

Both the Senate bill and the House amendment contained provisions exempting custom devices from otherwise applicable requirements respecting performance standards and scientific review or premarket approval.

The House amendment exempted from otherwise applicable requirements with respect to performance standards and premarket approval

custom devices which, in order to comply with the order of a physician, dentist or other specially qualified person, necessarily deviated from such requirements. This provision was applicable only to devices which were not generally available in finished form for dispensing on prescription or for commercial distribution and which were not generally available to other health professionals. It applied only to devices which were (1) intended for use by a patient named in an order by a physician, dentist, or other specially qualified person or (2) intended to be used solely by a physician, dentist, or other specially qualified person or a person under his professional supervision in the course of his professional practice.

The Senate bill exempted from otherwise applicable performance standards or requirements for scientific review custom devices ordered by a physician or other specially qualified person to be made in a special way for individual patients. Under the Senate bill, any such device was required to comply with all aspects of any performance standard except those specifically ordered to be changed.

The exemption was to apply only to devices ordered for individual patients. The Senate bill also required that custom devices not be used as a course of conduct and not be generally available in finished form for dispensing on prescription and not be made available through commercial channels.

The conference substitute conforms to the House amendment, except that the provisions with respect to the individuals (patients or health professionals) for whom the device is intended for use are clarified. Thus, the exemption is made applicable only to devices which are (1) intended for use by *an individual* patient named in an order by *an individual* physician, dentist or other specially qualified person and *to be made in a specific form for such patient* or (2) *intended to meet the special needs of* such physician, dentist, or other specially qualified person in the course of his professional practice.

Restriction on the Use of Devices

Both the Senate bill and the House amendment contained provisions authorizing the Secretary to limit the sale or distribution of devices.

The House amendment authorized the Secretary to require that the sale or distribution of a device be restricted if he determined that, because of its potentiality for harmful effect or the collateral measures necessary to its use, there could not otherwise be reasonable assurance of its safety and effectiveness. Under the House amendment, such a device could have been restricted to the extent that it could be sold or distributed only upon the oral or written authorization of a practitioner licensed by law to administer or use the device, or upon such other conditions as the Secretary might prescribe, except that no condition limiting the use of a device to categories of physicians defined by their training or experience could have been imposed.

The Senate bill authorized the Secretary to require that the sale or distribution of a device be restricted if (1) because of its potentiality for harmful effect or the collateral measures necessary to its use, the device was not safe for use except under the supervision of a practitioner licensed by law to administer or use the device or (2) the conditions of an approved application for scientific review limited

the device to use under the professional supervision of such practitioners. Under the Senate bill, such a device could have been restricted to the extent that it could be sold or distributed only upon the oral or written authorization of a practitioner licensed by law to administer or use the device, or upon such other conditions as the Secretary might prescribe.

The conference substitute conforms to the House amendment except that (1) it authorizes the Secretary to restrict the use of a device, as well as its sale or distribution, (2) it requires that no condition may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device and (3) it requires that no condition limiting the use of a device to such persons may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a board.

Special Treatment of "Devices" Regulated as "Drugs"

The House amendment contained transitional provisions designed to place articles which would be devices under the amendment's new definition of "device" but which are presently being regulated as new drugs into comparable regulatory status as devices. Under these provisions, all such products would be classified into class III and accorded treatment consistent with their status as drugs. Thus, for example, on the date of enactment, a product which was a device under the new definition, but which was the subject of an approved new drug application, would be regulated as a device with an approved application for premarket approval. In instances in which a new drug application had been filed but for which no order approving the application had been issued, the new drug application would be considered as an application for premarket approval, and the Secretary would be required to act on the application within the period in which he would have been required to act on the new drug application.

Under the House amendment, an article which would constitute a device under the new definition but which had in effect an exemption for investigational use as a drug prior to the date of enactment would retain its status as an investigational drug until 90 days after the promulgation of regulations implementing the amendment's new provisions with respect to exemptions for devices for investigational use. This provision was designed to afford the sponsor opportunity to submit and have approved an exemption for investigational use as a device.

Further, the House amendment provided that devices substantially equivalent to those described above, as well as those declared by the Secretary to be new drugs and those which were the subject of legal action because of the determination that they are new drugs, would be, under the transitional provisions, required to have approved applications for premarket approval on the date of enactment of the House amendment, with provision for the filing of a petition for reclassification or application for premarket approval. Such petition or application would be required to be acted upon within 60 days after the enactment date, and the filing of such a petition or application would operate to stay the requirement for premarket approval for a period of 120 days, or until the date of denial of the petition or application, whichever occurred first.

Finally, the transitional provisions of the House amendment provided that any device which had been regulated as an antibiotic drug prior to the date of enactment would remain regulated as an antibiotic drug until it had been classified as a class I device, or, if classified as a class II or III device, until the requirements of the proposed legislation for such devices were met.

The Senate bill contained no comparable provisions.

The conference substitute conforms to the House amendment, except that the provisions with respect to a device that has been declared by the Secretary to be a new drug and is therefore required to have an approved application for premarket approval in effect on the date of enactment are modified. Under the conference substitute, two provisions apply to a device which has been declared to be a new drug after March 31, 1976. First, the requirement to have in effect an application for premarket approval is not made applicable until 18 months after the date of enactment of the conference substitute unless the device is exempt from such requirements by virtue of having in effect an exemption for investigational use under new section 520(g) of the Act. Secondly, the conference substitute authorizes the Secretary, during the period beginning 180 days after the date of enactment and ending 18 months after such date, to restrict the use of the device to investigational use in accordance with requirements applicable under new section 520(g). The conference substitute requires that, if the Secretary restricts such a device to investigational use, the requirements made applicable under section 520(g) be made applicable in such a manner that the device is made reasonably available to physicians meeting appropriate qualifications prescribed by the Secretary.

This new provision applies solely to the intraocular lens, which, on April 6, 1976, the Commissioner of Food and Drugs declared to be a new drug under section 505 of the Federal Food, Drug and Cosmetic Act.

In the event that no petition for reclassification or application for premarket approval is submitted with respect to the intraocular lens or if such petition or application is denied, the conferees direct the Secretary's attention to the statutory admonition that any requirements for exemption for investigational use provide that such a device shall be made reasonably available to physicians meeting appropriate qualifications.

The conferees intend that, if the Secretary chooses to require the investigational use of the intraocular lens, he establish experience and training requirements such that all qualified ophthalmologists who meet such requirements and agree to adhere to the protocol for the investigation would be eligible to participate in the investigation. In establishing these requirements, the Secretary is expected to consult with appropriate organizations representing ophthalmologists and manufacturers of intraocular lenses as well as qualified scientific experts who do not have an interest in the device.

In the event that the Secretary exercises his authority to place the intraocular lens in investigational status, it is anticipated that there will be a reasonable notification period during which efforts will be

made to apprise manufacturers and physicians of the new requirements before the effective date of the investigational exemption.

Special Requirements With Respect to Exemptions for Investigational Use

Both the Senate bill and the House amendment contained provisions authorizing exemptions for devices for investigational use. Under both provisions, persons applying for such exemptions were required to assure that informed consent be obtained from human subjects of such investigations.

The Senate bill contained provisions, for which there were no comparable provisions in the House amendment, which set forth requirements respecting informed consent. These provisions defined informed consent as the consent of a person, or his legal representative, so situated as to be able to exercise free power without the intervention of force, fraud, deceit, duress, or other forms of constraint or coercion. Informed consent was to be evidenced by a written agreement signed by such person or representative, which included (1) an explanation of procedures to be followed, including an identification of any which are experimental, (2) a description of discomforts and risks, (3) an explanation of likely results should the procedure fail, (4) a description of any benefits to be expected. (5) a disclosure of appropriate alternative procedures, (6) an offer to answer inquiries and (7) an instruction that the subject is free to decline entrance into a project or discontinue participation. The agreement was to include no exculpatory language through which the subject is made to waive any legal rights or release an institution or its agents from liability for negligence.

The Senate bill required any organization which initiated, directed, or engaged in programs which require informed consent to keep a record of such consent and the information provided the subject and develop appropriate documentation and reporting procedures as an essential administrative function.

The conference substitute does not include these provisions. The specific provisions of the Senate bill were not adopted by the conferees because of their recognition that the concept of the adequacy of informed consent presently is the subject of study by the National Commission on the Protection of Human Subjects of Biomedical and Behavioral Research in view of changing social policy and advancing biomedical technology. However, the conferees emphasize that the fact that the detailed requirements with respect to informed consent of human subjects which were contained in the Senate bill are not included in the conference substitute is not to be construed as indicating that the conferees do not intend that these requirements be applicable to investigations of medical devices. The conferees would expect that the Secretary would use the requirements of the Senate bill as the basis for regulations implementing the conference report's provisions with respect to informed consent until such time as the Secretary has taken action in response to the recommendations of the Commission on the Protection of Human Subjects of Biomedical and Behavioral Research. In addition, the conferees expect the regulations to include requirements that patients be informed of the scope of the investigation, including the approximate number of patients involved in the investigation.

Provisions Respecting the Export of Devices and Drugs

Under existing law (section 801(d) of the Act) a food, drug, device, or cosmetic that does not conform to provisions of the Act may be exported if four requirements are met: it accords to the specifications of the foreign purchaser, it is not in conflict with the laws of the foreign country to which it is intended for export, it is labeled as intended for export, and it is not sold or offered for sale in domestic commerce. Further existing law prohibits the export of a new animal drug or animal feed medicated with a new animal drug that is unsafe within the meaning of section 512 of the Act. Existing provisions of the Act authorizing the export of drugs do not apply to unapproved "new drugs." The provisions of existing section 801(d) are, however, applicable to antibiotic drugs.

Provisions of the House amendment would have changed existing law to authorize the export of unapproved new drugs and of devices not in compliance with applicable provisions of new section 514 (relating to performance standards), new section 515 (relating to premarket approval), or which were banned under new section 516 to countries with appropriate health agencies that had reviewed and approved the articles as safe for their intended uses. This authorization was conditioned upon compliance with the requirements of existing law, described above. In addition, the exporters of such unapproved articles would have been required to submit annually a notice to the Secretary which identified such articles intended for export during the prospective 12-month period beginning 30 days after the date of notice, identified the countries to which such articles were to be exported and demonstrated that the articles had been reviewed and approved for use by the appropriate health agencies of the foreign countries to which they were intended for export.

The House amendment also authorized the export of unapproved new drugs and unapproved devices to countries without appropriate health agencies. However, approval was to be contingent upon application to the Secretary, opportunity for informal hearing, and a determination by the Secretary that the export of the article to such country was not contrary to public health and safety.

Further, the House amendment authorized the export of an unapproved new animal drug or animal feed containing a new animal drug, if, after submission of an application, the Secretary determined, after notice and opportunity for informal hearing, that (1) such drug or feed met the four requirements of existing law described above, (2) the export of the drug or feed was not contrary to the health and safety of persons within the United States, and (3) the appropriate health agency of the country to which the drug or feed was to be exported had authorized or approved it for its intended use, or, if there was no such agency, its export was not contrary to public health and safety.

Further, the House amendment authorized the Secretary, after providing notice and opportunity for an informal hearing, to issue an order prohibiting the export of any device which did not comply with requirements of new sections 514 or 515, or which was banned under new section 516; any antibiotic drug for which a regulation or release was not in effect under existing section 507; any new drug not in compliance with existing section 505; or any new animal drug or new animal feed bearing or containing a new animal drug, which had not

complied with the requirements of existing section 512, if he determined that the export of such device, drug, or animal feed was inconsistent with the health and safety of persons within the United States.

The Senate bill contained no provisions authorizing the export of unapproved new drugs and unapproved new animal drugs. It authorized the export of devices which did not comply with the requirements of new section 513 (relating to performance standards) or new section 514 (relating to scientific review) if the Secretary determined that such exportation was in the interest of public health and safety and had the approval of the country to which it is intended for export.

The conference substitute conforms to the intent of the Senate-passed bill. It retains the provisions of existing section 801(d) of the Act relating to the export of food, drugs, devices, cosmetics and new animal drugs (with nonsubstantive drafting changes), and authorizes the export of devices which do not comply with applicable requirements relating to performance standards or premarket approval, or are exempt from such requirements because they are in investigational use, or are banned only if (1) they meet the requirements of existing section 801(d) of the Act, (2) the Secretary has determined that the exportation of such devices is not contrary to public health and safety, and (3) the Secretary has determined that such devices have the approval of the countries to which they are intended for export.

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