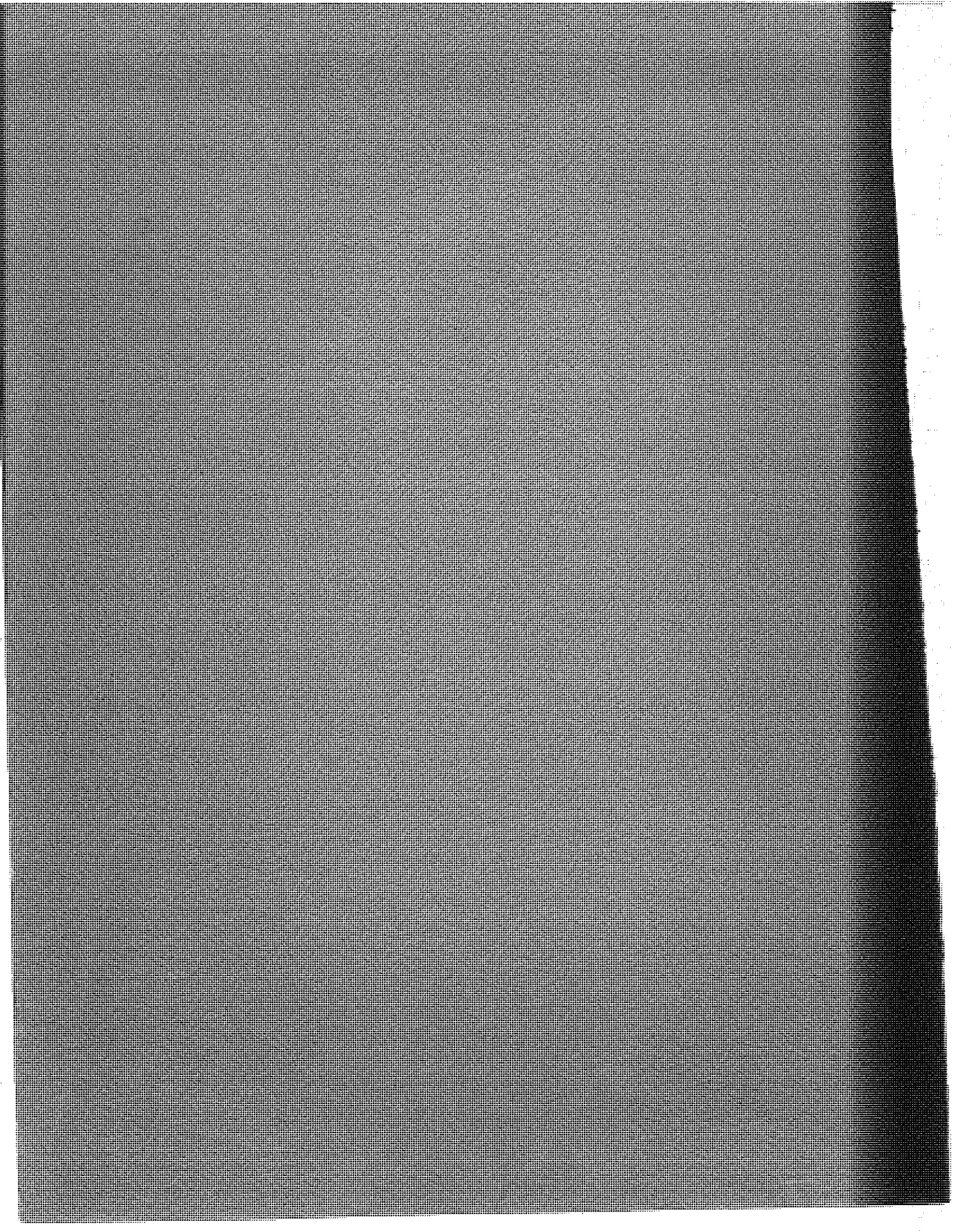
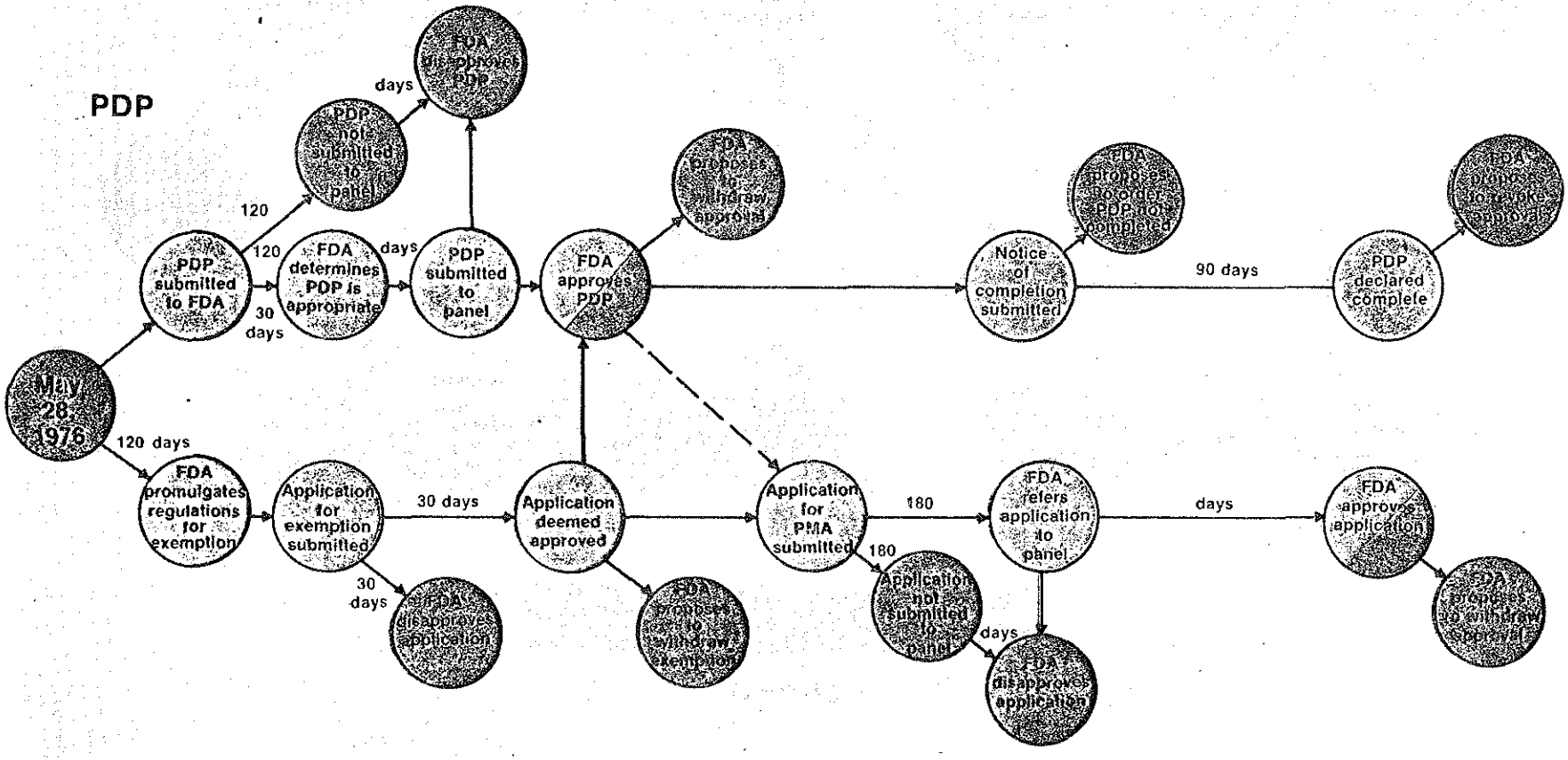


CHART II


PDP
May 28, 1976
PDP submitted to FDA
120
120
30 days
PDP not submitted to panel
days
FDA disapproves PDP
FDA determines PDP is appropriate
days
PDP submitted to panel
FDA approves PDP
FDA proposes to withdraw approval
Notice of completion submitted
FDA proposes to order PDP not completed
90 days
PDP declared complete
FDA proposes to revoke approval
120 days
FDA promulgates regulations for exemption
Application for exemption submitted
30 days
30 days
FDA disapproves application
Application deemed approved
FDA proposes to withdraw exemption
Application for PMA submitted
180
180
Application not submitted to panel
days
FDA disapproves application
FDA refers application to panel
days
FDA approves application
FDA proposes to withdraw approval
PMA

facilitate the completion of the second step of registration relating to the listing of devices.

d. Section C. The purpose of this section is to identify the individual designated as Official Correspondent.

(19) Official Correspondent. Enter name of designated official.

(20) Phone. Enter area code and telephone number of Official Correspondent.

(21) Business Name. Enter name of establishment, Owner/Operator, or other place of business, as applicable, with which Official Correspondent is associated.

(22) Number and Street. Enter number and street of Official Correspondent's place of business. Limit entry to 40 characters.

(23) City. Enter city name in which Official Correspondent's business is located. Limit entry to 20 characters.

(24) State. Enter two character state code of the U.S. Postal Service for the state, territory or possession.

(25) Zip Code. Enter U.S. Postal zip code.

(26) Foreign Country. Enter name or abbreviation of foreign country. Limit entry to 14 characters.

e. Section D. The purpose of this Section is to record other names for this establishment that are used on product labels that are different from the name under which the establishment is registering. The term does not include the names of distributors for which this establishment makes products. Do not list registered trade marks in use by the firm.

(27) Name. Enter each trading name. Limit entry to 40 characters. Use an attached sheet if the number of names exceeds six (6).

f. Section E. The signature (28) and title (29) of the designated Official Correspondent must appear in this section.

APPENDIX K

BUREAU OF MEDICAL DEVICES AND DIAGNOSTIC PRODUCTS

PROCEDURE FOR COMPLETING THE INITIAL REGISTRATION OF DEVICE ESTABLISHMENTS FORM

1. GENERAL INSTRUCTIONS

a. *Who Must Register.* Every person who owns or operates any domestic establishment engaged in or responsible for the manufacture, preparation, propagation, compounding, or processing of a finished device (including diagnostic product manufacturers) must register his principal place of business and all such establishments. The registration requirements pertain to any person who:

(1) initiates or develops specifications for a device which is to be manufactured for him for subsequent commercial distribution;

(2) manufacturers for commercial distribution a finished device either for himself or for another person;

(3) repackages or relabels a device; or

(4) initially distributes devices imported into the United States.

Foreign establishments are permitted and encouraged to register although this is not required.

b. *Who Is Not Required To Register.* The registration requirements *do not* pertain to any:

(1) manufacturer of raw materials or compenents, which are to be used in the manufacturing of a finished device;

(2) manufacturer, processor, etc. of a device to be used solely for a veterinary purpose;

(3) licensed practitioner who manufactures or otherwise alters devices solely for use in his practice. This includes physicians, dentists, clinical laboratories, optometrists, and similar practitioners;

(4) pharmacy dispensing or selling devices in the regular course of business at the retail level. (This exemption also applies to those situations where a generally available device with standard instructions for use and recognized claims is purchased by a pharmacy for subsequent distribution under its name. For example, a properly labeled health aid such as an elastic bandage, crutch, etc., indicating "distributed by" or "manufactured for" followed by the name of the pharmacy.);

(5) researcher, teacher, or analyst manufacturing or otherwise altering a device for research, teaching, or analysis and not introducing such device into commercial distribution;

(6) person who makes no revisions to the finished domestic device or its immediate container. For example, wholesaler, common carrier, etc.; or,

(7) person who facilitates the transmission of an otherwise finished device to the ultimate consumer and whose major responsibility is to provide a service necessary to provide the consumer with his device. For example, a hearing aid dealer, optician, hospital, clinic, dental laboratory, orthotic or prosthetic retail facility, etc. whose primary function is to process or modify a previously manufactured device in order to comply with the needs of the individual and ultimate consumer within the institution.

c. *Definitions*

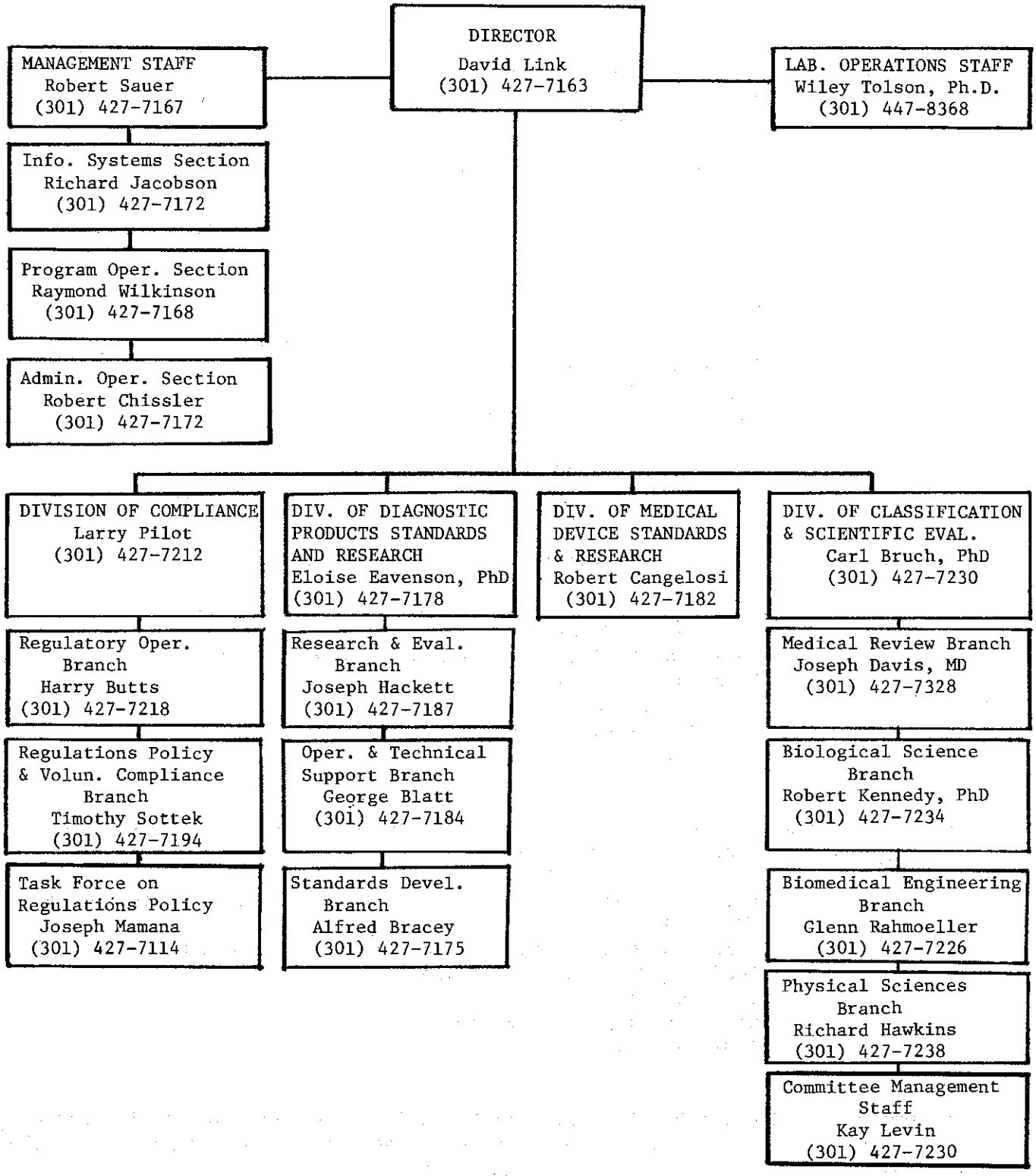
(1) Establishment - A place of business under one management at one general location at which a finished device is manufactured, assembled or otherwise processed. This includes the site performing a packaging, labeling, or repackaging activity.

(2) Finished Device - A device or accessory to a device which is ready to be used for its intended purpose whether or not packaged or labeled for commercial distribution. Examples of individual finished devices include: a hemodialysis unit; disposable hemodialysis tubing, blood filter, syringe, needle, diagnostic reagent, etc.

(3) Initial Distributor of Imported Devices - The person who is responsible for the initial distribution of a device in the United States. This includes United States subsidiaries of foreign companies but excludes carriers.

(4) Official Correspondent - The person designated by the Owner/Operator as responsible for the annual registration of the establishment; initial contact for subsequent device listing; maintenance, and availability of a current list of officers and directors; and who may be sent pertinent correspondence from FDA directed to and involving the Owner/Operator and/or any of its establishments.

ORGANIZATION CHART OF THE BUREAU OF MEDICAL DEVICES AND DIAGNOSTIC PRODUCTS



TITLE and NAME	TELEPHONE NO.	MAILING SYMBOL
Director, Bureau of Medical Devices and Diagnostic Products David M. Link (Acting)***	301-427-7163	HFK-1
Director, National Center for Toxicological Research Morris F. Cranmer	301-443-3155	HFT-1

The above listed people are located at: 5600 Fishers Lane
Rockville, MD 20852

with the exception of those marked with asterisks which are located as follows:

*200 C St., S.W.
Washington, D.C. 20204

**8200 Rockville Pike
Bethesda, MD 20014

***8757 Georgia Ave.
Silver Spring, MD 20910

Northern California, Nevada, Hawaii
Food and Drug Administration
50 Fulton St., Room 518
San Francisco, CA 94102
Phone: 415/556-0318

Puerto Rico
Food and Drug Administration
P.O. Box 4427, San Juan Station
San Juan, Puerto Rico 00905

Washington, Oregon, Idaho, Alaska
Food and Drug Administration
909 1st Ave., Room 5003
Seattle, WA 98104
Phone: 206/442-5304

TODAY's FDA

FDA performs hundreds of activities to help the public and to protect consumers. Some of these activities are:

- o FDA inspects plants where foods, cosmetics, or other products are made or stored to make sure good manufacturing practices are being observed.

- o FDA develops regulations for proper labeling. For example, FDA developed new regulations requiring nutrition labeling and cosmetic ingredient labeling on many foods and cosmetics.

- o FDA works with the industries it regulates to help them develop better quality control procedures.

As with the rest of the Department of Health, Education, and Welfare, FDA is "people helping people." FDA people are scientists, engineers, physicians, chemists, nutritionists, and microbiologists. They are consumer safety officers who inspect manufacturing plants and investigate consumer complaints. They are lawyers and compliance officers who interpret and enforce laws. They are consumer affairs officers, trained to work with consumers and consumer groups.

FDA District Offices and the State or States under its jurisdiction are listed below. You may call or write for assistance to the District Office serving your geographical location. In addition, many cities have Resident Inspection Posts. Check your phone book to find any which may be in your city under the Department of Health, Education, and Welfare, Food and Drug Administration.

FDA DISTRICT OFFICE AND GEOGRAPHICAL AREA COVERED BY EACH

North Carolina, South Carolina, Georgia,
Alabama, Mississippi
Food and Drug Administration
880 W. Peachtree St., N.W.
Atlanta, GA 30309
Phone: 404/526-3151

Maryland, West Virginia, Virginia,
District of Columbia
Food and Drug Administration
900 Madison Avenue
Baltimore, MD 21201
Phone: 301/962-4012

If the Commissioner believes the petition has reasonable merit, notice of its filing and availability is published in the FEDERAL REGISTER with a request for public comment. The Agency may also publish the petition and its own version of such a proposal, also for public comment, in which case the response to both proposals would be weighed in preparing a final regulation.

FDA ADVISORY COMMITTEES

FDA broadens its own expertise in areas it regulates by calling on experts outside the Agency to serve as advisers in their field of knowledge. Today these volunteers compose more than 66 groups. Their job is to discuss problems of concern singled out by the Commissioner and to offer what they consider the best solutions and alternatives.

Most of the advisory meetings are open to the public. Notification of the advisory meetings is announced in the FEDERAL REGISTER which also contains announcements of vacancies and invitations to nominate new members. A person may nominate himself or someone else, but all vital information on pertinent professional and academic accomplishment must be supplied to indicate qualification for membership. Qualifications sought by FDA vary depending on the type of committee, the individual seat, and the current areas of concern.

"CLEAN HANDS"

Consists of 35 color slides and 6½ minutes of taped narration (3 3/4 i.p.s.), produced by Industry Guidance Branch, Bureau of Foods, Food and Drug Administration.

Stresses the importance of good hygenic habits. It is intended to encourage employees to produce clean, safe food products. Although this slide presentation is oriented to the food industry, we believe it may be useful in employee training programs of the device and diagnostic industries in preventing microbial contamination of these products.

Available for purchase from the National Audiovisual Center, National Archives and Records Services, Washington, D.C. 20409. Price: $9.25.

VIDEOTAPES

Tapes on specialized subject matter prepared by the Bureau of Medical Devices and Diagnostic Products. Includes four ½ inch, reel to reel, black and white videotapes:

1. "Cardiovascular Implants" presented by Dr. Frederick L. Grover, M.D. (30 minutes)

2. "Product Sterilization and Biological Indicators," presented by Dr. Carl W. Bruch, Director, Division of Classification and Scientific Evaluation, Bureau of Medical Devices and Diagnostic Products. (32 minutes)

3. "Process Calculations and Parameters," presented by Dr. Carl W. Bruch, Director, Division of Classification and Scientific Evaluation, Bureau of Medical Devices and Diagnostic Products. (26 minutes)

4. "Ethylene Oxide Sterilization," presented by Dr. Carl W. Bruch, Director, Division of Classification and Scientific Evaluation, Bureau of Medical Devices and Diagnostic Products. (20 minutes)

WORKSHOPS--CONFERENCES--SEMINARS

FDA conducts national and local continuing programs of workshops, conferences, and seminars with industry and professional groups. These sessions are designed to explain and discuss new regulations, to provide guidelines for meeting requirements of the law and regulations, and to explore solutions to compliance problems. Such meetings often originate with the FDA District Offices, FDA Headquarters, or at the request of interested industry groups. The meetings cover, but are not limited to, such topics as good manufacturing practices, sterility, and medical device standards. For further information on workshops, conferences, or seminars contact any FDA District listed on page 18 or the Regulations Policy and Voluntary Compliance Branch, Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910.

The following proceedings are available for $25.00 each and can be obtained by writing: Sarah Bembower
Scientific Apparatus Makers Association (SAMA)
1140 Connecticut Avenue
Washington, D.C. 20036

Proceedings of the SAMA Workshop on "Corporate Liability, Personal Liability and the Freedom of Information Act" September 1975

Proceedings of the SAMA Workshop on "Materials Control Under a GMP Concept" June 1975

Proceedings of the SAMA Workshop on "Distributor and Marketing Responsibilities Under the IVD Regulations" April 1975

Proceedings of the SAMA Calibrator Product Class Standard Forum and Stability Testing Workshop, March 1975

Proceedings of the SAMA Workshop on "Plant Inspections" September 1974

Proceedings of the SAMA Workshop on "Product Class Standards" May 1974

Proceedings of the SAMA Workshop on "Hazardous and Toxic Materials" March 1974

Proceedings of the SAMA Workshop on "Efficacy-Proof of Claims" February 1974

Proceedings of the SAMA Workshop on "Labels and Labeling" January 1974

Proceedings of the SAMA Workshop on "Good Manufacturing Practices" December 1973

Proceedings of the SAMA Workshop on "Legal Aspects of In Vitro Diagnostics Regulations" November 1973

AN IMPORTANT NOTICE FOR WOMEN WEARING AN IUD

An FDA Consumer Memo concerning risks and recommended action for women wearing an IUD.

NOTICE TO STATE OFFICIALS REGARDING ACUPUNCTURE DEVICE SEIZURES

A statement of current FDA position on acupuncture devices along with information on FDA seizures.

WE WANT YOU TO KNOW ABOUT IMPACT RESISTANT EYEGLASS LENSES

A brochure covering what "impact resistant" means, what types of lenses are covered and what it means to the consumer.

"WINCHESTER: FACILITY WITH VERSATILITY"

An FDA Consumer Reprint (November 1975) explains how FDA's Winchester Engineering and Analytical Center tests medical devices, as well as drugs, foods, and radiological products for safety and efficacy.

"IN ONLY FOUR WEEKS"

An FDA Consumer Reprint (June 1975) about fraudulent weight-reducing devices.

"CONTRACEPTION WITH IUDs"

An FDA Consumer Reprint (February 1975) regarding the safety, efficacy and different types of intrauterine contraceptive devices.

"PACING THE HEART ELECTRICALLY"

An FDA Consumer Reprint (November 1973) concerning the five types of implanted pacemakers, how they work, and problems of which consumers should be aware.

"ACUPUNCTURE: PAST AND PRESENT"

An FDA Consumer Reprint (May 1973) on the ancient art of acupuncture and how it is regulated in this country.

BUREAU OF MEDICAL DEVICES & DIAGNOSTIC PRODUCTS PUBLICATIONS

COOPER COMMITTEE REPORT (MEDICAL DEVICES: A LEGISLATIVE PLAN)

Contains the original 1970 proposal for regulation and classification of medical devices.

REPORT TO THE CONGRESS, PUBLIC HAZARDS FROM UNSATISFACTORY MEDICAL DIAGNOSTIC PRODUCTS

A 67-page report given to Congress by the Comptroller General of the United States in April, 1975.

*NATIONAL HEALTH RELATED ITEMS CODE DIRECTION (NHRIC)

Contains all medical devices, including surgical treatment products and other non-drug items used in diagnosis and patient care. Provides an easily-used reference tool to obtain trade name, package size, and NHRIC numeric identification information for each product listed.
Stock No.: 017-012-00230. Price: $9.40.

A computer magnetic tape of the unformatted data base is available for $97.50 from the National Technical Information Services, Springfield, VA 22151.

MEDICAL DEVICE EXPERIENCE MONITORING NETWORK (MDEMN) - REPORTING FORMS

MDEMN is a centralized data collection system to process experience reports. Forms are available for reporting product experience data which includes: injuries, malfunctioning equipment, inadequate labeling or instructions for use, hazardous design, etc.

*COMPILATION OF SELECTED PUBLIC HEALTH LAWS

Volume 1 -- Health Law including Public Health Service Act.
Stock No.: 5270-01755. Price: $4.00.

Volume 2 -- Food, Drug, and Related Law, Food, Drug, and Cosmetic Act. Tea Importation Act, Federal Import Milk Act, Filled Milk Act.
Stock No.: 5270-01756. Price: $3.00.

§ FDA MANUALS AVAILABLE UNDER FOI

Administration Guidelines Manual	$ Free
Bureau of Foods Staff Manual Guide	10.00
Compliance Policy Guides	Free
Compliance Program Guidance Manual (5 volumes - Over 3,000 pages - 10 cents per page)	
Drug Autoanalysis Manual	Free
EDRO Data Code Manual	15.00
Field Management Directives	15.00
Food Additives Analytical Manual	Free
Hazard Analysis & Critical Control Point - A System for Inspection of Food Processors	131.95
Inspector Operations Manual	25.00
Inspector Training Manual	15.00
Inspector's Manual for State Food and Drug Officials	65.00
Inspector's Technical Guide	Free
Instrument Operations Manual	25.00
Laboratory Operations Manual	17.50
Pesticide Analytical Manual, Volumes 1-3	Free
Quantity of Contents Compendium	25.00
Regulatory Procedures Manuals	85.00
Staff Manual Guides - Organization & Delegations	
Volume I	60.00
Volume II	60.00
Volume III	30.00
Supervisory Inspectors Guide	28.50
Vitamin Analytical Manual	Free
Drug Registration Listing (+shipping)	54.00
Fair Packaging & Labeling Act - Requirements and Interpretations	22.00
Index to all Administrative Staff Manuals Listed	20.00

NOTE: Prices subject to change without notice because manuals are continually being revised. In order to receive revised programs for keeping your manual current, you must write to: Food & Drug Administration, Public Records & Document Center (HFC-18), 5600 Fishers Lane, Rockville, MD 20852.

You may order these manuals by sending a check or money order, made payable to the Food and Drug Administration, to the Accounting Operations Branch (HFA-120), Food & Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

GENERAL FDA PUBLICATIONS

*FEDERAL FOOD, DRUG, AND COSMETIC ACT

Contains the text of the Federal Food, Drug, and Cosmetic Act. It is updated periodically to include all amendments since the last printing. Revised, January 1975.
Stock No.: 017-012-00226-9. Price: $1.20.

* REQUIREMENTS OF THE UNITED STATES FOOD, DRUG, AND COSMETIC ACT

Revised February 1972, this publication is a synopsis of the principle requirements of the Federal Food, Drug, and Cosmetic with emphasis on aspects of special interest to foreign manufacturers and importers. (Formerly Pub. No. 2) 55 pages.
Order by GPO Stock No.: 1712-0138. Price: 85¢.

*FAIR PACKAGING AND LABELING ACT

Contains the text of the Fair Packaging and Labeling Act, to regulate interstate and foreign commerce by preventing the use of unfair or deceptive methods of packaging or labeling of certain consumer commodities distributed in such commerce.

*FREEDOM OF INFORMATION REGULATIONS

Contains all regulations issued under Title 21 of the Code of Federal Regulations for Freedom of Information.

*IMPORTS AND FDA

Describes the laws enforced by FDA and products covered. Features a concise "Import Procedure Flow Chart" showing the steps an import goes through up to its final disposition.

*FEDERAL REGISTER

Publishes all the regulations, proposed regulations and other notices issued by the Food and Drug Administration. It is revised annually.
Price: $50.00 per year or $5.00 per month.

The following is a list of U.S. Government Printing Office Bookstores. A typical bookstore stocks approximately 1,500 different publications and provides access to the 20,000 publications available by mail order from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Each store has a limited supply of FDA publications.

Atlanta Bookstore
Federal Building, Room 100
275 Peachtree St., N.W.
Atlanta, GA 30303
Phone: 404/526-6947

Birmingham Bookstore
2121 Building, Room 102A
2121 Eighth Ave., North
Birmingham, AL 35202
Phone: 205/325-6065

Boston Bookstore
John F. Kennedy Federal Bldg.
Room G25
Sudbury St.
Boston, MA 02203
Phone: 617/223-6071

Canton Bookstore
Federal Building
201 Cleveland Ave., S.W.
Canton, OH 44702
Phone: 216/455-4354

Chicago Bookstore
E.M. Dirksen Bldg., Room 1463
219 South Dearborn St.
Chicago, IL 60604
Phone: 314/353-5133

Cleveland Bookstore
Federal Bldg., First Floor
240 East 9th St.
Cleveland, OH 44114
Phone: 216/522-4922

Dallas Bookstore
Federal Bldg., Room 1046
1100 Commerce St.
Dallas, TX 75202
Phone: 212/749-1541

Denver Bookstore
Federal Bldg., Room 1421
1961 Stout St.
Denver, CO 80202
Phone: 303/837-3965

Department of Commerce Bookstore
14th & E Sts., N.W., Room 1605
Washington, D.C. 20230
Phone: 202/967-3527

Department of State Bookstore
21st & C Sts., N.W.
Washington, D.C. 20520
Phone: 202/632-1437

Detroit Bookstore
Federal Building, Room 229
231 W. Lafayette Blvd.
Detroit, MI 48226
Phone: 313/226-7816

Forrestal Bookstore
Forrestal Building, Room 1-J-001
1000 Independence Ave., S.W.
Washington, D.C. 20407
Phone: 202/426-7937

Government Printing Office Bookstore
710 North Capitol St.
Washington, D.C. 20402
Phone: 202/783-3238

Jacksonville Bookstore
Federal Building, Room 158
400 West Bay St.
Jacksonville, FL 32202
Phone: 313/226-7816

Kansas City Bookstore
Federal Office Building, Room 144
601 East 12th St.
Kansas City, MO 64106
Phone: 816/374-2160

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APPENDIX J

PREPRINT COPY

TOOLS FOR COMPLIANCE

FOR THE

MEDICAL DEVICE AND IN VITRO DIAGNOSTIC PRODUCT

INDUSTRIES

APPENDIX I

[Docket No. 76N-0205]

IMPLEMENTATION OF THE MEDICAL DEVICE AMENDMENTS OF 1976

The Food and Drug Administration (FDA) gives notice that the Medical Device Amendments of 1976 (Pub. L. 94-295) became law on May 28, 1976. This legislation, which amends the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.), provides new authority to assure the safety and effectiveness of medical devices.

Implementation of the Medical Device Amendments of 1976 (the Amendments) is the responsibility of FDA (21 CFR 2.-120(a)(1)) and its Bureau of Medical Devices and Diagnostic Products. References in the act to the "Secretary" should therefore be understood to refer to the Commissioner of Food and Drugs. Persons with questions concerning the Amendments may contact the Regulations and Policy and Voluntary Compliance Branch, Division of Compliance, Bureau of Medical Devices and Diagnostic Products (HFK-120), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, phone 301-427-7190 or 301-427-7194. The Commissioner of Food and Drugs has designated this Branch as the office to render assistance to small manufacturers of medical devices in accordance with section 10 of the Amendments and to respond to inquiries concerning requirements applicable to medical devices that are submitted under section 513(g) of the act.

Most provisions of the Amendments became effective upon enactment, although many such provisions do not become enforceable regulatory requirements until regulations promulgated by FDA become effective. The provisions that are not effective upon enactment are those prescribing transitional periods before FDA can enforce requirements concerning investigational devices (section 501(f)(2)(A) of the act) and premarket approval for devices in commercial distribution before enactment (section 501(f)(2)(B) of the act) and products formerly considered drugs, which are to be regulated as devices because of the new definition of "device" (section 520(1)(2) of the act).

A series of notices and proposed regulations concerning implementation of the Amendments will be published in the FEDERAL REGISTER in future months. These notices and proposed regulations

TITLE and NAME	TELEPHONE NO.	MAILING SYMBOL
Research and Evaluation Group (Diagnostics) Joseph Hackett, Ph.D.	301-427-7187	HFK-200
Standards Development Group (Diagnostics) Alfred Bracey	301-427-7175	HFK-200
Operations and Technical Support Group George Blatt (Diagnostics)	301-427-7184	HFK-200

Other Compliance Personnel

Industry Information Specialist Minna S. Leblang	301-427-7190	HFK-123
Freedom of Information Office Joseph N. Gaydos	301-427-7194	HFK-126
Registration and Device Listing Thomas V. Kelley	301-427-7190	HFK-124
Medical Device Experience Monitoring Chester T. Reynolds	301-427-7194	HFK-125
Recall Management Lee C. Matthews	301-427-7218	HFK-113
Regulatory Guidance Diagnostic Products Leighton W. Hansel	301-427-7208	HFK-115
Regulatory Guidance Medical Devices Bert L. Schrivener	301-427-7208	HFK-116

Classification Panel Executive Secretaries

Anesthesiology Franklyn K. Coombs	301-427-7226	HFK-450
Cardiovascular Glenn Rahmoeller	301-427-7226	HFK-450
Dental Darryl Singleton, D.D.S.	301-427-7238	HFK-460
Ear, Nose & Throat Harry Sauberman	301-427-7226	HFK-450
Gastro-Urology Thomas Anderson, M.D.	301-427-7238	HFK-460

or me-too device unless a finding is made that during that period continued availability of the device is necessary to the public health.

At the close of the permitted time, FDA either approves the application or denies approval on the basis of grounds stated in the statute. The grounds for denying approval of an application are lack of sufficient safety and effectiveness data, lack of proper good manufacturing practices requirements, false or misleading labeling, or lack of evidence of conformance to any applicable performance standard. Review of denial of applications for premarket clearance may be obtained by either an administrative hearing or an advisory committee of experts. Once a device is made subject to an approved application, FDA may only withdraw approval after notice and opportunity for informal hearing. Further, after a withdrawal, a manufacturer may be entitled to either a full administrative hearing or access to an outside committee of experts in an effort to show that the product should be permitted back on the market. Grounds for withdrawal of approval of the application are similar to those on which FDA may refuse approval of an application. Criteria for approving, disapproving, or withdrawal of approval of product development protocols are similar to that involving premarket clearance applications.

I regret the detail included in my remarks but unfortunately that is the nature of the bill.

I will be pleased to attempt to answer any questions you may have.

Terms Used in Presentation of Rodney Munsey*

1) **Enactment Day**
   The date upon which medical device legislation is signed into law by the President.

2) **Old Device**
   A device on the market on the enactment day.

3) **Me-Too Device**
   A device intended to be marketed by a manufacturer for the first time after the enactment day but which is within a type of device which was on the market before such day and is substantially equivalent to that device.

4) **Critical Device**
   A device which is either an implantable device or is a device intended for a use which is life-supporting or life-sustaining.

5) **Noncritical Device**
   Any device that is not a critical device.

---

*Most of these terms do not appear in the legislation but are used during the presentation as a kind of shorthand.

reasons why FDA did not think premarket clearance was necessary.

With regard to noncritical devices, they will be made subject only to general controls if such controls are sufficient to provide a reasonable assurance of the safety and effectiveness of the device. If such controls are not sufficient to provide such assurance, the device will be classified into the class of standards and if that class is not sufficient, the device will be made subject to premarket approval requirements. This is called the "tier" approach, that is, the noncritical device is to be subject only to enough regulation to assure safety and effectiveness of the product. Recommendations shall be accompanied by a summary of the reasons therefor, a summary of the data and identification of risks.

Thus, there are two basic differences between critical and noncritical devices in the supporting data required to classify the device into general controls or standards. First, a great deal more data will be required for critical devices and second, FDA will have to prove a negative for critical devices, that is, that premarket clearance is not necessary rather than that standards or general controls are sufficient.

When one compares the differences between the criteria used for classifying the critical device and those used for classifying the noncritical device (as opposed to comparing the type of supporting data required), it is difficult to find any *legal* difference between them. Critical devices must be subject to premarket clearance requirements unless general controls and standards are sufficient to provide a reasonable assurance of safety and effectiveness. Noncritical devices will be subject to general controls and/or standards and not to premarket clearance if general controls and/or standards are sufficient to provide reasonable assurance of safety and effectiveness. It seems to me the criteria are the same, that is, a device is to be subject only to the level of regulation required to assure safety and effectiveness. As a practical matter, however, it is likely that the difference in emphasis between the two sets of criteria will result in more of the critical devices being placed in the premarket clearance class than would be the case if the "tier" approach were applied to them. Certainly, when FDA and the panels are directed to place critical devices into premarket clearance unless they are willing to bear the burden of proving that premarket clearance is not necessary, they will tend to take the easier approach and leave them in premarket clearance.

Thus, it is more than likely that more devices will be placed in the premarket clearance class than should be. If the recent history of drug regulation is any indication of things to come in the device field, we must conclude that FDA will have insufficient staff and insufficient budget to handle the substantial number of applications that will be forthcoming.

Factors in addition to implementation of the classification criteria for critical devices will contribute to a large number of devices being placed in the premarket clearance class. Thus, for example, as noted earlier, a manufacturer must give FDA notice 90 days in advance of a device it wants to market for the first time after the law is passed. FDA must then decide within 90 days whether that product is a true old or me-too device, or is a new device automatically subject to premarket clearance in advance of marketing. Certainly a natural tendency of FDA in this situation will be to fire off a letter on the 89th day stating that in FDA's view the device is not a true me-too device. As noted earlier, the manufacturer would then have to decide whether it had sufficient faith in its opinion that the product was a me-too product to go ahead and market it and take a chance on FDA bringing enforcement action. Many manufacturers, because of their desire to avoid a legal hassle with FDA, would decide not to take the risk. In such case, he would have to file either a petition to reclassify the device from premarket clearance to standards or general controls or to file a device application to obtain approval to market the product. Since FDA would be permitted approximately the same amount of time to either take action on a reclassification petition or to approve or disapprove a device application, many manufacturers might take the position that the submission of an application was the most expeditious route to take. In many instances, much of the required data would have been obtained during the earlier proceedings.

Another factor which might lead a manufacturer to file the application rather than to request reclassification would be the fact that if the application was approved, he would have sole marketing rights of the device whereas if a petition to reclassify was approved, other manufacturers could also market the reclassified device.

Another subject Mike asked me to cover this afternoon is the transitional provisions of the device bill. These provisions can be divided into two categories: provisions relating to devices which FDA has never considered to be drugs, and devices which FDA has asserted are drugs. As many of you know, because of certain court decisions in 1969, FDA took the position that some products previously considered

The procedure to be used to determine which devices shall be subject to premarket clearance requirements and which to the lesser two regulatory classes varies depending upon when the device is first introduced to the market and how similar a device developed after enactment day is to a device on the market on enactment day. Please refer to the definitions attached.

Devices on the market on enactment day and devices first marketed after enactment day which are of the same type and are substantially equivalent to those on the market on enactment day are subject to one procedure and devices first marketed after enactment day which are not both of the same type and substantially equivalent to devices on the market on enactment day are subject to another. It is important to remember for reasons that I will explain later, that devices first marketed after enactment day which are of the same type and are substantially equivalent to devices on enactment day are treated basically the same as devices on the market on enactment day. For purposes of simplicity, I'll call devices on the market on enactment day "old devices" and devices later marketed which are of the same type and are substantially equivalent to devices on the market on enactment day as "me-too" devices. Devices first marketed after enactment day which are both of the same type and substantially equivalent to devices on the market on enactment day will be called "new devices".

Before discussing the procedure to be used in determining whether old devices and me-too devices will be placed in premarket clearance or in one of the lesser classes, we can quickly dispose of the new device category. Unlike old devices and me-too devices, all new devices will be automatically placed in premarket clearance and cannot be commercially marketed unless either an application is approved or the device is reclassified into standards or general controls.

The procedure for classifying old and me-too devices is basically a three-step process. I will call step 1 "recommended classification", step 2 "preliminary classification", and step 3 "final classification". The words "final classification" are used in a lay not a legal sense.

First, step 1, recommended classification for old and me-too devices. Advisory panels of experts, none of whom can be FDA employees, will make recommendations with substantiation to the Agency as to which devices should fall into which regulatory category. The panels shall be organized according to the various fields of clinical medicine and fundamental sciences in which the devices are used. Included in the membership of the panels will be a non-voting representative of industry and of consumer groups. The recommended classification of devices is to be accompanied by a summary of reasons, supporting data, and identification of any risks involved. The recommended classification is also to be accompanied by a recommendation for the assignment of priorities in applying any recommended standards or premarket clearance requirements. Lastly the recommendation is to be accompanied by suggestions as to which devices should be exempted from one or more of three of the general controls. The general controls from which exemptions may be granted are: records and reports, manufacturer and product registration, and regulations setting forth current good manufacturing practices regulations. So much for step 1, the recommended classification of old and me-too devices.

Step 2, for classification of old and me-too devices, is action by FDA on step 1 recommendations. After considering the recommendations received, FDA will publish in the *Federal Register* both the recommendations and its own suggested action on them. All interested persons will be given opportunity to file official comments on any FDA proposal. After receiving and evaluating any comments received, the Agency will publish a regulation which will constitute the preliminary classification of the old or me-too device. Included in the order of preliminary classification will be a schedule of priorities to be used for the promulgation of standards, for devices in the standards class, and the imposition of premarket clearance requirements for devices in the premarket clearance class. Also included will be decisions on panel recommendations on whether the devices will be exempt from requirements for registration, records and reports, and good manufacturing practices. If after going through step 2, the preliminary classification process, an old or me-too device is made subject to only general controls, the classification process for that device is completed unless a successful appeal is made that the device should be reclassified in either the standards or premarket clearance class. However, even after completion of step 1, recommended classification, and step 2, preliminary classification, the classification process is not necessarily completed for those old and me-too devices classified as either standards or premarket clearance.

A third step is required, that is final classification. That third step takes place just before proceedings are begun to devise a standard or to actually impose a requirement for the submission of a device application to the Food and Drug Administration. A preliminary classification into premarket clearance had

Class III Devices: New products classified in Class III because they are substantially equivalent to existing Class III devices may also be reclassified. Reclassification of the new product (and its pre-enactment counterpart) may be pursued when the FDA promulgates a regulation to require premarket approval under Section 515(b). The FDA will publish in the Federal Register a proposed regulation to require premarket approval for a type of device classified in Class III. The proposed regulation will offer the opportunity to request a change in classification of the device based upon new information. Interested persons are given fifteen days to request the change. The agency has 60 days after publication of the proposed regulation to act on the request. After consulting with the appropriate classification panel, the FDA will either deny the request or, if approved, publish a notice of intent to reclassify. Requests for reclassification which are denied may be appealed to the courts (Section 517(a)(3)).

Export of Devices - Section 801

Under existing law, devices which do not conform to the Federal Food, Drug and Cosmetic Act (i.e., devices which are adulterated or misbranded) may be exported if: (1) they accord to the specifications of the foreign purchaser; (2) they are not in conflict with laws of the country of destination; (3) they are labeled on the shipping package for export; and (4) they are not sold or offered for sale in domestic commerce (Section 801(d)). The former requirements apply to any device intended for export which would otherwise be adulterated or misbranded. However, the new law couples these conditions with additional conditions for export of devices which do not comply with an applicable performance standard or a requirement relating to premarket approval. Under Section 801(d)(2), such noncomplying devices may be exported if the FDA determines that exportation is not contrary to public health and safety and has the approval of the country of destination.

(Investigational Use of New Products)

If a new product is to be clinically tested on humans or their specimens obtained for that purpose, it must secure an exemption for investigational use. The requirement for an exemption applies to all products irrespective of their actual or potential classification. Within 120 days after enactment, the FDA is required, by regulation, to establish the procedures and conditions under which an exemption for investigational use may be granted.

(Restricted Devices)

Another consideration before marketing a new product is the applicability of restricted device provisions under Section 520(e). Restricted devices are similar in concept to prescription drugs, but the authority to restrict is broader. If a new product is substantially equivalent to a product on the market which is a restricted device, the new product must also comply with applicable restrictions. Restrictions may be imposed on sale, distribution or use of any device regardless of its classification. Restrictions for a particular type or class (not regulatory class) of device may be promulgated by regulations of the FDA. Also, new products, even though unlike other restricted devices, may have restrictions imposed at and perhaps after introduction to the market.

Considerations at Introduction of a New Product

(Adulteration and Misbranding)

As discussed in Part I: Summary of Major Provisions, the new law cites a variety of acts or omissions which would render a device as adulterated or misbranded upon introduction or thereafter. Thus, in introducing a new product, Sections 501 on adulteration and 502 on misbranding may be used by manufacturers as a checklist or means to ascertain that full consideration has been given to the requirements of general controls, performance standards or premarket approval, as applicable to the product.

(GMP's/Traceability)

Two provisions in the new law, Section 520(f) on good manufacturing practices and Section 520(j) on traceability, may affect the distribution plans for a new product. Regulations to be developed under authority of these sections may require some degree of traceability for certain products. Such rulemaking could apply to both devices on the market and those introduced after the regulation becomes effective. In the case of a me-too device, a requirement for traceability of its counterpart on the market would apply with equal force to the new market entry. Additionally, "new" devices which have received premarket approval may, as a condition for approval, be required to establish certain traceability for the product. Finally, no requirements for traceability may be required unless they are necessary to assure the protection of the public health (Section 520(j)).

A manufacturer's conclusion as to the appropriate classification of a device by the substantially equivalent test may be reviewed and perhaps disputed by the FDA. Manufacturers who choose to notify the agency of a device introduction under Section 510(k) will, in effect, submit their conclusion to challenge. If the agency disagrees with a finding of substantial equivalency, i.e., the device is a new device subject to premarket approval before introduction, the manufacturer has two options available. One option would be to market the device on the basis of a good faith difference with the agency. Such introductions could, however, be subject to an enforcement action. The other option would be for the manufacturer to petition the agency under Section 513(f)(2) for classification of the device in Classes I or II. The petition route is discussed below under "Classification of New Devices".

(Classification of New Devices)

The classification of a "new device" as a Class III device under Section 513(f) operates as a matter of law without any action of the FDA or a classification panel. In other words, a device intended for introduction after the enactment date which is not substantially equivalent to a pre-enactment device (or a post enactment device classified in Classes I or II) is in Class III and may not be marketed without premarket approval by the FDA unless it is down-classified. If the manufacturer contends the device is not "new" in the statutory sense or is new but Classes I or II would be sufficient for control, he may petition the FDA for classification as a Class I or II device under Section 513(f)(2). Such petitions are referred to the appropriate classification panel for their recommendations on approval or denial. An informal hearing is available to the petitioner. Approved petitions will order the device classified in Class I or II as indicated. Where a petition under Section 513(f)(2) is denied, the manufacturer or importer may not market the product until premarket approval has been obtained. The petition must be acted upon within 210 days after filing. The denial of a petition may be appealed to the courts.

New devices which are intended to be implanted in the human body or purported or represented for a use in supporting or sustaining human life are deemed by the statute to be in Class III. Thus, there is no difference in the initial classification of these products under Section 513(f) from other new devices. However, if the manufacturer or importer chooses to file a petition for classification in Classes I or II under Section 513(f)(2), the classification panels and the FDA are required to view the petition differently than a petition for any other type of new device. For new devices generally, the panel may recommend, and the FDA may order, approval or denial of the petition on the available evidence of safety and effectiveness. In contrast, panels asked to review a petition for an implant or life sustaining/life supporting device must recommend that the petition be denied unless they determine that Class III is not necessary to provide a reasonable assurance of safety and effectiveness (Section 513(f)(2)(B)). Similarly, the FDA will consider the recommendation but must deny the petition unless Class III is not necessary to provide the reasonable assurance (Section 513(f)(2)(C)). If the FDA decides to approve the petition (ordering classification in Classes I or II), the order must be accompanied by a full statement of the reasons with supporting documentation and data for the approval.

With respect to when Section 510(k) becomes effective, some FDA officials have indicated that it is effective on the date of enactment. Other persons have argued that the provision cannot be made effective until either regulations requiring the advance notice are promulgated or until manufacturers have filed their first establishment registration form.

The issue of which device introductions require advance notice is also subject to several interpretations. Under a broad interpretation, a manufacturer would provide 90-day advance notice when introducing a product not previously marketed by that company whether or not it is or may be substantially equivalent to a product marketed by another manufacturer. Following a narrow interpretation of Section 510(k), a 90-day notice would only be required for new devices, i.e., those which are not substantially equivalent to devices on the market before enactment of the law. Accordingly, a manufacturer would not be required to notify the agency when introducing essentially copies of other devices already on the market ("me-too devices") or when introducing devices with improvements or refinements which are not fundamental changes with reference to safety or effectiveness.

Indications are that the FDA intends to follow a broad interpretation of Section 510(k). Even so, each manufacturer may elect whether to provide notice on a product-by-product basis. In the absence of notice to FDA, the introduction of a product could be challenged by the agency. Experience with such FDA compliance actions will ultimately determine the practical and legal scope of Section 510(k).

Where the FDA is notified of the introduction of a device, Section 510(k) requires certain classification and compliance measures to be reported. Specifically required from the manufacturer are: (1) a determination of the device's classification or the absence thereof with an explanation for either determination, and (2) actions taken by the manufacturer to comply with a performance standard or premarket approval if applicable to the device. It should be noted that the FDA is under no statutory obligation to acknowledge receipt of, or respond to, this notice.

(Classification Procedure)

The classification of any new product is the single most important action which will determine the extent of controls applicable to the device. Manufacturers and others have the right and opportunity to participate in the classification of any product. Reclassification actions or appeals from a final classification order are available. However, these procedures may have limited general utility because they are after the fact. Business opportunities suggest that the manufacturer plan for and pay close attention to the initial classification of a new product.

For the majority of new products, a straightforward decision can be drawn on whether the product is a device. The FDA may have the option to review the manufacturer's decision according to a notification procedure on device introduction described later in these guidelines.

New Products Distinguished

Conventional business terminology such as new competitive products, innovative new products and improved new products is not generally recognized under the Amendments. Instead, the law differentiates between old, me-too and new products according to:

-- when the device was or will be introduced.

-- degree of similarity or dissimilarity to other products.

To aid the discussions of, and differences among device introductions under the new law, these guidelines focus on the categories of me-too devices and new devices (including new implants and new life sustaining/life supporting devices). Requirements of the law applicable to old devices are discussed in Part I: Summary of Major Provisions.

I. Me-too Devices

According to established practice in the medical device industry, manufacturers will continue to develop products in competition with existing products. If such products are "substantially equivalent", (me-too devices) in a statutory sense, to products on the market before enactment, they are afforded certain preferred treatment under the Amendments.

The Amendments do not define the term "substantially equivalent". Interpretative regulations of the FDA may eventually define the term, but the agency is under no statutory obligation to issue such regulations. Legislative history (House Report No. 94-853, dated February 29, 1976) offers some guidance. In general, the Report advises that substantially equivalent should not be regarded as meaning identical. However, the term would not automatically encompass a new product merely because it is intended to be used for the same general purposes as marketed products. The Report indicates a narrow interpretation of substantially equivalent is appropriate where necessary to assure safety and effectiveness. Differences in materials, design or energy source are given as examples of characteristics which may rule out a device as substantially equivalent if safety and effectiveness information on the differences is inadequate. On the other hand, devices which are essentially copies of existing products or with variations not substantially affecting safety and effectiveness are likely prospects for being substantially equivalent.

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10. Notification of device introduction: New Section 510(k) of the Amendments requires manufacturers or importers to notify the FDA at least 90 days prior to the introducion of a device. This provision is the subject of several interpretations on when it becomes effective and to which device introductions it will apply. For a discussion of these interpretations, see Part I: Summary of Major Provisions.

Conclusion

Perhaps the single most important result of enactment is that it fixes a date which governs the treatment of all devices.

Immediately upon enactment, all medical devices already introduced or delivered for introduction into interstate commerce for commercial distribution are pre-enactment or "old" devices. These "old" devices will remain on the market, subject to the immediate impact of the sections discussed above, and await final assignment into Class I (general controls), Class II (standards), or Class III (premarket approval) in accordance with a final regulation promulgated by the FDA. All devices no matter what their class, will be subject to general controls except those inconsistent with standards or premarket approval. If a product is assigned to Class I, general controls are the only controls to which that product is subject.

If classified in Class II (standards), the general controls will be the manufacturer's principal concern. This is the case because a performance standard will have to be drafted and issued in final form by FDA before it becomes applicable to a product. And, even after the standard is established, it would still usually not become effective before one year after the date of its issuance by FDA. Thus, a great deal of lead time will occur before Class II products are subject to standards.

If classified in Class III (premarket approval), the product's manufacturer must first concern himself with the general controls becoming fully effective as the implementing regulations unfold. In the meantime, the manufacturer will have at least 30 months after the classification of his device in Class III to secure premarket approval from the FDA.

B. Provisions which will become effective after enactment.

1. Records and reports: Section 519 enables the FDA to promulgate regulations enumerating what records must be maintained or reports made to the agency by medical device manufacturers, importers, or distributors in order to document safety and efficacy of devices. This authority is in addition to recordkeeping requirements to be imposed by GMP regulations.

2. Good manufacturing practices (GMP): Section 520(f) authorizes device GMP's. It should be noted that FDA, in anticipation of passage of the legislation, has been working on the preparation of a medical device GMP regulation since December, 1973. The most recent available draft was released in August, 1975. The agency expects to publish in the Federal Register proposed GMP's sometime during the summer or fall of 1976.

3. Restricted devices: The FDA must prepare and issue regulations to specify those products which are restricted as to the manner of sale, distribution, or use in accordance with Section 520(e).

4. Exemption of devices for investigational use: Section 520(g) must await the promulgation of implementing regulations, which are required to be issued within 120 days of enactment.

5. Release of safety and effectiveness data by FDA: Section 520(h) must await implementing regulations.

6. Inspections relating to devices: The new law amends Section 704 (factory inspection) of the Act. Under existing law, the FDA has been able to enter device manufacturing establishments and inspect equipment, finished and unfinished materials, containers and labeling - but not records. New Section 704(e) removes the limitation on record inspection and requires manufacturers to provide access to any record required under Section 519 (records and reports) or Section 520(g) (exemption for devices for investigational use).

   Section 704(a), as amended by the new law, also provides additional inspection authority for those establishments where restricted devices are manufactured, processed, packed or held. According to the statute, "inspections shall extend to all things therein (including records, files, papers, processes, controls and facilities) . . ." However, the law does not permit inspection of financial data, sales data other than shipment data, pricing data or personnel data.

Other provisions of Section 520(l) apply to devices which are subject to an investigational use exemption (IND) as a drug, me-too devices and those subject to litigation on the date of enactment. Articles which are devices under the new law and which have an IND in effect, will retain their status as drugs until 90 days after the FDA publishes regulations for investigational use exemptions for devices. Devices which are substantially equivalent (me-too) to those classified under Section 520(l) as well as those declared to be new drugs and those subject to legal challenge because of an FDA determination that they are new drugs are required to have an approved application for premarket approval on the date of enactment. However, the section provides for the filing of a reclassification petition which automatically stays the requirement for FDA approval for a period not to exceed 120 days.

Finally, Section 520(l) provides that any device currently regulated as an antibiotic drug shall remain so regulated (e.g. subject to certification) until it has been classified as a Class I device. If the antibiotic drug (device) is classified in Classes II or III, the item remains under antibiotic requirements until the effective date of a standard or until it is required to have an approved premarket application in effect, as applicable.

7. Device manufacturer registration: The new law amends Section 510 of the Act to provide for annual registration of device manufacturers with the FDA. The provision is immediately effective but will be implemented according to a time schedule established by the agency shortly after enactment.

8. Color additive certification: The new law amends Section 706 to make that section's color additive certification requirements applicable to color additives in or on devices when those additives come in direct contact with the body of man for a significant period of time. The effect of this requirement will be immediate upon enactment as any such additive will be deemed unsafe for the purpose of application of the Act's adulteration section, unless there is in effect a regulation issued by FDA listing the additive as safe for the specified use.

9. Pre-emption of state law by Federal law: Effective upon enactment, no state or municipality may continue to enforce an existing requirement or enforce a new requirement for medical devices concerning safety or effectiveness which is different from or in addition to Federal requirements. Thus, state and local laws which are inconsistent with the Amendments must yield to the Federal Law. (States may apply for an exemption to enforce more stringent requirements than those in the Federal law according to certain conditions set forth in the Amendments.)

3. Authority to ban devices: Under FDA's prior authority, medical devices could be removed from the market by seizure or injunction. Additionally a criminal action against the manufacturer could be (and may still be under the new law) used. In exercising such authority, FDA had to resort to court action and bear the burden of proving the device in question was adulterated or misbranded or otherwise violative of the Act. During litigation of the issue, the manufacturer could continue to sell the product unless the FDA applied for and was granted a temporary restraining order or preliminary injunction. The new authority to ban devices will give FDA additional power to deal with products on the market whether or not they are subject to Class I (general controls), Class II (performance standards) or Class III (premarket approval).

General Rule: New Section 516 authorizes the FDA to ban any device intended for human use if the agency finds that the device in question presents a substantial deception or an unreasonable and substantial risk of illness or injury. The procedure calls for the agency to consult the appropriate device classification panel with all available information; to make a positive determination that labeling changes would not be sufficient to correct or eliminate the problem; to initiate proceedings to promulgate a regulation to make the device a banned device; and to afford the opportunity for an informal hearing on the proposed regulation to ban before actually taking the product in question off the market.

Special Rule: However, if the FDA determines that the deception or risk presents an unreasonable, direct, and substantial danger to the health of individuals, the agency may, after notifying the manufacturer of the device in question, declare the proposed regulation banning the device effective upon its publication, and then hold an informal hearing and take final action on the proposed regulation. During these steps, the products would have to be taken off the market.

4. Authority to require hazard notification: Prior to enactment of the Amendments, FDA could rely only on the nonstatutory enforcement tool of voluntary recall or the issuance of a public warning to inform the public of risks presented by a device.

By virtue of new Section 518(a), the FDA, as of enactment date, is vested with the authority to require that notification of hazards be made to all health professionals who prescribe or use a device and additional persons including manufacturers, importers, distributors, retailers and device users when a device presents an unreasonable risk of substantial harm to the public health. It should be noted that the authority to require notification is intended to supplement and not preclude, other action considered appropriate by FDA, such as the use of voluntary recalls, public warnings, and the banned device authority.

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Other provisions which affect all devices or manufacturers do not require extensive discussion. These are: Section 709 (presumption of jurisdiction in interstate commerce for devices); Section 10 (of the conference bill) regarding small manufacturer assistance; Section 520(i)(requiring transcripts to be kept of advisory committee meetings; Section 520(k)(allowing the agency to engage in research and development with respect to devices); and certain aspects of Section 517 (on judicial review of agency actions).

Legislative History

House Report	No. 94-853 accompanying H.R. 11124 (Committee on Interstate and Foreign Commerce, February 29, 1976)
Senate Report:	No. 94-93 accompanying S.510 (Committee on Labor and Public Welfare, March 11, 1975)
Conference Report:	(H.Rept. No. 94-1090, May 6, 1976)
Signature by President and effective date:	May 28, 1976, P.L. 94-____

Even though summaries of safety and effectiveness information will be made available to the public, Section 520(h) places certain constraints on their release and potential use for competitive purposes. Attention has been focused on premature release of summaries where an application for premarket approval has been initially denied or a PDP has been initially declared not complete by the FDA. The FDA has agreed that Section 520(h) does not require the release of a summary for a particular device until it makes a final determination that the device cannot be approved, and all legal appeals have been exhausted. Even more importantly, Section 520(h) stipulates that no summary, after release, may be used to establish the safety or effectiveness of another device (product in competition) for purposes of the Act. However, the summaries will be publically available for any other purpose unless otherwise precluded from disclosure in a reclassification action described in Section 520(c).

Inspections Relating to Devices (Section 704)

(Introduction)

Under existing law, the FDA has been authorized to inspect the establishments of device manufacturers with respect to equipment, materials, containers and labeling -- but not records. The new law amends Section 704 (factory inspection) to additionally authorize inspection of certain records as described below. Important distinctions in authority are drawn in the statute between all medical devices and those declared to be restricted devices. In the case of restricted devices, the FDA has greater access to the records maintained by their manufacturers.

(All Medical Devices)

New Section 704(e) clearly states that all records required to be maintained under Section 519 (records and reports) or Section 520(g) (exemption for devices for investigational use) may be reviewed during an FDA inspection. In addition to such access, the inspector is authorized to verify the contents of records and may copy the records.

(Restricted Devices)

Inspection authority for restricted devices is identical to that for prescription drugs. Inspectors are authorized to inspect records, files, papers, processes, controls and facilities to determine if restricted devices are adulterated or misbranded.

State and Local Requirements - (Section 521)

New Section 521 establishes a general rule that no state or political subdivision thereof may establish or continue in effect any requirement which is:

Investigational Use of Devices (Section 520(g))

Section 520(g) of the Amendments establishes the requirements manufacturers must meet in order to be granted an exemption for investigational use of devices. The investigational procedures set forth need only be complied with if conducting the investigation would otherwise result in violation of the following sections of the Act, as amended: Sections 502 (misbranding, 510 (registration and listing), 514 (performance standards), 515 (premarket approval), 516 (banned devices), 519 (records and reports), 706 (listing and certification of color additives), 520(e) (restricted devices) or 520(f) (good manufacturing practices).

Within 120 days after enactment, the FDA is required, by regulation, to establish procedures and conditions under which an exemption may be granted. These include submission of an application to the FDA and the maintenance of records and making of reports to FDA as necessary to insure compliance with the conditions for exemption and to allow for agency review of the progress of the investigation. The procedures and conditions may vary depending upon the scope and duration of clinical testing to be conducted, the number of human subjects to be involved, the need to permit changes to be made in the device, and whether the device is being tested for the purpose of developing data to support commercial distribution.

Where a device is to be tested on human subjects, the investigator is required to develop a plan for proposed clinical testing. The plan must be submitted for approval to the local institutional review committee or, if none exists, to the FDA. If the device is to be distributed to other investigators for testing, the person applying for the exemption must obtain a signed agreement from such other investigators that the testing will be under the principal investigator's supervision and that informed consent will be obtained from each human subject or his representative. These agreements must be submitted to the FDA (Section 520(g)(3)(C)).

The Amendments specify that informed consent must be obtained from each human subject or his representative (Section 520(g)(3)(D). The details of informed consent are not present in the new law. However, legislative history instructs the FDA to develop regulations to cover all elements of informed consent as originally included in Section 514 (k)(5) of the Senate bill. Ultimately, such regulations must also conform to recommendations of the National Commission on the Protection of Human Subjects of Biomedical and Behavioral Research when these are adopted.

Applications for an investigational use exemption are deemed to be approved on the thirtieth day after their submission unless specifically disapproved by FDA and notice of disapproval provided to the applicant (Section 520(g)(4)(A)).

Premarket Approval/Product Development Protocol

(Regulation to Require Premarket Approval)

Section 515(b) provides that Class III devices on the market on the date of enactment are not required to have an approved application for premarket approval until the FDA promulgates a regulation to that effect. The regulation is in addition to the regulation first classifying the device and it can't require an approved application until 30 months after the publication of the regulation which first classified the device. Further, the regulation which requires the submission of an application can't require such submission for 90 days (Section 501(f)(2)). To initiate the procedure, FDA will publish a proposed regulation in the Federal Register. The Federal Register notice must contain the findings on degree of risk sought to be eliminated or reduced and must provide an opportunity (within 15 days) to request a change of classification based on new information about the device. If a petition for reclassification is filed, the FDA must consult with the appropriate classification panel and, within 60 days, either deny the petition or begin an action to reclassify the device. Absent a petition to reclassify, the FDA will proceed to publish a final regulation for premarket approval or publish a notice of termination and move to reclassify under statutory requirements.

Legislative history cautions that manufacturers who wait for a Section 515(b) regulation instead of taking full use of the 30-month grace period risk inadequate time to submit an approvable application or PDP. In such a case, the device would be required to be removed from the market.

(Procedure for Premarket Approval Application)

Premarket approval of a medical device is to be initiated by the filing of an application with the FDA (Section 515(c)). The application is to contain reports of investigations of the safety and effectiveness of the device; a statement of its components and principles; a description of the methods, facilities and controls used for its manufacture; a reference to any performance standard that would be applicable to the device if it were a Class II device; a sample of the device, where practicable, and if submission of a sample is not practicable, the location of a sample; specimens of labeling; and such other information as the FDA, with the concurrence of the appropriate classification panel may require.

An application for premarket approval must contain full reports of all information known or which reasonably should be known to the applicant concerning the safety and effectiveness of the device, including any information concerning its adverse effects on health.

A detention order may be immediately appealed to the FDA. Within five days the FDA must, after opportunity for an informal hearing, either confirm or revoke the order under appeal.

Performance Standards

(Effects of Classification)

A type or class of product classified in Class II will eventually be required to conform to a performance standard. Until a standard is adopted by the FDA and has become effective, the provisions of General Controls are the legal requirements applicable to Class II devices.

(Provisions of Standards - Section 514(a)(2))

The Amendments, at Section 514(a)(2), state the general rule that performance standards shall include provisions to provide reasonable assurance of safe and effective performance. Five specific types of provisions will also be included where necessary for safe and effective performance. These include: (1) provisions on construction, components, ingredients and properties and compatibility with power systems, (2) provisions for testing to assure conformity with the standard, (3) provisions for measurement of performance characteristics, (4) provisions on certification of test results and (5) provisions limiting sale or distribution consistent with Section 520(e) (restricted devices). If appropriate, the standard may also prescribe the use and content of labeling with respect to installation, maintenance, operation and use.

The Amendments require that the FDA provide for periodic evaluation of established standards to determine if new medical, scientific or technological data call for appropriate revision (Section 514(a)(4)).

(Procedure to Promulgate Standard)

Step One: The Amendments recognize that a considerable period of time may elapse between classification and a decision to develop a standard. Thus, the first step in this process requires the agency to publish in the Federal Register a notice of opportunity (within 15 days) to request a change in classification based on new information about the device in question (Section 514(b)). Requests for reclassification must be acted upon within 60 days. The agency has two options at this point. It may deny the request or find merit and publish a notice of intent to reclassify the device.

Step Two: If no reclassification is required, an invitation will be published in the Federal Register inviting any person (including any Federal Agency) to submit within 60 days an existing or proposed standard or an offer to develop a standard (Section 514(c)).

determined that: (1) the device presents an unreasonable risk of substantial harm to the public health, (2) the device was not properly designed and manufactured according to the state of the art when produced, (3) the unreasonable risk was not caused by a third party's failure to exercise due care in the installation, maintenance, repair or use of the device and (4) a notification order under Section 518(a) would not, by itself, be adequate to eliminate the unreasonable risk.

To carry out the repair, replacement or refund ordered, the FDA will require a plan to be submitted for approval. Plans unsatisfactory to the FDA may be revised and resubmitted. An informal hearing is available for both an initial or a revised plan. In the absence of a satisfactory plan, the FDA may prescribe the actions to be taken. Reimbursement between and among manufacturers, importers, distributors and retailers may be ordered if the FDA determines that it is required to protect the public health. However, the reimbursement requirement will not affect rights of contract. Finally, Section 518(d) provides that compliance with a plan to repair, replace or refund does not relieve any person from liability under Federal or State law.

(Records and Reports - Section 519)

New Section 519 authorizes the FDA to prescribe regulations for records and reports by manufacturers, importers and distributors. Several limitations are placed upon the FDA in promulgating such regulations. In general, records and reports will be limited to necessary procedures and submissions which are not unduly burdensome (including costs of compliance) and must be fully explained as to their purposes. Patient identity will be protected. Finally, records and reports with respect to Class I devices may not require maintenance or submission of information not in the possession of the manufacturer, importer or distributor.

(Good Manufacturing Practices - Section 520(f))

The FDA is authorized under new Section 520(f) to develop GMP regulations which manufacturers must adhere to. An advisory committee of nine persons (including two industry representatives) must be established to consider GMP recommendations. In the development of these regulations, the FDA is required to review recommendations from the advisory committee and to hold an oral hearing on the subject if requested by interested persons.

Exemptions or variances from GMP requirements may be obtained upon petition of interested parties. For an exemption from a GMP requirement, the petitioner must demonstrate that compliance with the requirement is not necessary to assure that the device will be safe and effective. If a variance is sought, the petitioner must describe his alternative approach and provide the agency with whatever additional information is requested. In contrast to the broad GMP development procedure, petitions for exemptions or variances are referred to the advisory committee as a matter of choice by the agency. The FDA has sixty days to act on a petition. An informal hearing may be requested on the decision after it is rendered.

(Prohibited Acts (Section 301))

To establish most violations of the Federal Food, Drug and Cosmetic Act, it is first necessary to allege the commission of a prohibited act (Section 301). Thus, the Amendments revise Section 301 to clearly state those prohibited acts which necessarily flow from new Sections 513, 514, 515, 516, 518, 519, and 520.

(Registration and Listing (Section 510))

According to the Amendments, manufacturers or processors of devices are required to register their facilities initially and annually thereafter with the FDA. Also, an initial listing of all devices and six-month updates on new products in June and December is required. Amended Section 510 also authorizes the FDA to develop and enforce a uniform system for identification of devices. Included in the registration requirements is the advance notice of marketing requirement noted above.

(Banned Devices (Section 516(a) - General Rule)

New Section 516 authorizes the FDA to ban a device from the market when it is established that continuing availability of the device presents either a substantial deception to the public or an unreasonable and substantial risk of illness or injury. Because this remedy is extreme, the statute provides both procedural and substantive checks on its use.

Four steps are involved in the banning of a device. First, the agency must find that continued marketing of a device presents a substantial deception or an unreasonable and substantial risk of illness or injury.

Second, the FDA is required to consult with the appropriate classification panel on the agency's findings. However, legislative history indicates that this procedure should not act to delay substantially the banning process.

Third, the FDA must make a positive determination that additional labeling or changes in labeling would not be adequate to correct or eliminate the deception or risk. Conversely, if the FDA determines that revised labeling would rectify the problem, the banning process will be suspended. The involved manufacturer must be notified in writing and be given the opportunity to comply with the agency's directives on labeling. The manufacturer will be afforded a reasonable but defined period in which to comply. If the manufacturer fails to comply, the banning process will be resumed.

Fourth, the banning process is consummated by publication of a proposed regulation in the Federal Register to ban a device. At this juncture, interested persons will be afforded an informal hearing before the agency. A device subject to a proposed banning regulation remains on the market until a final order is published in the Federal Register. The final order will either affirm, modify or revoke the proposed banning regulation. Proposed banning regulations which are made effective will require the expeditious removal of the device from the market. A final regulation banning a device under Section 516(a) is entitled to judicial review (Section 517(a)(5)).

With respect to when Section 510(k) becomes effective, some FDA officials have indicated that it is effective on the date of enactment. Other persons have argued that the provisions cannot be made effective until either regulations requiring the advance notice are promulgated or until manufacturers have filed their first establishment registration form.

The issue of which device introductions require advance notice is also subject to several interpretations. Under a broad interpretation, a manufacturer would provide 90-day advance notice when introducing a product not previously marketed by that company whether or not it is or may be substantially equivalent to a product marketed by another manufacturer. Following a narrow interpretation of Section 510(k), a 90-day notice would only be required for new devices, i.e., those which are not substantially equivalent to devices on the market before enactment of the law. Accordingly, a manufacturer would not be required to notify the agency when introducing essentially copies of other devices already on the market (sometimes referred to as "me-too devices") or when introducing devices with improvements or refinements which are not fundamental changes with reference to safety or effectiveness.

Indications are that the FDA intends to follow a broad interpretation of Section 510(k). Even so, each manufacturer may elect whether to provide notice on a product-by-product basis. In the absence of notice to FDA, the introduction of a product could be challenged by the agency. Experience with such FDA compliance actions will ultimately determine the practical and legal scope of Section 510(k).

Where the FDA is notified of the introduction of a device, Section 510(k) requires certain classification and compliance measures to be reported. Specifically required from the manufacturer are: (1) a determination of the device's classification or the absence thereof with an explanation for either determination, and (2) actions taken by the manufacturer to comply with a performance standard or premarket approval if applicable to the device. It should be noted that the FDA is under no statutory obligation to acknowledge receipt of, or respond to, this notice.

(Classification Changes - Section 513(e))

Section 513(e) of the Amendments provides that the final classification of any device may be changed on the basis of new information about the device. A change in classification would also revoke any regulation or requirement under Sections 514 (standards) or 515 (premarket clearance) as applicable. The procedure may be initiated by either the FDA or by petition of an interested party. A recommendation on the change from the appropriate classification panel may be sought by FDA but is not required. For devices changed from premarket clearance to standards, the reclassification order may delay the effective date of the change until a standard has been promulgated.

The above described criteria for classification of devices applies to different categories of devices in different ways. Devices on the market on enactment day and devices first marketed after enactment day which are of the same type and are substantially equivalent to those on the market on enactment day are subject to one procedure; devices first marketed after enactment day which are not both of the same type and substantially equivalent to devices on the market on enactment day are subject to another procedure. It is important to remember that devices first marketed after enactment day but which are of the same type and substantially equivalent to devices on enactment day are treated basically the same as devices on the market on enactment day. For purposes of simplicity, devices on the market on enactment day will be described in this summary as "old" devices, devices later marketed which are of the same type and are substantially equivalent to devices on the market on enactment day as "me-too" devices, and devices first marketed after enactment day which are not both of the same type and substantially equivalent to devices on the market on enactment day will be called "new" devices.

Before discussing the application of the classification criteria to "old" and "me-too" devices, the new device category can be quickly disposed of. Unlike old devices and me-too devices, all new devices will be automatically placed in premarket clearance and cannot be commercially marketed unless either an application is approved or the device is reclassified into standards or general controls. Old and me-too devices are subject to different procedures depending on whether they are either (1) implantable devices, or devices used in supporting or sustaining human life or (2) those which involve none of the three uses just mentioned. Implants, life-supporting and life-sustaining devices will be called "critical" devices for purposes of this discussion. The "all others" categories will be described as "noncritical" devices.

With regard to critical devices, they are to be placed in Class III unless FDA determines that premarket clearance is not necessary to provide reasonable assurance of their safety and effectiveness. Any order reclassifying a critical device out of the premarket approval class must be accompanied by a full statement. The statement must be supported by documentation and data and the order must identify the risks to health (if any) presented by the device.

With regard to noncritical devices, they will be made subject only to general controls if such controls are sufficient to provide a reasonable assurance of the safety and effectiveness of the device. If such controls are not sufficient to provide such assurance, the device will be classified into Class II (Standards) and if that class is not sufficient, the device will be made subject to premarket approval requirements.

Thus, there are two basic differences between critical and noncritical devices in the supporting data required to classify the device into general controls or standards. First, a great deal more data will be required for critical devices. SEcond, FDA will have to argue a negative for critical devices, that is, that premarket clearance is not necessary, rather than that standards or general controls are sufficient.

approved device application may require that a component of a device comply with a standard. Multiple classification may occur on the basis of two distinct rationales. In the first instance, the nature or use of a product may be such that a single regulatory class is inadequate to give a reasonable assurance of safety and effectiveness. Under the second rationale, devices with more than one claimed or common use may be classified in a different class for each use. An example would be a device which might have both diagnostic and therapeutic applications.

(Safety and Effectiveness Considerations)

The classification of medical devices is determined by the available evidence on safety and effectiveness. In evaluating the evidence, Section 513(a)(2) requires that consideration be given to: (1) the persons for whose use the device is represented or intended, (2) the conditions of use prescribed, recommended, or suggested in labeling, and (3) a weighing of any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

Rules for determining effectiveness of a device for classification (Section 513(a)(3)) also apply to an evaluation of effectiveness for purposes of setting performance standards, for passing upon premarket approval applications, and for determining effectiveness whenever it is required in the Amendments. Effectiveness of a device will be determined on the basis of one of two types of evidence. The first is on the basis of well-controlled investigations as described in regulations of the FDA. The second is "valid scientific evidence" (other than evidence derived from well-controlled investigations). In deciding whether other valid scientific evidence would be sufficient, the nature of the device in question must be considered as well as the scope of testing and experience generated from use of the device. Among the cases in which meaningful data from lesser investigative procedures may be accepted are where there is well-documented clinical or other experience or when well-controlled investigations would present undue risks to the test population. FDA is allowed to determine that other valid scientific evidence is sufficient only if it is satisfied that qualified experts could fairly and responsibly conclude that such evidence is sufficient.

(Class I - General Controls - Section 513(a)(1)(A))

In general, a device will be classified within Class I (general controls) if the requirements of Section 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned device), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions respecting control of devices) are found to be adequate to provide a reasonable assurance of safety and effectiveness. A device may also be assigned to Class I if there is inadequate information on safety and effectiveness, provided, that the device is not represented for a use in sustaining or supporting human life or for a use which is of substantial importance in preventing impairment of human health and, it does not present a potential unreasonable risk of illness or injury.

MEDICAL DEVICE AMENDMENTS OF 1976
Study Papers
Part I: Summary of Major Provisions

Introduction

Public law 94- consists of extensive amendments to the Federal Food, Drug and Cosmetic Act. They substantially increase the existing regulatory controls over medical devices. The new law is called the Medical Device Amendments of 1976 (hereinafter referred to as Amendments). Authority to implement the Amendments is vested in the Secretary of the Department of Health, Education, and Welfare. However, this authority will be exerted by the Commissioner of Food and Drugs (hereinafter referred to as FDA).

Products Subject to the Amendments

A definition for "device" has been present in the Act since 1938. Although intended to be mutually exclusive with the term "drug", the definition of device proved confusing to the industry, the general public and the Courts. The definition of device in the Amendments reflects a clear Congressional intent to draw a clear distinction between drugs and devices. The distinction is based upon mode of action of the device. The definition of "device" at Section 201(h) of the Act has been amended to read in relevant part:

> "(h) The term 'device' . . . 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."

MEDICAL DEVICE AMENDMENTS OF 1976
Study Papers
Part I: Summary of Major Provisions

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MEDICAL DEVICE AMENDMENTS OF 1976

Study Papers

This document contains three papers which cover various aspects of legislation, signed May 28, 1976, providing comprehensive regulatory authority over medical devices and diagnastic products. These papers are:

I. Summary of Major Provisions (Pages 1 to 24)

II. First Concerns Upon Enactment (Pages 25 to 34)

III. New Production Introduction (Pages 35 to 46)

These papers were prepared by the staffs of the Health Industry Manufacturers Association and the Pharmaceutical Manufacturers Association to provide a preliminary description of the new legislation. They may be revised as experience requires and should be read with three thoughts in mind:

-- They do not purport to predict what effect FDA will seek to give to all sections of the legislation or what effect may be given through judicial interpretation.

-- They do not give legal or practical advice as to the effect of any provision on any product or type of product.

-- All three papers are summaries only; legal and business decisions about specific products should be taken only after a careful reading of the legislation in its entirety and, as necessary, a review of applicable legal materials, such as legislative history, regulations and other statutes.

* * *

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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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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.

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 applica-

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

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).

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.

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.

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.

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.

(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 sec-

(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 estab-

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".

"(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.

"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:

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

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.

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.

"(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.*

"(ii) *on a periodic basis,*

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

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

"*Persons Exempt*

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

"(1) *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 dispens-*

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

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

"(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.

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 hear-

"(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

"(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*

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) *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*

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

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

"(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).

(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.

"(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,

"Sec. 514. Performance standards.
"(a) Provisions of standards.
"(b) Initiation of a proceeding for a performance standard.
"(c) Invitation for standards.
"(d) Acceptance of certain existing standards.
"(e) Acceptance of offer to develop standard.
"(f) Development of standard by Secretary after publication of subsection (c) notice.
"(g) Establishment of a standard.
"Sec. 515. Premarket approval.
"(a) General requirement.
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"Sec. 519. Records and reports on devices.
"(a) General rule.
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"Sec. 520. General provisions respecting control of devices intended for human use.
"(a) General rule.
"(b) Custom devices.
"(c) Trade secrets.
"(d) Notices and findings.
"(e) Restricted devices.
"(f) Good manufacturing practice requirements.
"(g) Exemption for devices for investigational use.
"(h) Release of safety and effectiveness information.
"(i) Proceedings of advisory panels and committees.
"(j) Traceability requirements.
"(k) Research and development.
"(l) Transitional provisions for devices considered as new drugs or antibiotic drugs.
"Sec. 521. State and local requirements respecting devices.
"(a) General rule.
"(b) Exempt requirements."
Sec. 3. Conforming amendments.
(a) Amendments to section 201.
(b) Amendments to section 301.
(c) Amendments to section 304.
(d) Amendments to section 501.
(e) Amendments to section 502.
(f) Amendments to section 801.
Sec. 4. Registration of device manufacturers.
Sec. 5. Device established and official names.
Sec. 6. Inspections relating to devices.

ject of an approved application under section 801(d)(4) if he determines that such export is inconsistent with the health and safety of persons within the United States.

Section 4 of the bill amends section 510 of the Act (relating to registration of manufacturers of drugs and listing of drugs) to make the provisions applicable to device manufacturers and to require that every establishment registered under the provisions of section 510 which is engaged in the manufacture, propagation, compounding, or processing of class II or class III devices be inspected at least once every two years pursuant to section 704 of the Act. This section of the bill also adds to section 510 of the Act a new subsection (k) which requires that each person required to register under section 510 and who proposes to introduce a device intended for human use into interstate commerce for commercial distribution shall, at least 90 days prior to such introduction or delivery, report to the Secretary (1) the class in which the device has been classified under new section 513 unless such person determines that the device has has not been classified, in which case he shall provide a statement of such determination and the basis for the determination that the device is or is not so classified, and (2) action taken to comply with requirements under sections 514 or 515 which are applicable to the device.

Section 5 of the bill amends sections 502(e) of the Act (relating to the use of established names for drugs) and 508 of the Act (which provides authority to establish official names for drugs) to make the provisions of these sections applicable to devices.

Section 6 of the bill amends section 704(a) of the Act (relating to inspection of establishments in which foods, drugs, devices or cosmetics are manufactured, processed, packed or held for introduction into interstate commerce) to render provisions now applicable to establishments in which prescription drugs are manufactured applicable to establishments in which restricted devices are manufactured, to render the provisions with respect to access to research data applicable to inspections with respect to restricted devices, and adds a new section 704(e) to assure access by officers or employees of the Secretary to records required to be maintained under new sections 519 or 520(g).

Section 7 of the bill amends section 304 of the Act (relating to seizure of products in violation of the Act) to add a new provision (section 304(g)) authorizing temporary administrative detention of devices in accordance with regulations. Detention is authorized for periods of up to 20 days unless the Secretary determines that a greater period is necessary to institute a seizure action under section 302(a) of the Act, in which case he may authorize a detention period of up to 30 days. Regulations are to require that an officer or employee designated by the Secretary must approve a detention order before a device may be detained. Detention orders may require detained devices to be so labeled. Persons whose devices are detained may, if they would be entitled to claim a device if it were detained under section 304(a) of the Act, appeal the detention to the Secretary, who must, after opportunity for an informal hearing, confirm or revoke the detention within five days of the appeal. Detained devices may not be moved until released or the detention period expires, except in accord-

the shipping package as intended for export, and (4) are not sold or offered for sale in domestic commerce. This provision is subject to additional conditions, described below, under which articles requiring approval for use in the United States, and for which such approval has not been granted—new drugs, new animal drugs, animal feeds bearing or containing new animal drugs, antibiotics and certain medical devices—may be exported.

New sec. 801(d)(2) limits the exemption afforded by section 801(d)(1) with respect to a device intended for export which has not complied with an applicable requirement of section 514 or 515, or which has been banned under the provisions of section 516, by requiring that such device, in addition to meeting the requirements of section 801(d)(1), satisfy one of the following alternative conditions. First, if the country to which the device is intended for export has an appropriate health agency to review the device and authorize or approve it as safe for its intended use (including investigational use) within the country and (1) such agency has so reviewed and authorized or approved the device, and (2) the Secretary has been provided notification as required by section 801(d)(6) (described below), the device may be exported to that country. Alternatively, if the country to which such device is intended for export does not have an appropriate health agency to review and approve the device, it may be exported to such country only if the Secretary determines, upon application and after provision to the applicant of opportunity for an informal hearing on the application, that such export is not contrary to public health and safety.

New sec. 801(d)(3) limits the exemption afforded under section 801(d)(1) with respect to an antibiotic drug for which a regulation or release is not in effect pursuant to section 507 by requiring that such a drug, in addition to meeting the requirements of section 801(d)(1), satisfy one of the following alternative requirements. First, if the country to which the antibiotic is intended for export has an appropriate health agency to review the antibiotic and authorize or approve it as safe for its intended use (including investigational use) within that country and (1) such agency has so reviewed and authorized or approved the drug, and (2) if notification has been provided to the Secretary in accordance with the requirements of section 801(d)(6), the antibiotic may be exported to that country. Alternatively, if the country to which such antibiotic is exported does not have an appropriate health agency to review and approve its use, the drug may be exported to such country only if the Secretary determines, upon application and after provision to the applicant of opportunity for an informal hearing on the application, that such export is not contrary to public health and safety.

New sec. 801(d)(4) modifies the provisions of existing law which prohibit the export of unapproved new animal drugs or animal feeds bearing or containing an unapproved new animal drug. This paragraph permits the export of such a drug or feed which is not the subject of an approved application under section 512 of the Act if an application is made to the Secretary for the export of such animal drug or feed and the Secretary determines that (1) the drug or feed meets the requirements of new sec. 801(d)(1); (2) its exportation is

party's expense. Transcriptions of hearings shall be included in the presiding officer's report of the hearing.

Sec. 3(b) of the bill includes amendments to section 301 of the Act (relating to prohibited acts) to render as prohibited acts failure to comply with applicable provisions of sections 513, 514, 515, 516, 518, 519, 520 and 707.

Sec. 3(c) of the bill amends section 304 of the Act (relating to court-ordered seizures) to render devices which are adulterated or misbranded subject to the provisions of section 304.

Section 3(d) amends section 501 of the Act which states the condition under which a device is to be considered as adulterated and thus subject to the prohibited acts and enforcement sections of the Act (sections 301, 302, 303 and 304). The amendments to section 501 make the following devices adulterated devices:

(1) devices which do not comply with applicable requirements of section 514 (performance standards).

(2) devices which do not comply with applicable requirements of section 515 (premarket approval).

The amendments delay in two cases the time when a device is to be treated as adulterated. First, in the case of a device which is a class III device because of section 513(f) (initial classification of devices not on the market before the date of the enactment of the bill) and which is intended solely for investigation use, the amendment to section 501 shall not apply to such device until 90 days after the promulgation of regulations under section 520(g) prescribing the procedures and conditions required for approval of an exemption from section 515 for devices for investigational use. Second in the case of a device which is subject to the requirements of section 515 because of a regulation under section 515(b), the amendment to section 501 shall not apply to such device until (1) the last day of the thirtieth calendar month beginning after the month in which the device was classified into class III under the provisions of section 513, or (2) the ninetieth day after the date of promulgation of the 515(b) regulation, whichever occurs later.

Section 501 is further amended to render a device adulterated in the following instances:

(1) If it is a banned device.

(2) If it does not conform to the requirements of section 520(f)(1) (relating to good manufacturing practices), or a condition prescribed by an order under section 520(f)(2) (relating to variances from good manufacturing practice requirements.

(3) 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 the exemption or any investigator who used the device fails to comply with a requirement prescribed by or under such section.

Sec. 3(e) of the bill amends section 502 of the Act (which prescribes instances in which drugs or devices are misbranded) to render devices misbranded in the following instances:

(1) a restricted device whose advertising is false or misleading or which is distributed in violation of regulations under section 520(e) restricting the sale or distribution of a device.

of a device for which a new drug application has been filed on or before the date of enactment but for which no order has been issued under section 505(c) or 505(d) of the Act, the new drug application shall be considered as an application for premarket approval under section 515 filed on the enactment date.

The Secretary is required to act on such application in accordance with section 515 within the period computed as follows: 180 days after the date of enactment (or such greater period as the Sceretary and the applicant may agree upon) less the number of days in the period beginning on the date that the new drug application was filed and ending on the enactment date. Following the expiration of such period, the device is required to have in effect an approved application under section 515 of the bill unless it is the subject of an approved application for an exemption for investigational use under section 520(g). A device which upon the date of enactment was the subject of an approved application for investigational use under section 505(i) of the Act shall be considered a new drug (and thus retain its status as an investigational drug) until the expiration of the 90 day period following the date of the promulgation of regulations under section 520(g) prescribing procedures and conditions relating to exemptions for devices for investigational use. Such devices are required to have in effect an approved application for premarket approval under section 515 after the expiration of such period, unless they are exempt under subsection 520(g) on such date.

Any device (1) which is substantially equivalent to a device which has an approved new drug application, for which a new drug application was filed or before the enactment date, or for which there is in effect an exemption for investigational use as a drug, (2) which, prior to the date of enactment, has been declared to be a "new drug" under section 505 of the Act, or (3) with respect to which on the enactment date there is pending in a United States court an injunction proceeding under section 302 of the Act, a criminal proceeding under section 303 of the Act, or a seizure action under section 304 of the Act is, except as provided below, required to have an approved application under section 515 on and after the date of enactment. However, if a petition for reclassification (described above) or an application for premarket approval under section 515 is filed for such a device within 60 days after the date of enactment (or within such greater period as the Secretary and the petitioner or applicant may agree upon), the Secretary is required to act with respect to such petition or application within 120 days after the date it is filed. The filing of such a petition or application within the 60 day (or greater) period operates to stay the application of the requirement to have in effect an approved section 515 application for premarket approval until the expiration of the 120 day period or, if such petition is denied or such application is denied approval, before the date of such denial, whichever occurs first.

Finally, this subsection provides that any device intended for human use which on the date of enactment was subject to the requirements of section 507 of the Act (relating to certification of antibiotics) shall remain subject to such requirements except as follows:

(a) if classified into class I until the effective date of the regulation so classifying the device;

thirtieth day after they are submitted, unless the Secretary, by order, disapproves the application and so notifies the applicant. Applications may be disapproved only if the Secretary finds that the investigation does not conform to procedures and conditions prescribed by regulations. Notifications of disapproval shall contain complete statements of the reasons for the disapproval and afford the applicant opportunity for an informal hearing. The Secretary is authorized to withdraw an exemption for investigational use upon his determination that the conditions applicable to the device for such exemption are not being met. Orders withdrawing an exemption may be issued only after opportunity for informal hearing except in instances in which the Secretary determines that the continuation of testing will result in an unreasonable risk to the public health.

New sec. 520(h) requires the Secretary to promulgate regulations under which a detailed summary of information respecting the safety and effectiveness of a device shall be made available to the public. This subsection requires that such information shall be made public upon approval, denial of approval, or withdrawal of approval of an application for premarket approval; revocation of an approved product development protocol, an order declaring a PDP completed or not completed, or an order revoking the approval of a device approved under the PDP procedure; or an order approving, disapproving, or withdrawing approval of an application for exemption for investigational use of a device under section 516. Each summary is required to include any information respecting the device's adverse effect on health.

This subsection further requires that each advisory committee established under section 515(g)(2)(B) (which are established for the purpose of reviewing contested actions by the Secretary with respect to action taken on class III devices) 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. Such information shall be made available only after the Secretary issues the order with respect to which the recommendation was made. Each summary is required to include any information respecting the device's adverse effects on health. Finally, this subsection requires that any information required to be made available to the public under this subsection may not be used to establish the safety or effectiveness of other devices by any person other than the person who submitted the information which has been made available, and requires that the information shall only be made available subject to section 520(c) (relating to the protection of trade secrets).

New sec. 520(i) requires that each classification panel, each advisory committee established to review performance standards, and each advisory committee established to review the Secretary's actions with respect to class III devices shall make and maintain a transcript of any of its proceedings. Such panels or committees are required to delete from any such transcript information considered confidential under section 520(c).

New sec. 520(j) requires that no regulation under this Act may impose requirements for the traceability of a type or class of device unless

520(f) or (g) which is exempt from disclosure pursuant to section 552(b) of title 5, United States Code (relevant provisions of the Freedom of Information Act), shall be considered confidential and shall not be disclosed and may not be used as the basis for reclassification of a device from class III to class II or as the basis for establishment or amendment of a performance standard for a device reclassified from class III to class II. Such information may, however, be disclosed to other officers or employees concerned with carrying out the Federal Food, Drug and Cosmetic Act, or when relevant in any proceeding under the Act (except section 513 or 514).

New sec. 520(d) requires that all notices of proposed rulemaking under section 513, 514, 515, 516, 518, or 519, other notices relevant to an action under such sections, and each publication of findings under such sections set forth the manner in which data may be examined and the period in which comments may be presented, orally or in writing. Such period is to be at least 60 days and may not be more than 90 days unless extended by the Secretary for good cause.

New sec. 520(e) authorizes the Secretary to require by regulation that the sale or distribution of a device be restricted to written or oral authorization of a practitioner licensed by law to administer or use such device or under such other conditions as may be prescribed in the regulation (other than any condition that would limit use of a device to categories of physicians defined by training or experience) if, because of its potential for harmful effect or collateral measures necessary to its use, the Secretary determines there cannot otherwise be reasonable assurance of the safety and effectiveness of the device. The label of such device, called a restricted device, must bear such appropriate statements of restrictions as the Secretary may prescribe and is deemed misbranded if it does not bear such label.

New sec. 520(f) authorizes the Secretary to prescribe regulations requiring that the manufacture, packing, storage, and installation of devices conform to good manufacturing practice requirements. Such regulations may be promulgated only after opportunity for oral hearing and only after opportunity to submit recommendations with respect to such proposed regulations has been afforded to a nine person advisory committee established by the Secretary consisting of representatives of government; and persons representative of the interests of industry, physicians and other health professional, and the general public. Persons subject to good manufacturing practice requirements may petition for exemptions or variances from such requirements. Petitions for exemptions must set forth the basis for the petitioner's determination that compliance with the applicable requirement is not necessary to assure that the device will be safe, effective and otherwise in compliance with the Act. Petitions for variances must include proposed methods to be used in lieu of the methods prescribed by the contested requirements. Such petitions may be referred to the advisory committee for recommendations (which must be submitted within 60 days). A petition for exemption for a device may be approved if the Secretary determines that compilance with the contested requirement is not necessary to insure that the device is safe, effective, and otherwise in compliance with the Act. A petition for a variance for a device may be approved if the Secretary determines that the methods proposed in the petition (and required to be prescribed in an order ap-

New sec. 518(b) authorizes the Secretary, if he finds, after opportunity for an informal hearing, (1) that a device presents an unreasonable risk of substantial harm to the public, (2) that there are reasonable grounds to believe that it was not properly designed and manufactured with reference to the state of the art that existed at the time of its design and manufacture, (3) that the risk was not due to failure to exercise due care in installation, maintenance, repair, or use of the device, and (4) that notification under section 518(a) is not sufficient to eliminate the risk, to order the manufacturer, importer, or distributor of the device to submit a plan to repair, replace or refund the purchase price of the device. An order directed to more than one person shall specify which person may decide on the action to be taken under the plan. 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 make this determination or determines that the protection of the public health requires that such decisions be made by a person other than the person who bears such responsibility. The Secretary is required to approve a plan submitted to him unless he determines, after affording opportunity for an informal hearing, that the actions proposed to be taken under the plan will not assure that the risk will be eliminated. If the Secretary disapproves a plan, he shall order a revised plan to be submitted within a reasonable period. If, after opportunity for an informal hearing, the Secretary determines that the revised plan is unsatisfactory, or if no revised plan or no initial plan has been submitted to him within the prescribed time, he shall prescribe a plan to be carried out by the person or persons directed to do so in the order. Alternatively, he may prescribe a plan to be carried out by a person to whom the order was not directed, but who is a manufacturer, importer, distributor or retailer of the device with respect to which the order was issued. Any person (other than a manufacturer, importer, distributor or retailer) who avails himself of a remedy provided under an order to repair, replace, or refund the purchase price of a device, may not be charged for availing himself of such a remedy, and the person subject to the order shall reimburse each person who is entitled to repair, replacement, or refund for any reasonable expenses actually incurred in availing himself of the remedy.

New sec. 518(c) authorizes the Secretary to include in the section 518(b) order a requirement that manufacturers, distributors, or retailers reimburse other manufacturers, distributors, or retailers for expenses incurred in carrying out the order if reimbursement is required for the protection of the public health. This requirement shall not affect rights or obligations under any contract to which a person receiving or making reimbursement is a party.

New sec. 518(d) makes it clear that compliance with a section 518 order does not relieve persons from liability under Federal or State law, although any value received by a plaintiff as a result of such order shall be taken into account in awarding damages.

Section 519 establishes requirements with respect to records and reports on devices intended for human use.

New sec. 519(a) requires manufacturers, importers, and distributors of devices to establish aud maintain records. make reports and pro-

and made public. The Secretary is then to either affirm or reverse the disputed order.

New sec. 515(h) requires that orders of the Secretary under section 515 be served in person, or by registered or certified mail.

New section 516 authorizes the Secretary to ban certain devices.

Section 516(a) authorizes the Secretary to initiate a proceeding to promulgate a regulation to ban any device intended for human use which after consultation with the appropriate classification panel he finds to present substantial deception or an unreasonable and substantial risk of illness or injury. It provides that in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary has determined could be corrected or eliminated by labeling or changes in labeling and with respect to which the Secretary provided the manufacturer written notice, such proceeding shall be initiated unless appropriate labeling or change in labeling was done within the period specified in the written notice from the Secretary. Interested persons are afforded opportunity for an informal hearing on such regulations.

New sec. 516(b) authorizes the Secretary to declare a proposed regulation banning a device effective upon its publication if he determines that the deception or risk of illness or injury associated with use of the device presents an unreasonable, direct, and substantial danger to the health of individuals. Prior to the date of publication of such regulations, the Secretary is to notify the manufacturer of the device subject to the regulation that such regulation is to be made so effective. If the Secretary takes this action, he shall, as expeditiously as possible, afford notice, opportunity for informal hearing, and affirm, modify or revoke the proposed regulation.

New section 517 prescribes procedures for judicial review of regulations and orders of the following:

(1) the promulgation of a regulation under section 513 classifying a device into class I, changing the classification of a device to class I, or an order under section 513(f)(2) classifying a device in class III or denying a petition for reclassification of a device automatically classified into class III;

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

(3) an order under section 514 or 515 denying a request for reclassification;

(4) a regulation under section 515 requiring a device to have an approval of a premarket application, or amending or revoking such regulation, and an order issued after the review authorized by section 515(g);

(5) a regulation under section 516 making a device a banned device (except for a proposed regulation made effective upon its publication pursuant to section 516(b));

(6) an order under section 520(b)(2) respecting a petition for an exemption or variance from good manufacturing practices; 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 such section withdrawing such an exemption.

where practicable, to be accompanied by information informing the applicant of measures necessary to gain approval. Persons whose applications are denied are afforded 30 days to seek review in accordance with section 515(g) (providing an adjudicative hearing or review by a special advisory committee). Interested persons may also obtain review in accordance with section 515(g) of an order approving an application.

New sec. 515(e) provides that the Secretary shall, upon obtaining advice on scientific matters from a classification panel, after notice and opportunity for an informal hearing, issue an order withdrawing approval of an application for premarket approval of a device if he finds (1) that the device subject to the application is unsafe or ineffective, (2) that on the basis of new information with respect to such device, there is a lack of reasonable assurance that the device is safe or effective, (3) that the application for premarket approval contained an untrue statement of a material fact, (4) that the applicant has failed to establish a system for maintaining records as required under section 519 or has repeatedly or deliberately failed to maintain records or make reports as required by such section, (5) has refused to comply with the requirements of section 704 with respect to access to such records, (6) has not complied with the requirements of section 510 (relating to registration of establishments manufacturing or processing of devices), (7) that, on that basis of new information, the methods used in the manufacture of such device do not conform with good manufacturing practices required under section 520(f), (8) that, on the basis of new information before him, the labeling of such device is false or misleading in any particular and was not corrected following receipt of notice of such fact, or (93 on the basis of new information, such device does not comply with a performance standard, compliance with which was a condition to approval of the application. Persons holding applications subject to an order withdrawing approval thereof may obtain review of such order in accordance with section 515(g) upon filing a petition on or before the thirtieth day after notice of such withdrawal.

New sec. 515(f) authorizes an alternative procedure for gaining approval of an application for premarket approval of a class III device whereby, in lieu of such approval, a notice of completion of a product development protocol (PDP) approved by the Secretary has become effective. Any person is authorized to submit to the Secretary a proposed PDP with respect to a device and the Secretary is required, within 30 days of receipt of a PDP, if he determines that a PDP procedure is appropriate for such a device, to refer the proposed PDP to the appropriate classification panel for recommendations respecting approval. The Secretary may approve a PDP only if he determines that the PDP procedure is appropriate in lieu of the premarket approval procedure and that the PDP provides (1) descriptions of (a) the device and proposed changes in it, (b) preclinical trials and the required results of such trials before commencement of clinical trials, (c) clinical trials and required results of such trials before the filing of a notice of completion, and (d) methods of manufacture and installation; (2) references to applicable performance standards; (3) specimens of proposed labeling; and (4) requirements for submission of

ceeding, in which case he shall initiate a section 513(e) proceeding to reclassify the device unless the proceeding has been terminated because the device has been banned under section 516. Following receipt and consideration of comments (including appropriate comments from an expert advisory committee, described below, especially established to submit scientific recommendations on proposed standards) the Secretary must either promulgate a regulation establishing a standard or terminate the proceeding, in which case he shall initiate a section 513(e) proceeding to reclassify the device, unless the device has been banned under section 516. A regulation establishing a standard is not to take effect before one year after its publication unless an earlier date is necessary to protect the public health and safety, or the standard has been established for a device which, upon the effective date of the standard, has been reclassified from class III to class II. The date upon which the standard is to become effective is to be established so as to minimize economic loss to and disruption of trade. The Secretary is authorized to amend or revoke standards, and may declare a proposed amendment to be effective during the period beginning immediately upon its publication and until the effective date of final action on the amendment, although this expedited procedure may not prohibit the introduction into interstate commerce of a device that conforms to the standard (except for the proposed amendment) during this period. In other words, the fact that a device does not, solely by reason of the amendment, conform to the new performance standard, does not make the introduction of the device into interstate commerce a prohibited act under section 301. This subsection further provides that the Secretary is to establish advisory committees to assist him with respect to the development of regulations for the establishment, amendment, or revocation of a performance standard. These committees, which may not be classification panels established under section 513, are to be comprised of persons of diversified professional background, and shall include as non-voting members one representative of consumer interests and one representative of interests of the device manufacturing industry. The Secretary is authorized on his own initiative, and is required upon the request of an interested person, to refer such proposed regulations to an advisory committee for a report and recommendation with respect to any matter involved in a proposed regulation which requires the exercise of scientific judgment. The advisory committee is to submit a report and recommendation respecting such regulation to the Secretary within 60 days of the referral to it.

New section 515 prescribes authority and responsibilities of the Secretary with respect to premarket approval of devices classified in class III. (Amendments to sections 301 and 501 made by section 3 of the bill provide sanctions for class III devices required to have premarket approval which do not have such approval.)

New sec. 515(a) prescribes the conditions under which the premarket approval requirements are to be applied to devices in class III which are not exempt under section 520(g) (authorizing investigational use of devices). If the device has been classified in class III under section 513(f) (initial classification of a device not on the market before the date on enactment of the bill), the device must comply

New sec. 513(g) provides that within 60 days of the receipt of a request of any person for information respecting the classification of a device or the requirements applicable to a device under the Act, the Secretary is to provide such person a written statement of information sought.

New sec. 513(h) provides definitions of "general controls," "Class I," "Class II," "Class III," and "panel under section 513".

New section 514 prescribes authority for the establishment of performance standards for devices classified in class II and procedures the Secretary is to follow in establishing such standards. (Amendments to sections 301, 501 and 502 of the Act made by section 3 of the bill prescribe sanctions against class II devices which do not meet applicable standards.)

New sec. 514(a) authorizes the Secretary to establish, by regulation, a performance standard for a class II device (including a device in class III the reclassification of which into class II is effective upon the effective date of a performance standard for it). It requires that performance standards provide reasonable assurance of safe and effective performance and, where necessary, include provisions with respect to construction, components, ingredients, and properties of the device and its compatibility with power systems; testing of the device; demonstration that the device is in conformity with portions of the standards for which tests were required; and the measurement of the performance characteristics of the device. Where necessary, a performance standard may require that distribution of the device be restricted to the extent authorized under section 520(e). Performance standards shall where appropriate prescribe certain labeling for the device. A standard may not include a provision not required or authorized by this subsection. The Secretary is required to provide for periodic evaluation of performance standards. The Secretary is to use the personnel of, and consult with, other Federal agencies and invite participation of private organizations in carrying out his responsibilities with respect to the establishment of standards.

New sec. 514(b) provides that the procedure to initiate a proceeding for the development of a performance standard for a device is publication of a notice of opportunity to request a change in classification of the device (which request must be made within fifteen days of publication of the notice). If such a request is received, the Secretary is to deny the request or give notice of intent to initiate such a change under section 513(e). Prior to acting on a request, which action must be taken within 60 days of the publication of the notice, the Secretary is to consult with the appropriate classification panel.

New sec. 514(c) provides that after the notice to initiate a performance standard proceeding is published (and after resolution of any request for change in classification), the Secretary shall publish a notice inviting the submission, within 60 days after publication of the notice, of an existing standard as a proposed performance standard or an offer to develop a proposed standard. A notice with respect to an offer is to specify the period within which a proposed standard is to be developed. This period may be extended by the Secretary for good cause. The notice is also to include a description of the device, a statement of the nature of the risks associated with the use of the device, a summary of

device; and weighing any probable benefit to health from use of the device against any probable risk of illness or injury from such use. Further, it provides that the effectiveness of a device is to be determined 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. It is further provided that if the Secretary determines that other valid scientific evidence is sufficient to determine the effectiveness of a device, he may authorize the effectiveness of the device to be evaluated on the basis of that evidence.

New sec. 513(b) requires the Secretary to classify all devices (other than a device classified by section 513(f)) intended for human use into one of the three classes established by section 513(a). It requires the Secretary to establish panels of experts to make recommendations to him with respect to classification. Panels are to be comprised 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 is to include as non-voting members a representative of consumer interests and a representative of interests of the device manufacturing industry.

New sec. 513(c) requires the Secretary to organize the classification panels according to the various fields of clinical medicine and fundamental sciences in which devices intended for human use are used and to refer devices to appropriate panels for review. Following review, the panels are to submit their recommendations for classification to the Secretary, a summary of the reasons therefor, and, to the extent practicable, recommendations for the assignment of priorities for the application of performance standards or premarket approval for devices recommended for classification in class II or III. Recommendations submitted to the Secretary are to contain a summary of the reasons for the recommendation, a summary of the data upon which the recommendation is based, and an identification of any risk to health presented by the device for which the recommendation is made. To the extent practicable, a recommendation is to 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. A recommendation for the classification of a device into class I is to include a recommendation as to whether the device should be exempted from the requirements of section 510 (registration), 519 (records and reports) or 520(f) (good manufacturing practices).

This section contains special provisions with respect to panel recommendations for devices intended to be implanted in the human body. These provisions require that with respect to such devices which have been introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of the bill, or are within a type of device so introduced or delivered and substantially equivalent to another device within that type, panels shall recommend classification into class III unless they determine that such classification is not necessary to provide reasonable assurance of safety and effectiveness. If panels do not recommend that such de-

plement the new medical device authority would be approximately $15 million, a $9.3 million increase over the current expenditure although obviously the amount will be determined by Appropriations Acts. In the Committee's view, this increase in expenditures is entirely justified when balanced against the benefits to the public health of safe and effective medical devices. When these costs are weighed against the costs of implementing existing authority (prohibitions against adulteration and misbranding, and efforts to classify certain devices as drugs) undertaken principally through lengthy and expensive court action, the increased costs to the Federal government of the proposed legislation are minimal.

Concern has been expressed with respect to the costs to the economy of increased regulation of the medical device industry. While the Committee recognizes that the new regulatory authority will add to the costs of manufacturing medical devices, particularly those devices which are sophisticated and potentially hazardous to health and which may be required to undergo premarket approval requirements, it strongly believes it to be essential that the American public, including health professionals, is protected from hazardous or ineffective medical devices. The Committee, has, however, included several provisions in the reported bill which are intended to minimize the costs to the industry consistent with the protection of the public health. Such provisions include the authority to exempt certain class I devices from registration, recordkeeping and reporting, and good manufacturing practices requirements; the product development protocol route to premarket approval; and the direction to the Secretary that he is to differentiate between classes of devices in implementing the recordkeeping and reporting requirements such that such requirements will not be unnecessarily burdensome. The reported bill also includes provisions which will enable drugs and devices unapproved for use in this country to be exported, thus providing increased employment opportunities in the United States and enhancing the balance of trade.

Thus, in the Committee's view, H.R. 11124 represents a carefully developed proposal which will assure the safety and effectiveness of medical devices without imposing an unnecessary inflationary burden on the Federal government or the regulated industry.

This subject was never raised by any witness or member of the Subcommittee at hearings on the device legislation. This Department strongly opposes any amendment to the criminal liability provisions of the Act. Our position has been set forth in prior testimony and is summarized in the appended enclosure.

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

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

Sincerely,

MARJORIE LYNCH,
Under Secretary.

Enclosure.

The following enclosure accompanied the Under Secretary's letter:

STRICT CRIMINAL LIABILITY

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

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

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

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

"Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity for informing themselves of the existence of conditions imposed for the protection of con-

cies as determined by the Secretary. However, approval would be contingent upon application to the Secretary, opportunity for informal hearing, and a determination by the Secretary that the export of the drug to such country is not contrary to public health and safety.

The proposed bill contains identical provisions with respect to devices that are not in compliance with section 514 or 515 or that are banned under section 516, as well as antibiotic drugs for which a regulation or release is not in effect under section 507. Existing law with respect to foods and cosmetics is not changed by the proposed legislation.

Further, the reported bill would authorize the export of an unapproved new animal drug or animal feed containing a new animal drug, if, after submission of an application, the Secretary determines, after notice and opportunity for informal hearing, that (1) such drug or feed meets the four existing requirements described above. (2) the export of the drug or feed is 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 is to be exported has authorized or approved it for its intended use. or, if there is no such agency, its export is not contrary to public health and safety. The requirement for affirmative approval by the Secretary in order to export unapproved new animal drugs or feeds was included by the Committee because of its concern that such drugs could be reintroduced into the United States through the importation of treated animals or carcasses.

An additional safeguard is provided in order to insure that an unapproved drug, device or animal drug which is being exported is not reintroduced into the United States, thereby threatening the health or safety of persons in this country. Under new section 801(d)(7), the Secretary is authorized, after providing notice and opportunity for an informal hearing, to issue an order prohibiting the export of any device which does not comply with requirements of section 514 or 515, or which is banned under section 516; any antibiotic drug for which a regulation or release is not in effect under section 507; any new drug not in compliance with section 505; or any new animal drug or new animal feed bearing or containing a new animal drug, which has not complied with the requirements of section 512, if he determines that the export of such device, drug, or animal feed is inconsistent with the health and safety of persons within the United States. This amendment will insure that even if such an article has been approved by a foreign country (and thus authorized to be exported under the reported bill except in the case of animal drugs or medicated feeds) or has been authorized by the Secretary to be exported, its continued export may nevertheless be prohibited.

The amendments do not modify existing law with respect to the export of articles which have received approval under the Act but which, in order to meet export requirements, are not in a form identical to that sold in the United States. Such articles would be deemed "adulterated", "misbranded" or otherwise in violation of the law but for the exemption afforded by section 801(d), as amended.

The Committee has given extensive consideration to the scope of review courts are to afford agency actions under the proposed legislation. Under relevant provisions of the Administrative Procedure Act, actions of the Secretary taken under the proposed legislation would be reviewable under the arbitrary and capricious test, and not on the basis that agency action was unsupported by "substantial evidence" since the latter test is required only in instances in which a trial-type hearing is required to be conducted by an administrative agency. However, the Committee recognizes that some actions to be taken under the proposed bill involve extremely significant economic and public health considerations. Thus, the proposed legislation provides that (1) promulgated regulations that establish, amend or revoke a performance standard for a device, (2) orders issued after the administrative review afforded to actions taken by the Secretary with respect to applications for premarket approval or product development protocols, and (3) promulgated regulations making a device a banned device (other than a proposed regulation made effective upon its publication) are subject to the substantial evidence of record test provided under 5 U.S.C. 706(2)(E). All other actions reviewable under the proposed legislation would, under 5 U.S.C. 706(2)(A), be reviewed on the basis of the "arbitrary and capricious" test.

The Committee recognizes that recent case law casts doubt on whether differences exist between the scope of review to be provided under a "substantial evidence" test and the requirement that agency action not be "arbitrary and capricious". The distinction between the two types of review has been eroded by recent decisions and any difference in the extent to which these standards require scrutiny into the factual basis for agency action is no longer clear. However, the courts are insisting that actions reviewable under the "substantial evidence" test be supported by an elaborate record which facilitates searching review. Thus, in requiring that certain actions of the Secretary which involve significant economic and public health implications be reviewed on the basis of substantial evidence, the Committee is insisting that the administrative record of such proceedings be adequate to permit courts to scrutinize the reasons for agency action.

Finally, the proposed legislation stipulates that the bill's provisions authorizing judicial review are in addition to, and not in lieu of, other remedies provided by law. Except for regulations and orders specifically authorized to be reviewed under the provisions of section 517, review would be governed by provisions of the Administrative Procedure Act and title 28, United States Code.

ASSISTANCE FOR SMALL MANUFACTURERS OF DEVICES

During hearings and development of the reported bill, the Committee became cognizant of the potentially detrimental economic impact implementation of this legislation might have on small device manufacturers. For this reason, several provisions of the bill are designed to avoid unnecessary regulation of medical devices. Provisions authorizing the exemption of class I devices from certain provisions of the bill, limiting traceability and recordkeeping and reporting requirements, and authorizing the use of product develop-

During the Classification Process.—(1) the promulgation of a regulation classifying a device into class I, (2) the promulgation of a regulation changing the classification of a device to class I, and (3) an order in response to a petition to reclassify a "new" device initially classified into class III.

During the Standard-Setting Process.—(1) an order denying a request for reclassification after initiation of a standard-setting proceeding, and (2) the promulgation of a regulation establishing, amending or revoking a performance standard.

During the Premarket Approval Process.—(1) an order under section 515 denying a request for reclassification after initiation of a proceeding to require premarket approval of a device, (2) the promulgation of a regulation requiring that a device have an application for premarket approval, (3) the promulgation of a regulation amending or revoking such requirement, and (4) an order issued following the administrative review authorized under section 515(g).

Banned Devices.—the promulgation of a regulation making a device a banned device (except for a proposed regulation made effective immediately upon its publication, since final action on that regulation does not occur upon publication).

Good Manufacturing Practices.—an order with respect to a petition for variance or exemption from a good manufacturing practices requirement.

Exemptions for Investigational Use.—(1) an order disapproving an application for an exemption of a device for investigational use, and (2) an order withdrawing such exemption.

The proposed legislation authorizes persons adversely affected by such regulations or orders to obtain review by filing a petition in the United States Court of Appeals for the District of Columbia or for the circuit in which the adversely affected person resides or has his principal place of business. As under present law, "persons adversely affected" can include consumers. Provisions of Title 28, United States Code, and the Federal Rules of Civil Procedure can be used to consolidate multiple challenges to regulations and orders and thus prevent duplication and waste.

After receipt of a petition for judicial review under section 517, the Secretary is to file with the court the record of the proceeding on which he based the regulation or order. The "record" of the proceeding is defined in the proposed legislation as consisting of all notices and other matter published in the Federal Register, all information submitted to the Secretary with respect to the regulation or order, proceedings of any advisory committee, proceedings of any hearing that is held, and any other information identified by the Secretary at the time of the administrative proceeding as being relevant to the regulation or order. The purpose of this definition is to reduce confusion concerning what is included in the record of a medical device regulation or order which is to receive judicial review. The Administrative Procedure Act provides that a reviewing court shall examine the "whole record" compiled by an agency in determining whether an agency action is adequately supported (5 U.S.C. 706). However, there has been confusion as to what this record includes, particularly in instances in which there has been no formal evidentiary hearing. Thus,

TRACEABILITY

The ability to trace a device through the various channels of commercial distribution can serve as a valuable regulatory tool in protecting the public health. Individual or batch numbering or coding of products that present significant health hazards would greatly facilitate the recovery of such products when necessary. For example, if it is discovered that a type of cardiac pacemaker is defective, it is of critical importance to know where each such device is located. On the other hand, traceability can be extremely expensive and would be unnecessary for many medical devices, particularly those which are unlikely to pose a health hazard. For these reasons, the reported bill contains a provision (new section 520(j) of the Act) specifying that no regulation under the provisions of the Federal Food, Drug, and Cosmetic Act as amended by the bill may impose requirements for the traceability of a type or class of medical device unless necessary to assure the protection of the public health. The Committee would expect the Secretary, in implementing this provision, to establish categories of products for the purpose of defining the degree of distribution traceability needed to protect the public health.

THE INFORMAL HEARING

At several stages of the regulatory process contemplated by the proposed legislation, persons adversely affected by actions taken by the Secretary are provided an opportunity for an informal hearing. Opportunity for an informal hearing is authorized prior to the reclassification of a "new" device initially classified into class III or of a device regulated as a "drug" prior to the date of enactment of the bill. Before the Secretary makes an amendment to a performance standard effective upon its publication, withdraws approval of an approved premarket approval application, revokes an approved product development protocol, declares an approved product development protocol not completed, or revokes approval of a device provided by the declaration that a product development protocol has been completed, opportunity for an informal hearing must be provided. In addition, opportunity for informal hearing is authorized prior to banning a device (except in instances in which a proposed regulation banning a device is made effective upon its publication in which case opportunity for informal hearing is to be provided before final action on the proposed regulation is taken), prior to disapproving a plan to repair, replace or refund the purchase price of a device, after an order disapproving an application for exemption for investigational use, and prior to withdrawing such exemption. Informal hearings are also available under the provisions authorizing the export of certain drugs and devices. Finally, an informal hearing serves as the mechanism for appeal of an order temporarily detaining a device.

The Administrative Procedure Act requires administrative agencies to hold a trial-type hearing prior to taking regulatory action in certain cases. Other actions are governed by the requirements of notice and opportunity for comment. In the Committee's view, neither procedure would be an appropriate mechanism with respect to the major health decisions described above. Trial-type hearings are often cumbersome

would expect the Secretary to afford a device manufacturer opportunity to demonstrate the need for confidentiality prior to releasing such data and information if the Secretary has reasonable question concerning their status.

Second, proposed new section 520(c) of the Act, would place restrictions on information relating to medical devices obtained by the Secretary under relevant provisions of the bill which is exempt from disclosure pursuant to 5 U.S.C. 552(b)(4). Under this provision, such information may not be disclosed by the Secretary except to officers and employees of the Department of Health, Education, and Welfare involved in the implementation of the proposed legislation. In addition, consistent with the "competitive advantage" characteristics of a trade secret, new section 520(c) requires that such trade secret information may not be used by the Secretary as the basis for reclassification of a device from class III to class II or as the basis for the establishment or amendment of a performance standard for a device reclassified from class III to class II.

Obviously, absent these provisions, trade secrets could be used to destroy competitive advantage without being disclosed to the public. To use trade secret information submitted in connection with a class III device as the basis for "downgrading" it into class II status—and thus allowing it to be replicated by competitors to conform to a standard—would destroy the originator's competitive advantage and could serve to stifle the initiative for innovation.

The Committee recognizes that the question of what constitutes a trade secret which is to enjoy protection under the Federael Food, Drug, and Cosmetic Act and other statutes has been the subject of litigation, and further litigation is likely in the future. The provisions of the bill are not intended by the Committee to alter in any way existing law respecting what constitutes a trade secret. The Committee does expect that, where appropriate, data submitted in connection with medical devices should be granted such confidential status as is required by law to be granted with respect to data submitted with new drug applications.

Release of Trade Secret Information to Contractors.—As noted above, under section 301(j) of the Act, the Secretary is prohibited from releasing trade secret information obtained under certain provisions of the Act except in the course of legal proceedings. This provision has prevented the Secretary from using contractors for computerization of information concerning new drugs. In order to overcome this problem, and avoid similar problems in implementing the new authorities concerning medical devices, the proposed legislation would add a new section to the Act (section 707) which authorizes the Secretary to release information exempt from disclosure under 5 U.S.C. 552(b)(4), and which the Secretary is not prohibited from using, to a person not in his employment if such person requires the information in connection with an activity undertaken by contract with the Secretary. Further, this new section provides that as a condition to the release of such trade secrets and other confidential information to contractors. the Secretary shall require that the person receiving it take prescribed security precautions.

tion order who completes processing of the device assumes the risk that the finished product may be subject to further regulatory action if a court upholds the determination of the inspector and deems the product adulterated or misbranded.

TRADE SECRETS AND PUBLIC AVAILABILITY OF INFORMATION

Background.—The Committee recognizes the need for protection of any trade secret material submitted to the Food and Drug Administration under the provisions of the proposed legislation by manufacturers of medical devices if their competitors are not to gain unfairly from the time and financial commitment expended in developing a device. It also recognizes the need for the public to receive information gained by a manufacturer during the development of a device so that the public may assess the propriety of actions taken by the Secretary with respect to medical devices. In the Committee's view, the proposed legislation accomplishes both purposes.

The status of trade secret information acquired by the Secretary is governed by the interaction of three statutes. First, section 301(j) of the Federal Food, Drug, and Cosmetic Act prohibits the using by any person to his advantage, or the revealing of, any information acquired under relevant sections of the Act concerning any method or process which as a trade secret is entitled to protection. (Exceptions are made for officers and employees of the Department of Health, Education, and Welfare and the courts.) Second, the general Federal confidentiality statute (18 U.S.C. 1905) prohibits officers or employees of the United States from divulging information which concerns or relates to trade secrets. Third, the Freedom of Information Act contains a provision (5 U.S.C. 554(b)(4)) which exempts "trade secrets and commercial or financial information that is privileged or confidential" from the requirement of mandatory public disclosure.

The difficulty with these provisions is that they provide no definition as to what constitutes a trade secret. Indeed, it is widely recognized that an exact definition of a trade secret is impossible, since such subjective considerations as the extent to which information is generally known and the value of information to competitors govern whether information constitutes a trade secret. According to the Restatement on Torts, if there is a key to determining whether information has trade secret status, it is that it has characteristics that give its possessor an opportunity to obtain an advantage over competitors who do not know it.

Protection of Trade Secret Information.—The proposed legislation contains two provisions designed to protect the confidentiality of trade secrets and prohibit their use to a competitor's advantage. First, section 3(b)(3) of the bill would extend the prohibitions of section 301(j) of the Act to trade secret material received under relevant provisions of the proposed legislation relating to medical devices. The concept of "competitive advantage" will be extremely important to the implementation of the provisions of section 301(j). As is described elsewhere in this report, all class III devices will be required to undergo premarket approval. Thus, a manufacturer of a class III "pioneer" device which has an approved application for premarket approval enjoys some protection from mere replication of the device by a com-

the requirement would not cause the device to be in violation of a requirement under the Act.

In the Committee's view, requirements imposed under the California statute serve as an example of requirements that the Secretary should authorize to be continued (provided any application submitted by a State meets requirements pursuant to the reported bill).

INSPECTIONS RELATING TO DEVICES

In its present form, section 704 of the Act authorizes the Secretary to inspect establishments in which medical devices are manufactured or held. This authority is limited to physical examination of equipment, materials, containers, and labeling and does not extend to records. Section 704 contains comparable authority with respect to non-prescription drugs but authorizes, with certain limitations, the inspection of records concerning prescription drugs.

The proposed legislation would amend section 704 of the Act to (1) make its provisions with respect to establishments in which prescription drugs are manufactured or held applicable to establishments in which restricted devices are manufactured or held and (2) require each person required to maintain records under section 519 and section 520(g) to permit access to and verification of such records.

Thus, under the reported bill, inspectors would be authorized to inspect records, files, papers, processes, controls and facilities to determine whether restricted devices are adulterated or misbranded. As is the case with respect to inspection authority concerning prescription drugs, inspection of establishments manufacturing or holding restricted devices may not extend to financial data, sales data (other than shipment data), pricing data, personnel data (other than that relating to the qualifications of technical and professional personnel), or research data.

In addition to the authority described above with respect to restricted devices, inspection authority is also provided for records that are required to be maintained under regulations promulgated under the records and reports requirements of new section 519 of the Act, or under the investigational device provisions of new section 520(g). Inspection authority under this provision is not limited to restricted devices but applies to any device for which there is an applicable record-keeping regulation under section 519 or 520(g). This authority is intended by the Committee to be applicable to any person required under such regulations to maintain records and to any person who is in charge of or has custody of such records. It is intended by the Committee to apply to records within testing facilities as well as records maintained in manufacturing establishments.

Under section 510 of the Act (relating to registration of drug manufacturers) each establishment required to register with the Secretary must be inspected pursuant to section 704 at least once every two years. The Committee was disturbed to learn that lack of adequate manpower and resources has precluded the Food and Drug Administration from inspecting such establishments every two years, despite the statutory mandate. This situation, in the Committee's view, presents a potentially grave threat to public health and safety.

Third, the reported bill requires that informed consent be obtained from each human subject of a proposed investigation or his representative. This requirement is subject to a very limited exception: Where the investigator conducting or supervising the proposed testing determines in writing that there exists a life-threatening situation involving the subject which necessitates the use of the device, that it is not feasible to obtain informed consent from the subject, and that there is not sufficient time to obtain such consent from his representative, the requirement to obtain informed consent does not apply. Such determinations are to be concurred in by a licensed physician not involved in the testing of the device, unless immediate use of the device is necessary to save the life of the subject and there is not sufficient time to obtain such concurrence. In the Committee's view there are very few circumstances in which the exception from informed consent can be, or should be, applied. In prescribing the conditions to which this exception is subject, the Secretary should provide that any investigator who is unable to obtain informed consent under the exception shall promptly report his determination to the person who has received the exemption for submission to the Secretary.

The Committee recognizes that the concept of the adequacy of informed consent is the subject of study by the National Commission on the Protection of Human Subjects in view of changing social policy and advancing biomedical technology. Until the report from the Commission is completed, the Committee would expect the Secretary to adopt regulations governing informed consent similar to those now in effect with respect to biomedical research supported by the Department of Health, Education, and Welfare.

The reported bill provides that applications for exemptions for investigational use are to be deemed approved on the thirtieth day after their submission unless disapproved by the Secretary. This provision is not applicable to applications to investigate a banned device, however. Such applications must be affirmatively approved before testing may commence.

CUSTOM DEVICES

Medical devices are sometimes ordered from manufacturers by members of the health professions to conform to their own special needs or to those of their patients. In some instances, health professionals themselves develop or alter devices to serve such needs. Among examples of devices in which important features are customized are orthopedic and other prosthetic devices, dental devices, and specially-designed orthopedic footwear. Although the Committee believes that it would be inappropriate to authorize the commercial distribution of such devices in instances in which they do not conform to performance standards or would be required to undergo premarket approval, there are instances in which limited use of so-called "custom devices" is appropriate.

Thus, the Committee proposal (new section 520(b) of the Act) would exempt from otherwise applicable performance standards or requirements under the premarket approval provisions of the bill custom devices which, in order to comply with the order of a physician, dentist or other specially qualified person, necessarily deviate from such requirements. This provision is applicable only to devices which

class II, he may provide that the reclassification not take effect until the effective date of the performance standard for such device. General controls would continue to apply to a class II device unless specifically superseded by a provision of a standard.

Class III Devices.—If a new device is classified into class III, it may not be marketed until it meets premarket approval requirements. If it is a device which is on the market before the date of enactment, it is not required to have an approved application for premarket approval until the Secretary promulgates a regulation requiring premarket approval. Upon promulgation of such regulation, an application for premarket approval or a notice of completion of a product development protocol must be filed for the device within 90 days after the regulation was promulgated, or 30 months after the device was classified, whichever is later. General controls continue to apply to class III devices unless specifically superseded by action of the Secretary respecting premarket approval of the device. In some instances, approval of a premarket approval application may be contingent upon a demonstration of conformance with an applicable performance standard.

Thus, classification of a device into class II and classification of a device on the market before the date of enactment into class III do not trigger immediate application of performance standards or premarket approval requirements. Classification into class III does, however, serve the important purpose of providing notice to manufacturers and importers of such devices that they must begin preparation for submission of applications for premarket approval.

The Committee believes that the thirty month "grace period" afforded after classification of a device into class III before a device must obtain premarket approval is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket approval. Because of this thirty month moratorium, the Committee did not provide for an extension of the ninety day period after promulgation of a regulation requiring premarket approval within which an application for premarket approval or a notice of completion of a product development protocol must be submitted. If manufacturers and importers of class III devices initiate investigations only upon promulgation of the regulation requiring premarket approval, they risk having inadequate time to submit an approvable application or PDP. In such cases their devices would be required to be removed from the market.

EXEMPTIONS FOR DEVICES FOR INVESTIGATIONAL USE

The Committee recognizes the necessity to encourage the discovery and development of medical devices intended for human use and the need for scientific investigators to maintain freedom to do so. On the other hand, research on medical devices in the developmental stage must not endanger the public health and must assure the highest ethical standards, including informed patient consent.

Thus, the reported bill contains a provision (new section 520(g) of the Act) authorizing the Secretary to exempt devices from otherwise applicable provisions of the Act relating to adulteration and from major new provisions of the proposed legislation to permit their shipment for investigational use. Under the bill, the Secretary is required to prescribe procedures and conditions under which devices may

are to be ongoing committees constituting an integral part of the regulatory scheme under this legislation.

Classification panels are required to submit their recommendations with respect to all devices on the market before the date of enactment within 1 year after the date on which funds are first appropriated for the implementation of the provision. Each recommendation for the classification of a device is to be accompanied by a summary of the reasons for the recommendation, a summary of the data on which the recommendation was based and an identification of any risks to health which may be associated with the device. In the case of a recommendation for class II or class III classification, the recommendation shall, where practicable, include a recommendation for the assignment of a priority for the application of the requirements of performance standards or premarket approval. As noted earlier in the report, a panel must recommend that any device intended to be implanted in the human body which was marketed prior to the date of enactment be classified into class III unless it determines that such classification is not necessary to provide reasonable assurance of safety and effectiveness. In such cases, panel recommendations are to include reasons for not recommending classification into class III. If a panel recommends classification of a device into class I, it must also recommend whether the provisions of sections 510 (registration), 519 (records and reports), or 520(f) (good manufacturing practice requirements) should apply to the device.

In requiring a panel's classification recommendation to include a summary of the reasons for the recommendation and a summary of the data upon which the recommendation is based, the Committee's objective is to assure that the record accurately reflects the basis for the panel's recommendation. The use of the term "data" is not intended to refer only to the results of scientific experiments but should also consist of less formal evidence, other scientific information, or judgments of experts, when available. The requirement is not intended to imply that a panel must have received evidence with respect to safety and effectiveness of a device before it can make a classification recommendation. Under the proposed legislation, the burden of providing evidence substantiating the safety and effectiveness of a medical device rests upon the manufacturer, and the absence of sufficient data may be referred to in a panel's recommendation as the reason for classification of a device in class III.

Classification by the Secretary.—Following receipt of a recommendation from a classification panel, the Secretary is to publish the recommendation, provide opportunity for comment, and, by regulation, classify the device. The proposed bill contains requirements respecting classification of devices into class I and respecting implantable devices which parallel those required of the panels. It requires the Secretary to classify all devices on the market before the date of enactment which are intended to be implanted in the human body into class III unless he determines that such classification is not necessary to provide reasonable assurance of safety and effectiveness, in which case the proposed regulation classifying the device is to be accompanied by a statement of the reasons therefor. A regulation classifying a device into class I is to prescribe which, if any, of the requirements of

ment of the legislation and not substantially equivalent to a device on the market prior to such date be classified into class III and undergo premarket approval prior to entry on the market. Reclassification is not available to a "new" implantable device before the device has an approved application for premarket approval.

The Committee expects that these provisions will have the effect of requiring that such types of devices as heart pacemakers, intraocular lenses and intrauterine devices, as well as other types of devices which have been associated with incidents of significant illness or injury, be classified into class III. Those devices which have a long experience with safe use, such as dental devices, bone screws and hip pins, would normally not be classified into class III. New implantable devices, for which no market experience exists, will be required to undergo premarket approval to assure safety and effectiveness.

Special Treatment of "Devices" Regulated as "Drugs".—The reported bill's expanded definition of "device" clarifies the types of articles subject to regulation under provisions of the new legislation. As a result, several products currently being regulated as drugs and antibiotic drugs will fall within the new definition of device.

For this reason, the proposed legislation (new section 520 (*l*) of the Act) contains certain transitional provisions designed to place articles which are devices under the new definition but which are presently being regulated as new drugs into comparable regulatory status as devices. Under these provisions, all such products are automatically classified into class III and are accorded treatment consistent with their status as drugs. Thus, for example, on the date of enactment, a product which is a device under the new definition, but which was the subject of an approved new drug application, is automatically considered to be a device with an approved application for premarket approval. In instances in which a new drug application has been filed but for which no order has been issued, the new drug application is considered as an application for premarket approval, and the Secretary is required to act on the application within the period in which he would have been required to act on the new drug application.

An article which would constitute a device under the new definition but which has in effect an application for investigational use as a drug is to retain its status as an investigational drug until 90 days after the promulgation of regulations implementing the bill's new provisions with respect to exemptions for devices for investigational use. This will afford the sponsor opportunity to submit and have approved an application for investigational use as a device.

Opportunity to petition for reclassification to class II or I is afforded the manufacturer or importer of any device classified into class III as a result of these provisions.

Devices substantially equivalent to those described above, as well as those declared to be new drugs and those which are the subject of legal action because of the determination that they are new drugs, are, under the transitional provisions, required to have approved applications for premarket approval upon the date of enactment of the proposed bill, with provision for the filing of a petition for reclassification which operates to stay the requirement for a period not to exceed 120 days.

the premarket approval category if there is insufficient information that general controls will assure reasonable safety and effectiveness and there is insufficient information upon which to establish a standard which will provide such assurance. In some cases, there may be sufficient information to classify a device for an important use in the standards category (e.g., a battery-operated drill) while another device for the same use may be required to undergo premarket approval (e.g., a nuclear-powered drill) because of the need for investigation and review of additional data on safety and effectiveness.

The phrase "presents a potential unreasonable risk of illness or injury" has two significant features. First, the requirement that a risk be unreasonable contemplates a balancing of the possibility that illness or injury will occur against benefits from use. Second, the risk need only be a potential one. The risk may be one demonstrated by reported injuries or it may simply be foreseeable. The fact that a device is being marketed without sufficient testing is an adequate basis for the Secretary's conclusion that the device presents a potential unreasonable risk to health.

Classification of "New" Devices.—The reported bill contains special provisions with respect to the classification of medical devices not on the market prior to the date of enactment of the bill. These provisions govern any device which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment unless it is substantially equivalent to a device so introduced or delivered, or substantially equivalent to a device that was not so introduced or delivered, but which has subsequently been classified into class I or II. These so-called "new" devices are automatically classified into class III and cannot be marketed until they have in effect an approved application for premarket approval or have been reclassified into class I or II by the Secretary. Reclassification may be accomplished by petition to the Secretary who, after consultation with the appropriate classification panel and opportunity for informal hearing, is to affirm or deny the petition within 180 days after it is submitted.

Obviously, whether or not a product is in "commercial distribution" on the date of enactment will be of critical importance to many device manufacturers. "Commercial distribution" is the functional equivalent of the popular phrase "on the market". It is not intended to include mere announcements of intent to market a device.

The term "substantially equivalent" is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The Committee believes that the term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not so narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness. Thus, differences between "new" and marketed devices in materials, design, or energy source, for example, would have a bearing on the adequacy of information as to a new device's safety and effectiveness, and such devices should be automatically classified into class III. On the other hand, copies of devices marketed prior to enactment, or devices whose variations are immaterial to

The first type of review is an adjudicative hearing pursuant to the provisions of the Administrative Procedure Act. This review is to be required upon the request of a petitioner unless the Secretary finds the petition to be without good cause. Alternatively, review is afforded through referral of the contested action to an expert advisory committee (which may not be a classification panel) established by the proposed bill for review and issuance to the Secretary of a report and recommendations. Such reports and recommendations are to be made public.

These types of review are mutually exclusive and are available at the option of the petitioner except, as noted above, where the Secretary finds a petition for an adjudicative hearing to be without good cause and denies the request.

Neither form of administrative review operates to stay the contested action under review.

CLASSIFICATION OF MEDICAL DEVICES

The primary mechanism by which the proposed legislation would distinguish between devices which are simple in design and represent little risk to health and those which are sophisticated and potentially hazardous is a carefully-designed classification process, similar to that recommended by the Cooper Committee.

Proposed new section 513 of the Act requires the classification of all medical devices intended for human use into one of three categories depending upon the degree of regulation necessary to provide reasonable assurance of safety and effectiveness. The three categories, in ascending order of restrictiveness, are class I, general controls; class II, performance standards; and class III, premarket approval. The hierarchy is achieved by specifying that (1) standards are to be required only in instances in which general controls are insufficient to provide reasonable assurance of safety and effectiveness, and (2) premarket approval is not to be required unless insufficient information exists to determine that general controls are adequate or to establish a standard to provide reasonable assurance of safety and effectiveness.

General Controls.—Under the proposed legislation, two types of devices are to be classified into class I. The first is comprised of those devices for which the controls authorized under sections 501, 502, 510, 516, 518, 519, or 520 (referred to as "general controls" and described in detail earlier in this report) are sufficient to provide reasonable assurance of safety and effectiveness. The second type of device which is to be classified into class I consists of those devices for which insufficient information exists with which to determine that general controls are sufficient or to establish a standard to assure safety and effectiveness, but which (1) do not purport or are not represented to be for uses of substantial importance in supporting, sustaining, or preventing impairment of human life or health, and (2) do not present potential unreasonable risks of illness or injury. The Committee recognizes that no device may fall into this latter category. It is, however, necessary to include it in the proposed legislation in view of the requirements (described below) that two determinations be made prior to classification of a device into class III.

an application should be construed by the Secretary as receipt of an application containing all information required by the proposed legislation and regulations issued thereunder. However, the Committee is well aware of the current practice of the Food and Drug Administration with respect to new drug applications (which also must be approved or disapproved within 180 days of receipt) whereby such applicants are often notified of the need for more information only a few days before the 180 day statutory period expires. The Committee does not intend that this be the practice with respect to applications for premarket approval of devices. Applicants should be notified of deficiencies promptly, and should be afforded statements of the measures required to place their applications in approvable form so that they may be submitted to classification panels.

Approval of an application may be conditioned on restrictions on the sale or distribution of a device authorized under new section 520(e) of the Act, described elsewhere in this report.

The reported bill authorizes the Secretary to withdraw approval of an application for premarket approval if he finds, after obtaining advice on scientific matters from the appropriate classification panel and after providing opportunity for an informal hearing, that the device is unsafe or ineffective; that new information indicates a lack of showing of reasonable safety or effectiveness; that the approved application contained an untrue statement of a material fact; that the applicant has failed to maintain records, make reports, permit access to records, or has failed to register or list devices; that new information indicates a failure to comply with good manufacturing practices; that the labeling of the device is false or misleading; or that the device fails to comply with an applicable performance standard.

New information justifying withdrawal of approval may be based upon a reevaluation of data that enables experts to identify a problem with a product that had not previously been known to exist. A device may have been approved based upon an evaluation of the safety and efficacy of certain of its aspects; later, it may be discovered that other aspects of the product relevant to its safety and effectiveness necessitate withdrawal of approval.

Product Development Protocol.—The Committee recognizes that many medical devices are subject to frequent modification during development. For this reason, it has designed a provision, termed a product development protocol (PDP), whereby the investigation of a device and the development of information necessary for its approval are merged into one regulatory mechanism.

A PDP for a class III device is to be submitted to the Secretary for approval. It is to contain a description of the device to be developed under the protocol, a description of any preclinical or clinical trials to be conducted on the device, including results to be expected from them, and any other relevant information. A protocol is to be approved or disapproved within 120 days of receipt.

Approval of a PDP for a device is contingent upon the Secretary's determination that the procedure is appropriate in lieu of the requirements to submit an application for premarket approval after a device has been developed and investigated. The Secretary cannot require that a device undergo development through the PDP pro-

respect to the development of proposed standards. Of course, a final regulation can differ from a proposed performance standard, although the Committee would expect that any significant departures from the proposed standard would be explained in the preamble to the final regulation. Although the standard-setting process does not require a hearing prior to establishment of a standard, the Committee believes that significant public participation is insured through the extensive opportunities for public comment and participation and the opportunity for review of scientific issues by the advisory committee.

Advisory committees established to review proposed regulations respecting standards will be subject to the requirements of the Federal Advisory Committee Act. These requirements include the establishment of a charter for the committee, opportunity for interested persons to participate, the keeping of minutes, and the requirement that, except as authorized by that Act, committee meetings be open to the public. The Committee does not intend that the reported bill's prohibitions on the use of classification panels as standard-setting advisory committees preclude the appointment of individual members of classification panels to such advisory committees.

Effective Dates of Standards.—As a general rule, standards do not become effective immediately upon their promulgation. The Committee recognizes that it will take some time for devices on the market on the date of the establishment of a performance standard to conform to the standard. Thus, the reported bill requires that a regulation establishing a performance standard is not to take effect before one year after the date of publication unless an earlier date is necessary for the protection of public health and safety. Further, the bill requires that the effective date is to be established so as to minimize, consistent with public health and safety, economic loss to and disruption of domestic and international trade. These provisions are intended to allow depletion of inventories of class II devices which do not conform to newly promulgated standards, but which do not present a risk to health.

Under the bill, "stockpiling" of nonconforming devices is discouraged, since standards will apply to all devices in commercial channels on their effective date.

A proposed amendment to a performance standard may be made effective upon its publication if the Secretary determines, after opportuntiy for an informal hearing, that such action would be in the public interest. A device which does not conform to the amended standard could, however, continue to be marketed until final action is taken on the proposed amendment. This expedited approach is intended to stimulate desirable changes in standardized products without penalizing manufacturers of products on the market that conform to existing standards.

PREMARKET APPROVAL

Introduction.—Devices classified into class III will be required to undergo premarket approval. As presented in greater detail elsewhere in this report, there are three instances in which devices may be classified into class III. First, devices on the market before the date of enactment may be classified into class III by the Secretary following receipt of recommendations of classification panels.

a standard should be sufficient to advise interested persons of problems to be addressed by a performance standard. Both the statement of risks and summary of data should include pertinent portions of panel classification recommendations with respect to the device.

In order to assure that only the offers of qualified persons are accepted, the proposed legislation requires that the Secretary promulgate regulations requiring offerors to submit relevant information respecting their financial stability, expertise, experience, and potential conflicts of interest (including financial interests in the device for which a proposed standards is to be developed). The disclosure requirements will permit the Secretary to disqualify offerors whose efforts would be in any way impeded by financial interests or other conflicts of interest. In instances in which more than one offer is submitted by technically competent persons, the Committee would expect the Secretary to afford priority to an offeror who has no proprietary interest in devices for which a standard is to be developed.

Third, the proposed legislation provides two alternatives to acceptance of offers to develop performance standards. If the Secretary determines that a Federal agency, including the Food and Drug Administration, can develop a standard, he may (if the determination is made with respect to any agency within the Department of Health, Education, and Welfare) proceed to develop the standard, or authorize another Federal agency to develop a standard. Or, if the Secretary determines that an appropriate performance standard has been or is being developed by a Federal agency or other qualified entity, he may accept that standard as a proposed performance standard or as the basis upon which one may be developed.

The Committee understands that the Food and Drug Administration has undertaken activities with respect to performance standards and, in fact, has developed or assisted in the development of several standards for medical devices. These standards may be acceptable as proposed performance standards under the provision described above.

The Committee also understands that several "voluntary" medical device standards have been developed or are in the process of being developed by various standard-setting organizations. If the Secretary determines that a standard-setting organization has appropriate qualifications and that a voluntary standard has been subjected to appropriate scientific consideration, it may be accepted, in whole or in part, as a proposed performance standard.

Fourth, if the Secretary does not determine that a Federal agency has developed or can develop a performance standard or that a standard has been or is being developed, he shall accept one—and may accept more than one—offer to develop a performance standard if he determines the offeror is technically competent and qualified under the criteria described above. In order to enable standards to be developed by consumer and professional organizations not financially able to develop standards, the proposed legislation authorizes the Secretary to contribute to the costs of develonmept of a proposed standard.

The proposed legislation requires the Secretary to prescribe regulations governing the development of performance standards by persons whose offers are accepted. These regulations must require that such standards be supported by test data or other information, provide opportunity for interested persons to participate in the development of

provide such assurances. Persons subject to an order with respect to a petition for an exemption or variance are entitled to an informal hearing on the order.

PERFORMANCE STANDARDS

Devices classified into class II eventually will be required to conform to performance standards. Performance standards are to be promulgated by regulation, usually after opportunity for submission of existing standards developed by public entities or by private standard-setting organizations as proposed standards or opportunity for public or private entities to develop proposed standards. The proposed legislation would add a new section 514 to the Federal Food, Drug, and Cosmetic Act to govern the content of performance standards and the procedures for their development and establishment.

Content of Performance Standards.—A performance standard established for a device under the proposed legislation must provide reasonable assurance of a device's safe and effective performance. Although use of the term "performance standard" reflects a preference for standards which allow the fullest use of technological alternatives, the Committee does not intend the term to be construed as excluding design-related requirements, as it is when it is used in the engineering community. Design-related requirements that are necessary to provide reasonable assurance of safe and effective performance or that improve device safety and effectiveness by reducing the likelihood of human error should be included in a performance standard.

The reported bill further provides that, where necessary to provide reasonable assurance of safety and effectiveness, a standard shall include (1) provisions respecting the construction, components, ingredients and properties of the device and its compatibility with power systems, (2) provisions for the testing of the device by the manufacturer to assure conformity with the standard, or, where no more practicable means are available, by the Secretary or a person at his direction, (3) provisions for the measurement of the performance characteristics of the device, (4) provisions requiring that the results of tests show the device is in conformity with portions of the standard for which tests are required, and (5) a provision requiring that the sale and distribution of the device be restricted. In addition, a performance standard can require certain labeling for the proper use of a device.

The Committee intends that the provisions authorizing testing permit both clinical testing and testing relevant to technical characteristics of a device. Instances in which the Secretary requires third-party testing of sample or individual devices should not be regarded as government procurement.

Provisions for the measurement of performance characteristics of a device may include quality control procedures, means for users to ascertain device performance, and methods for use by the Secretary in judging compliance with a performance standard.

The Committee would expect that the bill's authority to require that a performance standard include a demonstration that a device is in conformity with portions of a standard for which tests are required would ordinarily be implemented through procedures whereby manufacturers either certify to purchasers that the device conforms to an

the public health and to facilitate implementation of the Act. Second, each request for submission of a report must state the reason for the request and identify the requested information. Third, a manufacturer, importer, or distributor of a class I device may not be required to maintain records not in his possession with respect to such a device or submit reports not in his possession or on a periodic basis unless necessary to determine if the device should be reclassified or is adulterated or misbranded.

These limitations are designed to insure that the Secretary carefully considers and documents the need for records and reports before requiring that they be maintained or submitted. They should not be construed, however, as limiting the Secretary's authority to obtain information needed to insure that the public is protected from potentially hazardous devices. For example, the limitation on submission of periodic reports by manufacturers of class I devices should not be construed as limiting the Secretary's authority to prescribe general requirements that all manufacturers, distributors and importers provide notification of significant product defects or of recalls of devices. Moreover, they are not intended to prohibit the Secretary from requiring the keeping of records with respect to quality control, product distribution, and product administration, where necessary to protect the public health.

Licensed practitioners who manufacture or import devices solely for use in their own professional practices and persons who manufacture or import devices solely for use in research or teaching and not for sale are exempt from the requirements to keep records and make reports. Obviously, physicians and other licensed practitioners are not exempt from these requirements if their use of a device extends beyond ordinary professional practice into commercial activity. The exemption for persons using devices for research and teaching is a limited one; if such persons are using a device for investigational purposes, they would be subject to recordkeeping and reporting requirements under new section 520(g).

Restricted Devices.—Because of the sophistication and potentially hazardous nature of some medical devices, the proposed legislation authorizes the Secretary to require that the sale or distribution of a device be restricted if he determines that, because of its potentiality for harmful effect or the collateral measures necessary to its use, there cannot otherwise be reasonable assurance of its safety and effectiveness. Under this provision (new section 520(e) of the Act), such a device may be restricted to the extent that it may 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 may prescribe, except that no condition limiting the use of a device to categories of physicians defined by their training or experience may be imposed.

This provision supersedes and adds to existing authority utilized by the Food and Drug Administration to require that certain devices be dispensed only upon prescription. (This authority is derived from section 502(f) of the Act, which authorizes exemptions to the requirement that all devices bear adequate directions for use. The Food and Drug Administration's contention that such an exemption may be con-

to a device introduced or delivered for introduction into interstate commerce upon four determinations by the Secretary: First, that the device presents an unreasonable risk of substantial harm to the public health; second, that there are reasonable grounds to believe that it was not properly designed and manufactured with reference to the state of the art that existed at the time of design or manufacture; third, that the risk was not caused by the failure of a person other than a manufacturer, importer, distributor or retailer to exercise due care in the installation, maintenance, repair or use of the device; and fourth, that notification authorized under new section 518(a) is insufficient to eliminate the risk.

Upon making such determinations, the Secretary is authorized to issue an order directing the manufacturer, importer, or distributor of the device, or any combination of such persons, to submit to him a plan to take one or more of the following actions:

(1) Repair the device so that it does not present the risk.

(2) Replace the device with one in conformity with applicable requirements of the Act.

(3) Refund the purchase price of the device (less a reasonable allowance for use if the device was in the possession of the user for at least a year at the time notification was ordered under new section 518(a) or at the time the device user received actual notice of the risk, whichever occurred first).

An order of the Secretary requiring submission of a plan by more than one person is to specify which person is to decide the action to be taken under it. This will be the person who the Secretary determines bears the financial responsibility for action to be taken under the plan unless the Secretary cannot make such a determination or determines that the decision should be made by a person other than the person bearing such responsibility. The Secretary is to approve a plan unless he determines, after providing opportunity for informal hearing, that the action to be taken under the plan will not assure elimination of the risk, in which case he shall order submission of a revised plan. If, after opportunity for an informal hearing, a revised plan is determined to be unsatisfactory, or if no initial or revised plan is submitted, the Secretary is to prescribe a plan.

The proposed legislation contains three provisions designed to assure that the repair, replacement, or refund action will not cause unjustifiable economic loss to participants in the procedure. First, it provides that no charge may be made to any person (other than a manufacturer, importer, distributor, or retailer of a device) for availing himself of remedies for repair, replacement or refund and requires that persons subject to an order to carry out a plan to reimburse persons entitled to a remedy for expenses incurred in obtaining the remedy. Second, proposed new section 518(c) authorizes a repair, replacement, or refund order to require a manufacturer, importer, distributor, or retailer of a device to reimburse other manufacturers, importers, distributors, or retailers for expenses incurred in carrying out the order if required to protect the public health. Third, as is the case with notification orders, proposed new section 518(d) specifies that compliance with an order requiring repair, replacement or refund shall not relieve any person from liability under Federal or

hearing would occur after the issuance of a proposed regulation and before any final action on the regulation, and the device would not be removed from the market until the effective date of the final order. Only if the Secretary determines that the deception or risk of illness or injury associated with the use of the device presents an unreasonable, direct, and substantial danger to the health of individuals can he require that the device be removed from the market upon publication of the proposed regulation and prior to the informal hearing.

Finally, as mentioned above, the proposed legislation would give the Secretary the authority to remove a device from the market immediately if the deception or risk presents an unreasonable, direct, and substantial danger to the health of individuals. The concept is that the injury involved must be a serious one, and one the Secretary believes will endanger the health of individuals exposed to the device. The danger need not be imminent, and may involve a serious long term risk, such as a significant likelihood of carcinogenicity. What is relevant is the degree of danger, not whether injury is likely to occur immediately. If the Secretary makes the determination that the deception or risk involved is so serious that a device should be removed from the market effective upon the date of the publication of a regulation proposing that a device be banned, he must, as expeditiously as possible, give prompt notice of his action, provide an opportunity for an informal hearing, and either affirm, modify, or revoke such proposed regulation. While the Committee believes that it is essential to give the Secretary this authority, the Committee would caution the Secretary that this procedure is an extraordinary one, and one that should not be used except when it is deemed necessary to protect the public health.

Notification of Risks Presented by Devices.—The proposed legislation would afford the Secretary important new authority to insure that the public and health professionals learn of risks presented by unsafe medical devices. Proposed new section 518(a) of the Act authorizes the Secretary to require that adequate notification is made to all health professionals who prescribe or use the device and to other appropriate persons, including device users as well as manufacturers, importers, distributors, and retailers with respect to a device which presents an unreasonable risk of substantial harm to the public health. Notification is required if the device which presents the risk is introduced or delivered for introduction into interstate commerce for commercial distribution and if the Secretary determines that such a procedure is necessary to eliminate the risk and that no other more practicable means to do so are available under the Act. Notification is to be provided by the persons and means best suited under the circumstances and only after the Secretary consults with the persons who are to give notice. All health professionals who prescribe or use the device presenting the risk are to be notified, and all persons exposed to the risk must be notified unless the Secretary determines that notification by the Secretary or by a manufacturer, importer, distributor or retailer presents a greater danger to the health of such persons than no such notice. In such instances, the Secretary is to require health professionals who prescribe or use the device to notify the persons whom they have treated with the device of the risk it presents and action which may be taken to reduce or eliminate such risk. This procedure is designed to

authority would be continued under the proposed legislation. Existing authority prohibiting drugs whose containers are composed of poisonous or deleterious substances or which contain unsafe color additives would be made applicable to devices.

Prohibitions Against Misbranded Devices.—Existing section 502 of the Act prohibits the introduction into interstate commerce of a medical device whose labeling is false or misleading in any particular, does not bear certain information or is dangerous to health. The bill would add to section 502 a requirement that the official, common, or usual name of a device appear on the label of the device and that, in the case of a class II device, the label conform to an applicable performance standard. Continuation of this authority, and amendments to it, will help assure that consumers and health professionals are not misled by information contained on labels of devices.

Registration of Device Manufacturers.—Section 510 of the Act presently requires manufacturers and other specified processors of drugs to register with the Secretary and provide a list of all drugs manufactured in any establishment they own or operate. The reported bill amends section 510 to apply similar requirements to manufacturers and processors of medical devices to enable the Secretary to develop and maintain an accurate, up-to-date inventory of medical devices.

In addition to requiring registration of device manufacturers and processors, and the listing of devices, proposed amendments to section 510 authorize the Secretary to prescribe and enforce a uniform system for identification of devices. The amendment also require persons who provide a list of devices to submit a brief statement of the basis for their belief that each such article is a device and not a drug, information respecting the applicability of a performance standard, of the requirement for premarket approval, or of any restriction on the distribution or sale of the device.

Under existing law, the requirements of section 510 are inapplicable to pharmacies, licensed practitioners, certain researchers and teachers, and other persons exempted by the Secretary. The reported bill would make these exemptions applicable with respect to devices.

Banned Devices.—As noted earlier in this report, the existing authority of the Secretary to protect the American public from dangerous or fraudulent medical devices is limited to seizure and injunction. To sustain a court action against such devices, the Secretary has the burden of proving that such a device is misbranded or adulterated, and, throughout the usually lengthy court proceeding, the device manufacturer may continue marketing his product.

The reported bill provides significant new authority for the Secretary to ban hazardous or deceptive devices including those which have been approved by the Secretary. Proposed new section 516 of the Act authorizes the Secretary to ban, by regulation and after opportunity for an informal hearing, any device intended for human use if he finds, based on all available data and information and after consultation with the appropriate classification panel, that such a device presents a substantial deception or an unreasonable and substantial risk of illness or injury. If the Secretary determines that the deception or risk presents an unreasonable, direct and substantial danger, he may, after notifying the manufacturer of such a device, declare a proposed regulation banning the device effective upon its publication,

safety and effectiveness of medical devices. This requirement is predicated upon the recognition that no regulatory mechanism can guarantee that a product will never cause injury, or will always produce effective results. Rather, the objective of the legislation is to establish a mechanism in which the public is afforded reasonable assurance that medical devices are safe and effective.

Determination of Safety and Effectiveness.—The proposed legislation provides statutory criteria for the determination of safety and effectiveness to be utilized during the classification process, the development of standards, and in determinations with respect to premarket approval. (These principles are contained in proposed new sections 513(a)(2) and 513(a)(3) of the Act).

The reported bill provides that the safety and effectiveness of a device are to be determined (1) with respect to the persons for whose use the device is represented or intended; (2) with respect to the conditions of use prescribed, recommended, or suggested in the device's labeling; and (3) weighing any probable benefit to health from the use of the device against any probable risk of illness or injury from such use.

The criteria of safety and effectiveness are intended by the Committee to include reliability of a device.

While the proposed bill is focused primarily upon the need for protection of patients and consumers, the persons for whom the use of a device is represented or intended may also include health professionals. Thus, in some instances, the safety and effectiveness of a device intended for use only by health professionals should not be evaluated in terms of suitability for use by lay individuals.

The requirement that safety and effectiveness are to be determined on the basis of the conditions of use prescribed, recommended or suggested in labeling is not intended to preclude the Secretary from considering the actual uses to which a device is put, or those uses promoted through advertising. This requirement, which is derived from drug law, relates to the requirement in existing law prohibiting misbranded devices, as well as proposed new authority which would require that devices subject to performance standards conform to labeling requirements and new authority which would deny or withdraw approval of an application for premarket approval. Thus, the proposed legislation broadens the Secretary's authority to assure that every device is appropriately labeled. Such labeling authority could include labeling intended for patients, health professionals, or both. Labeling authority would extend to requirements with respect to the contents of instruction manuals.

The phrase "conditions of use" is intended to include consideration of the environment in which a device is to be used. However, a device is not to be regarded as unsafe merely because the device is to be used in circumstances in which collateral risks themselves pose a degree of danger to patients. Thus, a device used to administer anesthetics during a surgical procedure could not be deemed unsafe under proposed conditions of use merely because anesthetics are potentially hazardous.

The key concept that safety and effectiveness of a device are to be determined "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use" makes it clear that the proposed legislation recognizes that prod-

articles commonly considered to be "devices" in order to subject them to more extensive regulation under the Act, including requirements for premarket testing. In most instances, the courts have upheld FDA's attempts, although, as the Supreme Court has observed, ". . . it must be conceded that the language of the [Federal, Food, Drug, and Cosmetic Act] is of little assistance in determining precisely what differentiates a 'drug' from a 'device'." (*U.S.* v. *Bacto—Unidisk*, 394 U.S. 784, 799 (1969).)

The Committee proposal amends the existing definition of "device" in section 201(h) of the Act to draw a clear distinction between a "device" and a "drug". The new definition retains (in somewhat more precise detail) provisions of existing law that a device is an article or component thereof which is (1) recognized in the official National Formulary or the United States Pharmacopeia, (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. These characteristics, which also are used in the definition of a "drug" in section 201(g) of the Act, are modified by the proposed legislation to include the distinction that an article is a device if it "does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and [if it] is not dependent upon being metabolized for the achievement of any of its principal intended purposes". This distinction means that articles dependent upon chemical action or being metabolized, and otherwise falling within the definition of "drug" in section 201(p), are to be regulated as drugs and not as devices. Thus, the proposed new definition of "device" removes the gray area that exists under present definitions of "drug" and "device".

Products regulated as "drugs" prior to the proposed bill's enactment date, and which fall within the new statutory definition of "device", would be subject to regulation as devices. Under the proposed legislation, such products would be regulated in a manner comparable to their regulatory status as drugs.

Although the definition of a "device" encompasses animal devices as well as devices intended for human use, and provisions of existing law and certain provisions of the proposed legislation applicable to devices do not distinguish between human use and animal use devices, the Committee has determined that, because the legislation was developed as a response to the rising incidence of injuries to humans from unsafe or ineffective devices, the major new authorities proposed by H.R. 11124 should be limited to devices intended for human use. This is not to say, however, that a manufacturer of a device that is banned by the Secretary, for example, can escape the ban by labeling the device for veterinary use. The Secretary may consider the ultimate destination of a product in determining whether or not it is for human use, just as he may consider actual use of a product in determining whether or not it is a device.

Finally, despite the fact that generally the term "device" is used in the bill to refer to an individual product or to a type or class of products, there may be instances in which a particular device is intended to be used for more than one purpose. In such instances, it is the Com-

facturer may continue marketing his product. Absent clear, statutory authority to regulate medical devices, the FDA cannot safeguard the health of the American public by assuring the safety and effectiveness of such products.

Committee Proposal and Views

INTRODUCTION

After lengthy hearings and careful consideration, the Committee has developed a balanced regulatory proposal intended to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in medical device technology are not stifled by unnecessary restrictions. The bill makes distinctions between those devices which are simple in design and represent little risk to health and those which are sophisticated and potentially hazardous, and it acknowledges the need for the widest range of scientific expertise to assist in the regulatory process. It would prohibit, pursuant to a determination by the Secretary of Health, Education, and Welfare, the marketing of a new device until the safety and effectiveness of the device has been established, would provide the Secretary with the authority to remove dangerous devices from the marketplace expeditiously, and would require notification of health professionals and others of newly identified hazards associated with medical device use. It reflects the need to develop innovative new devices, consistent with the need to protect the subjects of device research. Finally, it recognizes that this significant new authority must not unnecessarily burden the small manufacturers of medical devices who have been responsible for the development of a host of important and innovative devices.

H.R. 11124 proposes that all medical devices be classified into one of three categories depending on the extent of regulation necessary to assure safety and effectiveness: class I, in which general controls relating to adulteration, misbranding, banning, notification, reporting, registration, restrictions on sale or distribution, and good manufacturing practices are considered sufficient; class II, in which performance standards in addition to general controls are considered sufficient; and class III, in which premarket, approval as well as application of general controls, is determined to be necessary to assure safety and effectiveness.

Pursuant to the recommendations of the Cooper Committee, and in an effort to afford the Food and Drug Administration the best possible scientific advice and expose the agency's decisions to public scrutiny, the bill relies heavily on the proceedings of outside experts, with ultimate authority vested in the Secretary. Expert advisory panels are to consider and recommend classification of devices. Such outside groups are also to advise the Secretary with respect to performance standards, good manufacturing practices, banning of devices, and, in some instances, administrative review of contested actions.

In an effort to curtail lengthy and cumbersome trial-type proceedings that have often resulted in years of delay before FDA can take necessary regulatory action, the proposed bill would establish an

lems in the foreseeable future. . . . the study group believes that present and potential hazards, and the need for reliability and effectiveness of devices necessitates explicit legislation."

One of the recommendations of the Study Group was that medical devices be classified into three distinct regulatory categories as follows:

(1) Devices exempt from standards or pre-clearance;

(2) Devices for which adequate existing standards or data permit the certification of old standards or the establishment of new safety and performance standards together with compliance tests for design, manufacture, installation, and operation; and

(3) Devices which should be made subject to performance review prior to clinical application and marketing because existing data do not permit the development of standards.

In addition, it recommended ancillary regulatory authority to ensure the efficient and effective implementation of the proposed legislative framework. The supplemental authority was to include provisions for defect notification, mandatory industry adherence to good manufacturing practices, factory inspection, record and report keeping authority, and the mandatory registration of all device manufacturers with FDA. The Committee also recommended a peer review mechanism within the industry to oversee the development of new devices with the specific view toward protection of the potential patient users.

In summary, the Cooper Committee concluded:

(1) Many hazards associated with medical devices do not arise from their design or manufacture, but rather from the manner in which the devices are used. Devices are often not properly labeled as to specific operating instructions. Accordingly, electrical and other hazards may result from improper installation and interconnection of devices with one another and with the patient.

(2) Medical device problems are too often related to faults in design and manufacture. Standards might be established and enforced for some devices, although it is not feasible to establish single standards for many devices where the complex interaction of many components is involved. In the latter case, safety and effectiveness of the device can best be assured by the orderly development and scientific review of data supporting the manufacturer's claims and the tested performance of the device.

(3) Developers and manufacturers are not sure of their legal liability and the responsibilities of Federal agencies for device review prior to marketing. This has resulted in the recognition by most developers, manufacturers, and users of medical devices, including the Federal government, that there is a need for a system of device regulation which assigns appropriate roles both to the Federal government and to nongovernmental peer-review groups.

(4) Those involved in the development, promotion, and application of medical devices generally agree that the public deserves more protection against unsafe, unproven, ineffective, and experimental medical devices. But this belief is counterbalanced by an equally strong conviction that excessive or ill-conceived Federal device regulation would stifle progress in this field.

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 testing, quality control in materials selected, or patient consent.

An example of a legitimate medical device which was marketed without adequate premarket testing is the Dalkon Shield. In November of 1970, the Dalkon Shield was introduced to the medical profession as a safe and effective contraceptive device. Patient product brochures advised prospective users that the Shield was a comfortable and safe method of contraception, that it was 98% effective in preventing pregnancy, that available evidence indicated that IUDs did not cause abortion, and that complications such as infection and perforation of the uterus were rare. In less than two years the Shield had been adopted by 1,497 family planning clinics in the United States and was also being used in world population control programs. The manufacturer reported that more than one million Shields had been sold. In May of 1972, the Family Planning Digest, an official HEW publication, reported that, based on an eighteen month study of 937 patients in family planning programs in California, the pregnancy rate with the Shield was 5.1%, the removal rate for medical reasons was 26.4%, the infection rate was 5%, and the continuation rate after eighteen months was under 60%. By mid-1975 the Shield had been linked to sixteen deaths and twenty-five miscarriages. Presently, more than 500 lawsuits seeking compensatory and punitive damages totalling more than $400 million are pending against the manufacturer of the Shield, which is no longer being marketed. Clear statutory authority for the FDA to prevent the marketing of medical devices which have not had adequate premarket testing could have prevented the deaths and injuries associated with the use of IUDs like the Shield.

Experience with two other types of devices further demonstrates the need for increased statutory authority. Significant defects in cardiac pacemakers have necessitated 34 voluntary recalls of pacemakers, involving 23,000 units, since 1972. A recent investigation in four States of eleven patients who experienced unusual eye infections following implantation of intraocular lenses revealed serious impairment of vision in all patients and the necessity to remove the eye of five patients.

The increased sophistication of medical devices coupled with the expanded authority to regulate drugs under the 1962 amendments to the Food, Drug, and Cosmetic Act have encouraged FDA to regulate some products generally regarded as devices as drugs. Two court decisions in the late 1960s upheld FDA's authority to regulate certain medical devices as drugs. In the first case (*AMP Inc.* v. *Gardner*, 389 F2d 825 (1968), cert. denied, 393 U.S. 825 (1968)), the United States Court of Appeals for the Second Circuit held that a product consisting of a disposable applicator, a nylon ligature loop, and a nylon locking disc used to ligate severed blood vessels during surgery was a drug. FDA had classified the product as a new drug subject to premarket clearance. The manufacturer, on the other hand, claimed that it was a medical device. The court found that the product was essentially a

duct. There were no provisions in the 1906 Act to regulate medical device safety or claims made for such devices.

Strong support for reform of the 1906 Act developed in the 1930s. False therapeutic claims for medical devices were being presented to the public through radio and newspaper advertising; product cheapening had become widespread. There was a growing awareness that the absence of any authority to regulate the safety and reliability of medical devices presented a serious danger to the American public.

The Federal Food, Drug, and Cosmetic Act of 1938 provided the Federal government with expanded authority to regulate food and drugs, including the authority to require premarket approval of new drugs for safety substantiation, and, for the first time, authorized the regulation of cosmetics and medical devices. The term "device" was defined to mean any instrument, apparatus, or contrivance, including any of its components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or intended to affect the structure or any function of the body of man or other animals. From the legislative history it is clear that 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.

The regulatory authority provided the Food and Drug Administration by the 1938 Act, which has not been amended with respect to its device authority since its enactment, is limited to action after a medical device has been offered for introduction into interstate commerce and only when the device is deemed to be "adulterated" or "misbranded". A device is adulterated if it includes any filthy, putrid, or decomposed substance, or if it has been prepared, packed, or held under insanitary conditions. A device is misbranded if its labeling is false or misleading; unless it identifies the manufacturer, packer, or distributor and quantity of contents; if required labeling statements are not conspicuous; if it fails to bear adequate directions for use or adequate warnings; or if it is dangerous to health when used as indicated. Once a device has been determined to be in violation of the Act, the FDA is limited to seeking seizure of the device by court order, seeking an injunction against the violation, or recommending criminal prosecution.

At the time the 1938 Act became law, many of the legitimate devices on the market were relatively simple items which applied basic scientific concepts such that experts using them could readily recognize whether the device was functioning properly; the major concern with respect to these devices was assuring truthful labeling. In the early years of its authority over devices, FDA's activity essentially involved grossly hazardous products such as lead nipple shields which exposed nursing infants to possible lead poisoning. FDA also attacked stem pessaries used for contraception or abortion which had the potential effect of causing puncture of the uterus or infection. FDA actions against thermometers which failed to record properly stimulated the development of standards for these products which greatly improved their reliability; similarly, FDA efforts against unreliable prophylactics forced industry measures to reduce the incidence of defects in these products.

4. The bill authorizes a procedure—termed a product development protocol—whereby the development of a product and the development of data necessary to demonstrate safety and effectiveness evolve simultaneously. Approval by the Secretary of a notice of completion of a product development protocol is the equivalent of approval of an application for premarket approval.

5. The bill authorizes the Secretary to exempt a device from the requirements of the Act if it is intended solely for investigational use, and, in the case of testing involving human subjects, if the person seeking an exemption for a device submits a plan demonstrating that the testing of the device will be supervised by an institutional review committee, insures appropriate patient consent, and maintains certain records and reports.

6. The bill authorizes the Secretary to ban a device which presents a substantial deception or substantial unreasonable risk of illness or injury.

7. The bill authorizes the Secretary, in instances in which a device presents an unreasonable risk of substantial harm, to require notification of all health professionals who prescribe or use the device and of any other person (including a device user) who should properly receive such notification in order to eliminate such risk. If the Secretary determines that notification by itself would not be sufficient to eliminate the unreasonable risk of substantial harm, he may require the manufacturer, importer or distributor of such a device to repair or replace the device or to refund its purchase price.

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

9. The bill authorizes the Secretary to restrict the sale or distribution of a device if there cannot otherwise be reasonable assurance of its safety and effectiveness.

10. The bill authorizes the Secretary to prescribe good manufacturing practices with respect to the manufacture, packing, storage, and installation of devices is consistent with assuring their safety and efficacy.

11. The bill preempts State and local requirements for medical devices that differ from requirements established by the Secretary, although the Secretary may exempt a requirement of a State or locality from the preemption provision if the requirement is more stringent than the Federal requirement or if the requirement is required by compelling local conditions and if a device which complies with the requirement will not be in violation of the Act.

12. The bill prohibits the export of devices that do not comply with provisions of the Act unless they accord to foreign specifications, are not in conflict with the laws of the importing country, are labeled as intended for export, and the health agency of the foreign country (or the Secretary if there is no such agency) determines export is not contrary to public health. It amends existing law with respect to the export of drugs subject to regulation under 1962 amendments to the Act and antibiotic drugs to conform those provisions of the law to the new provisions respecting medical devices and contains similar provisions with respect to the export of animal drugs.

Page 29, line 8, insert an opening parenthesis before "unless", and in line 9 insert a closing parenthesis after "516".

Page 33, beginning in line 14 strike out "on or".

Page 37, line 18, strike out "Section 520(1)(3)(d)(ii)" and insert "section 520(l)(3)(D)(ii)".

Page 47, line 8, strike out "(A)" and insert "(B)".

Page 52, strike out lines 10 through 19 and insert in lieu thereof the following:

> "(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;

Page 62, line 11, strike out "who avails" and insert in lieu thereof "for availing".

Page 64, line 22, insert "for such a device" after "maintain".

Page 65, line 1, insert "for such a device" after "submit".

Page 66, line 19, strike out "503" and insert "502".

Page 80, beginning in line 22 strike out "a summary of any".

Page 80, line 23, insert "any" after "respecting".

Page 81, line 11, strike out "a summary of any".

Page 81, line 12, strike out "the" first time it appears and insert in lieu thereof "any".

Page 81, line 16, after "subsection" insert "(A)"; and insert before the period in line 19 the following: ", and (B) shall be made available subject to subsection (c) of this section".

Page 82, line 19, strike out "1975" and insert "1976".

Page 85, line 1, after "days" insert "from the enactment date".

Page 88, line 17, strike out "(1)".

Page 92, line 16, strike out "520(g)" and insert "520".

Page 93, line 2, strike out "any" and insert in lieu thereof "Any".

Page 94, strike out "initially" in lines 3, 10, and 15.

Page 94, line 5, strike out "an approval of an" and insert in lieu thereof "in effect an approved"; and beginning in line 8 on that page strike out "an approval under section 515 of an application for premaket approval" and insert in lieu thereof "such an application in effect".

Page 97, beginning in line 12, strike out "notification or other".

Page 103, line 5, strike out "subparagraph" and insert in lieu thereof "paragraph".

Page 103, line 18, strike out "or".

Page 103, insert "or" at the end of line 20 and strike out lines 21 through 25 and insert in lieu thereof the following:

> "(D) new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 512 and with respect to which an application has been approved under paragraph (4) of this subsection,

if the Secretary determines that the export of

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APPENDIX D

94th Congress
2d Session
HOUSE OF REPRESENTATIVES
REPORT
No. 94–853

MEDICAL DEVICE AMENDMENTS OF 1976

REPORT

BY THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

[To accompany H.R. 11124]

together with

MINORITY VIEWS

FEBRUARY 29, 1976.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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ADMINISTRATIVE RESTRAINT

21 USC 334.

SEC. 7. (a) Section 304 is amended by adding at the end the following new subsection:

Detention.
21 USC 374.

"(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.

21 USC 332.
Regulations.

Appeal.

"(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.".

21 USC 331.

(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

21 USC 379.

"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

(E) by amending clause (ii) of paragraph (1)(B) to read as follows:

21 USC 353.

"(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

Ante, pp. 546, 552.

(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:

Report.

"(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

Ante, p. 540.

"(2) action taken by such person to comply with requirements under section 514 or 515 which are applicable to the device.".

21 USC 331.

(b)(1) Section 301(p) is amended by striking out "510(j)," and inserting in lieu thereof "510(j) or 510(k),".

21 USC 352.

(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".

21 USC 360.

21 USC 381.

(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

21 USC 352.

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

21 USC 352.

Notice, hearing.

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).

21 USC 321.

"(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.

Ante, p. 546.

"(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.".

Ante, p. 562.

Ante, p. 564.

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

Amendments to Section 801

21 USC 381.

(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.

21 USC 360b.

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

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

Ante, p. 552.

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

Ante, p. 560.

"(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,

Statement.

"(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.

Report.

"(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.

Review.

Transcription.

"(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

21 USC 331.

(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).

Ante, pp. 562, 565.

Ante, p. 564.

"(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 708".

(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

21 USC 334.

(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

21 USC 351.

(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.

Ante, p. 546.

"(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

Ante, p. 552.

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.

21 USC 357.

"(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.

Ante, p. 546.

"(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.

Ante, p. 552

"STATE AND LOCAL REQUIREMENTS RESPECTING DEVICES

"General Rule

21 USC 360k.

"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

Notice, hearing.

"(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.".

"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;

21 USC 355.

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

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

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

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

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

21 USC 332-334.
21 USC 331.

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.

Petition.

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

Notification.

Hearing.

Ante, p. 540.

ing, 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);

Notification.

"(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.

Application approval.

Ante, p. 560.

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

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

Hearing.

Exemption withdrawal.

"(5) The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the

"(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—

Recommendations.

"(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.

Hearing.

"(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.

Advisory committee, establishment.

"(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 parargaph (1)(A) and the approval or disapproval of petitions submitted under paragraph (2). The advisory committee shall be composed of nine members as follows:

Members.

"(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

5 USC 5332 note.

"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) is 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).

Ante, pp. 540, 546, 552, 560, 562, 564.
21 USC 374.

"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.

Publication in Federal Register.

"(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

21 USC 360i.

"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;

"Finality of Judgments

Review. "(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

21 USC 360h. "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

Hearing. "(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 commer-

"BANNED DEVICES

"General Rule

21 USC 360f.

"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—

Ante, p. 540.

"(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.

Hearing.

"Special Effective Date

Proposed regulation, publication in Federal Register.

"(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.

Notice, hearing.

"JUDICIAL REVIEW

"Application of Section

21 USC 360g.

"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,

Ante, p. 546.

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

Ante, p. 552.

"(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 pre-

"(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,

Hearing. 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

Order. 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.

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;

Post, p. 565.

"(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.

Ante, p. 546.

"(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.

Ante, p. 540.

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

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

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

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

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

"(iii) a description of the clinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the filing of a notice of completion of the

"(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;

Ante, p. 546.

"(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.

Ante, p. 540.

"(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—

Post, p. 565.

"(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—

graph (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.

Report and recommendation.

"(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).

Advisory committees. Ante, p. 540.

5 USC 5332 note.

"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.

21 USC 360e.

Post, p. 565.

"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

mitted 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;

Audit, access to books.

"(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

Reports.

"(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.

Notice, publication in Federal Register.

"(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,

Notice, publication in Federal Register.

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—

Notice, publication in Federal Register.

"(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

Notice, publication in Federal Register.

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

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

tion (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).

21 USC 360.
Post, pp. 564, 565.

"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

21 USC 351, 360.
Post, pp. 552, 560.

"(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

Ante, p. 540.

"(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

Regulation.
21 USC 360d.

"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,

Testing.

"(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

"Classification

Panel recommendation., publication in Federal Register.

"(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.

21 USC 360.

Post, pp. 564, 565.

"(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.

Post, p. 552.

Post, p. 546.

"Classification Changes

Regulation.

Recommendation, publication in Federal Register.

"(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

"(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,

Post, pp. 546, 552.

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.

Panels of experts.

5 USC app. I.

"(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.

5 USC 5332 note.

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REGULATION OF MEDICAL DEVICES

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

"CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE

"Device Classes

21 USC 360c.

"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.

21 USC 351, 352, 360.

Post, pp. 560, 562, 564, 565.

"(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

APPENDIX B

Medical Device Amendments of 1976

Statement by the President Upon Signing S. 510 Into Law. May 28, 1976

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

NOTE: As enacted, the bill (S. 510) is Public Law 94-295, approved May 28, 1976.

APPENDIX A

PROGRAM

HIMA/PMA Conferences
on
Medical Device Legislation for Manufacturers

New York City, June 21, 1976
Chicago, June 25, 1976

Los Angeles, June 29, 1976
Atlanta, July 1, 1976

Co-Chairmen

Frank E. Samuel, Jr., Esq.
Vice President and General Counsel
Health Industry Manufacturers Association

Rodney R. Munsey, Esq.
Vice President
Medical Devices & Diagnostic Products
Pharmaceutical Manufacturers Association

WELCOME AND INTRODUCTION

New York and Atlanta
C. Joseph Stetler
President, Pharmaceutical Manufacturers Association
Chicago and Los Angeles
Harold O. Buzzell
President, Health Industry Manufacturers Association

OVERVIEW OF MEDICAL DEVICE AMENDMENTS

Frank E. Samuel, Jr., Esq.

INITIAL CONCERNS AFTER ENACTMENT

Rodney R. Munsey, Esq.

CLASSIFICATION OF MEDICAL DEVICES

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PERFORMANCE STANDARDS

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PREMARKET APPROVAL/PRODUCT DEVELOPMENT PROTOCOLS

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Executive Vice President, Secretary and General Counsel
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INVESTIGATIONAL USE EXEMPTION/CUSTOM DEVICES/RESTRICTED DEVICES

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e. Restricted devices, regulations for advertising - Section 502(r).
f. Labeling under performance standards - Section 502(s).

5. Restricted devices, label statements - Section 520(e)(2).
6. Custom devices, labeling and advertising constraints - Section 520(b).
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   b. Restrictions in premarket approval - Section 515(d)(1)(B)(ii).
4. Restricted devices - Section 520(e).
5. Custom devices - Section 520(b).

which individual practitioner may receive it and the prohibition against general availability of the product.

I would like to apologize for the detailed nature of these remarks. We have to stick rather closely to the statute since few regulations and even less experience is available to help interpret the new law as it applies to new product introduction. I have stressed the need to be familiar with the Medical Device Amendments because I firmly believe that the FDA, as a practical matter, can focus its attention more closely on new products as opposed to existing pvoducts. In other words, the manufacturer who introduces a new product is more at risk from the regulatory perspective than those persons who have well established devices in commercial distribution.

I would hope that the outline you have plus this talk might be a first step or encouragement toward the development of a standard operating procedure within your company for the introduction of a new product. Obviously, your own familiarity with manufacturing and distribution and not my legalisms is the most important element of an effective SOP in this area.

Finally, I must stress the need to get all the elements of management involved with the new rules for introduction of products. As you are well aware by now, the law would appear to demand new lines of communication and perhaps new relationships within management to assure that business opportunities are in agreement with regulatory demands.

they apply to any device regulated under the Act. Therefore, even though we will be emphasizing new product concerns, the same requirements are of importance in any compliance review of characteristics or manufacture of old devices.

Numerous provisions of the new law require affirmative labeling content, while certain others preclude specific labeling actions. To a lesser extent, there are some restrictions with respect to advertising. When discussing labeling and advertising, we are obliged to look mostly to enforcement provisions for the do's and don't's.

In addition to the overall prohibition against misbranding a device, there are two provisions of Section 301 (Prohibited Acts) which address product labeling. Section 301(l) advises that a manufacturer may not represent or suggest on the labeling of a device, or in advertising, that the product has been approved for marketing by the FDA. Also, you may not indicate that the product has been sanctioned by FDA or investigational use. Section 301(l) further notes that no representation or suggestion may be used to indicate compliance with the provisions in the Act for premarket approval or investigational use.

The other prohibited act which concerns labeling and advertising is Section 301(n). It states that one may not make any reference in labeling, advertising or other sales promotion to any report or analysis which may have been furnished to FDA to comply with Section 704 on factory inspections. Even though this Section does not reference any named articles regulated under the Act, it clearly applies to them all, including devices.

There are a significant number of misbranding provisions applicable to devices. Some apply to all devices while others apply to devices by their classification status.

Running through Section 502 on misbranded drugs and devices, there are five subsections which allude to misbranding through labeling or advertising. Subsection (e)(2) notes that where a device has an established name, the *label* of that product must prominently display the established name in type at least half as big as that used for the proprietary name. Further, the existence of an established name bars the use of any other non-proprietary name on the product label. If these rules are not followed, the device would be misbranded.

In a straightforward fashion, subsection (o) notes that a device would be misbranded if it does not bear the symbols to identify it when the FDA develops a uniform system for identification of devices. Use of the term "bear" in this provision suggests, at least, a requirement that the symbols appear on the label and perhaps in labeling as well.

Moving on in Section 502, it should be noted that subsection (q) would deem a *restricted device* to be misbranded if its advertising is false or misleading in any particular. The subsection which immediately follows also addresses advertising for restricted devices. Thus, subsection (r) requires that a restricted device advertisement and other descriptive matter must include at least two elements, and perhaps a third element at the risk of misbranding. These are: (1) the established name of the device printed prominently and half as big as the trade or brand name used; (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications; and (3) where necessary to protect the public health, a full description of the components or formula with quantitative identification of each ingredient. In the case of this third requirement, the law states that it may only be applied to specific devices subject to a regulation published by the FDA. Finally, the provision affirmatively states that it is *not* applicable to *labeling* as that term is defined in the Act.

Before we leave subsection (r), I would like to make a brief comment on it. In order to describe what is specifically required in restricted device advertising, the FDA will probably issue certain regulations. Manufacturers should be aware of this eventuality and be prepared to strongly object if the regulations which are proposed are unnecessary or burdensome.

To complete this discussion of potential for misbranding, we should note subsection (s). That provision, in readily understandable language, states that a device which is required to meet a performance standard, must bear any special labeling which is required by the standard. Otherwise, it would be misbranded.

Having reviewed the misbranding provisions with respect to labeling, there are two other sections of the law which will influence product labeling. I would like to mention these as part of the checklist. Concerning restricted devices, Section 520 which controls these products, states that the label of a restricted device must bear appropriate statements of the restrictions which are stated in the governing regulation. The label of a custom device under Section 520(b) is also subject to a constraint. That provision indi-

One of the fundamental problems with Section 510(k) is the long waiting period before a device may be placed in commercial distribution. Promising market opportunities could be lost, a competitor might enhance market share during the interim period or knowledge of new product plans may be gained by a competitor. One strategy which has been suggested to minimize disruption of product introduction is to notify the Agency well in advance of the 90 days before the intended date of commercial distribution. This strategy is based on the fact that the law establishes a minimum advance notice period but no maximum. This approach may be particularly useful if the manufacturer anticipates that the FDA will press for premarket approval of the product before introduction and a petition for reclassification seems likely.

There is a second strategy which could be useful to those manufacturers who introduce new products through exhibit programs. Section 510(k) may be read to say that advance notice to FDA is only required 90 days prior to the date when a customer can first order the product. In other words, introduction of a product for commercial distribution could be well after the first announcement or exhibit of the product. Thus, under this strategy, a product could secure the market advantage of early customer interest and then sometime later give the FDA a 90-day notice prior to the first order accepted for the device. I must emphasize that this view of Section 510(k) deserves additional legal study. To be successful on this approach it would have to be firmly established that the exhibit of a product is *not* an introduction for commercial distribution under the Federal Food, Drug and Cosmetic Act.

Introduction of a Class I Device

As you know by now, a Class I device will bear the fewest number of regulatory controls. This being the case, we can expect that introduction of those products which are of the same type and substantially equivalent to pre-enactment devices would be the least difficult. The primary concern upon introduction is to assure that the product is not adulterated or misbranded according to the law. A second major concern would be to assure that the new product was manufactured in conformance with good manufacturing practice regulations when these are published by the FDA.

I would like to remind you of an important exemption which Class I devices may enjoy. During the classification process you will recall that certain devices and perhaps groups of related devices may be exempted from three areas of general controls. Therefore, a pre-enactment device in Class I could be exempted in whole or part from good manufacturing practice requirements, registration and listing and records and reports. When considering introduction of a new product destined for Class I, it would behoove your company to check the classification results for similar devices. Although it is not expressly stated in the law, there is strong reason to believe that substantially equivalent Class I devices are afforded the same exemptions which have been granted to their counterparts. If the pre-enactment device which one is using as the model has not been officially classified, it would be important to urge the classification panels to consider appropriate exemptions even though your new product may already be on the market.

Introduction of a Class II Device

All the compliance considerations which apply to Class I devices, except the exemptions just mentioned, will apply to Class II devices upon entering the market where there is no performance standard in effect. If there is a standard in effect, the new market entry would have to meet the standard but could, of course, exceed the performance requirements if not inconsistent with them. Additionally if a standard is in effect, the manufacturer would not have to comply with those general controls which are either superseded by or inconsistent with the provisions of the standard.

Before or after a manufacturer introduces a Class II device, at least for the next half year or so, it is important to check the tentative classification results of the FDA panels. Classification of the pre-enactment counterpart to the new product may be Class II but there could be sufficient reasons to have the product regulated under Class I. Therefore, the manufacturer of a substantially equivalent new product is perfectly free to take an initiative with the panels who will be recommending the final classification of the device in question. Convincing the panels that Class I treatment is sufficient would avoid the more formal and perhaps less successful attempts to down classify a product when classification is proposed in the *Federal Register.*

Assuming the new product will be eventually subject to a performance standard, it is important to stay abreast of developments. For example, the manufacturer should know whether a priority has been assigned to the standard and how high the priority is with respect to other products. In a realistic sense,

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5. TRANSITIONAL PROVISIONS
SEC. 520

A. Six categories
B. A device with an approved NDA is in class III and considered having an approved application under SEC. 515.
C. A device where an application field—considered as having an application filed under SEC. 515.

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6. STATE AND LOCAL REGULATIONS
SEC. 521

A. State law preempted
B. State may apply for exemption if state requirement more stringent; there are compelling local conditions and not in conflict with federal law.

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7. EXPORT OF MEDICAL DEVICES
SEC. 801

A. Four requirements basic to drugs and devices:
   1. Accords to specification of foreign purchaser.
   2. Not in conflict with laws of the foreign country.
   3. Labeled for export.
   4. Not offered for sale in domestic commerce.
B. In addition—if device does not comply with a standard or premarket approval requirement; investigational device; or banned device, need:
   1. Approval of foreign country.
   2. Approval of FDA.

Slide 14

8. COLOR ADDITIVES
SEC. 706

Color additive regulated only if in contact with body for significant period of time.

Slide 15

9. ASSISTANCE TO SMALL MANUFACTURERS
SEC. 10

Regulations and policy and voluntary compliance branch, division of compliance, bureau of medical devices and diagnostic products.

9. *Assistance to Small Manufacturers - Section 10* - From the very inception of the idea of the device amendments, there has been much concern expressed in government as well as in industry that the burden on small manufacturers resulting from compliance with the new law would be horrendous and that, in fact, many small manufacturers would be forced out of business. Congress attempted to mitigate the effect of the new law on small manufacturers through a new provision in the Food, Drug, and Cosmetic Act which require HEW to establish an identifiable office to provide technical and other nonfinancial assistance to manufacturers of medical devices to assist them in complying with the requirements of the device amendments. While this provision is not an exemption for small manufacturers from the requirements of the new law, it is anticipated that the FDA may be more flexible in the enforcement of the device amendments as they relate to small manufacturers. In a *Federal Register* notice dated June 4, the Commissioner of Food and Drugs designated a new Regulations and Policy and Voluntary Compliance Branch, Division of Compliance, Bureau of Medical Devices and Diagnostic Products, as the office to render assistance to small manufacturers of medical devices in accordance with Section 10 of the Amendments. Congressman Paul Rogers has apparently raised questions concerning the adequacy of the Branch the FDA has set up and has indicated FDA conformance with Section 10 will be a subject taken up in future oversight hearings.

The description of the exemptions which I have just given are, of necessity, brief, as the descriptions of these exemptions in the new law are similarly brief. While the exemptions are relatively clear in the Amendments, we will probably have to await regulatory expansion and interpretation of these Amendments to develop a more complete knowledge as to how the FDA will react to applications for discretionary exemption and as to how the FDA will interpret those exemptions granted as a matter of right by the statute.

Statutory exemptions, on the other hand, are afforded as a matter of right, depending upon the type of device involved. There appear to be nine major areas where exemptions are afforded under the Act.

1. *Records and Reports on Devices - Persons Exempt - Section 519(b)* - Section 519(a) requires every person manufacturing, importing, or distributing a device to establish records and make reports as required by regulation. Regulations are to be developed to assure that a device is not adulterated or misbranded and to assure safety and effectiveness. These requirements, however, will not apply to three classes of persons. First, regulations will not apply to any practitioner licensed by law to prescribe or administer a device or second to those who manufacture or import devices solely for such person's use in research or teaching and not for sale. Third, the regulation will not apply to any other class of persons as the Agency may exempt on the basis of a finding that compliance is not necessary to assure that a device is not adulterated or misbranded or to assure its safety and effectiveness.

2. *Custom Devices - Section 520(b)* - The requirements relating to performance standards and premarket approval will not apply to any device which, to comply with the order of an individual physician, dentist or other designated, qualified person, necessarily deviates performance standards and premarket approval from these requirements. This is true only if the device we are talking about is not generally available in finished form for purchase and not offered through labeling or advertising for commercial distribution, and if the device is intended for use by a designated individual patient. Furthermore, the device must be made in a specific form for such patient or made to meet the special needs of such practitioner and must not be generally available to or generally used by other practitioners. Thus, this exemption will still allow the manufacturer to utilize new, innovative ideas submitted to it by practitioners for the specific use by those practitioners. Later investigational use of a Class III device originally exempt under this Section or subsequent marketing of such a device will require compliance with the Act and will not be so exempted.

3. *Trade Secrets - Section 520(c)* - Section 520(c) provides that any information obtained by the FDA under those sections of the Amendments relating to classification of devices, performance standards, premarket clearance, banned devices, replacement or refund, records and reports, inspections, good manufacturing practices, or devices for investigational use; which is exempt from disclosure under the Freedom of Information Act, shall be considered confidential and will not be disclosed. Furthermore, this information may not be used by FDA as a basis for the reclassification of a device from Class III to Class II or as the basis for the establishement or amendment of a standard for a device reclassified from Class III to Class II. Under the pre-Amendment law, pertaining to the release of information on new drugs, trade secret information contained in an IND or NDA was to be kept confidential. The impact of the new Amendments, as they relate to devices, is the imposition of additional limitations on the FDA not to disclose, through certain classification actions, information which is basically protected by the Freedom of Information Act. Today, the Agency may not use or publish such information as part of the public rulemaking process for reclassification of a device from Class III to Class II nor may FDA use or publish it as the basis for establishment or amendment of a performance standard for a device reclassified from Class III to Class II. As with drugs, the FDA will, upon request, release detailed summaries of safety and effectiveness information submitted to the Agency under new section 520(h).

4. *Exemption of Devices for Investigational Use - Section 520(g)* - This provision was covered in detail earlier, and I will only point out here that the FDA must exempt such a device from certain provisions of the Act if the conditions required are complied with. The FDA may disapprove an application for such an exemption only if it is found that the investigation does not conform to procedures and conditions prescribed under regulation and as required under this provision of the Act.

5. *Transitional Provisions - Section 520(l)* - The transitional provisions relate generally to devices which previously had been considered new drugs or antibiotic drugs, and which are presently on the market. These transitional provisions vary depending upon the particular status of the former new drug. The devices formerly considered new drugs or antibiotic drugs now fall into six categories which are each handled a little bit differently under the new provisions of the law. The six types are as follows:

(1) The device which, upon enactment date, had an approved NDA.

(2) The device for which an NDA was filed before enactment date and has not been refused or approved.

(3) The device for which, on enactment date, an investigational exemption was in effect.

devices, some have implied that this procedure would be routinely necessary in obtaining patient specimens. Comments at FDA's regional meetings from Agency officials have indicated that a relaxed or minimal informed consent requirement will be applied in the diagnostic area. Manufacturers should evaluate the regulations when proposed to assure that informed consent requirements will not interrupt established industry practices in this area.

The custom device provision falls short of an industry goal for providing custom-made diagnostics ucts are subject to a performance standard. Clinicians can request that a diagnostic product be made at variance with a standard in force and the manufacturer will decide if it can be lawfully sold. The FDA is not a partner in this decision — it rests solely with the manufacturer's interpretation of custom device regulations when they are promulgated.

The custom device provision falls short of an industry goal for providing custom-made diagnostics which do not meet the labeling regulations. Thus, there is no exemption from labeling unless the product must also comply with a performance standard (or premarket approval). Manufacturers may wish to consider approaching the FDA collectively to discuss a labeling exemption for *any* custom-made product.

Restricted device provisions are important to diagnostic product manufacturers because there is some potential for widespread use among classes of products. Statements by Agency officials have indicated some thinking that diagnostics fit squarely within the language of the statute, i.e., their limitation to use by professionals with special training. If the Agency pursues this direction, manufacturers should be prepared to argue against class findings in favor of a product-by-product approach through individual rulemaking actions.

X. Statutory/Discretionary Exemptions

Perhaps the most significant exemption available to diagnostic manufacturers is in the area of GMP's. Umbrella GMP's like the first FDA effort (August, 1975) proved awkward across the breadth of instruments, systems and reagents which comprise manufactured diagnostics. Should this Agency approach be carried forward in the formal regulations, manufacturers will want to consider petitions for GMP exemptions or variances. Both of these alternatives are discretionary with the FDA.

An exemption from GMP's could prove useful for those manufacturers who produce relatively simple products according to established controls which have and continue to assure the integrity of the product. The GMP variance route might be pursued especially by instrument manufacturers. FDA emphasis on product effectiveness checks sharply contrasts with the performance appraisals and assurances which are typical in instrument manufacture. Thus, a variance from GMP regulations demonstrating the validity of alternative controls may be essential if the FDA regulations prove to be cost prohibitive or unwieldy for this segment of the industry.

The FDA advisory committee for GMP's has two slots for industrial representatives. Diagnostic product manufacturers would be well served to nominate qualified individuals for these positions. Trade associations will, at the appropriate time, encourage the FDA to select individuals who can clearly be identified with both devices and diagnostics, respectively.

XI. Introduction of New Products

The vast majority of in vitro diagnostic products do not fit the statutory criteria for Class III, premarket approval devices. However, new products (new technology) are forced into this posture by the legal requirement that all "new devices" (not substantially equivalent) are automatically in Class III. Therefore, the petition route for reclassification (Section 513(f)(2)) is extremely important to diagnostic manufacturers. If these petitions are approved, the new diagnostic can reach the market and perhaps at a later time be obliged to meet a standard when developed. Even though reclassification is a viable tool, the law allows up to 210 days for the Agency to make its decision on the petition. That period seems excessively long when a responsible showing is made at filing. Accordingly, industry trade associations will be encouraging the FDA to cut short the period for consideration where the product seems likely, as a class, to fall into standards or general controls. Diagnostic manufacturers should be prepared to support these efforts.

Act (Section 351) and the Federal Food, Drug and Cosmetic Act. Congress has reaffirmed this relationship in the legislative history of the Medical Device Amendments. Thus, it is unlikely that there will be any major changes in regulatory practices of the FDA for biological diagnostic products.

To complete this overview discussion, it must be restated that diagnostic manufacturers should pay close attention to the early regulations - most notably those for the investigational device exemption. FDA officials have advised that they will accommodate the essential differences between devices and diagnostics in future rulemaking. They have also said, however, that they will be unresponsive to broad appeals for lesser controls on diagnostic products absent a well-developed rationale. In other words, the Agency does not plan to have a double standard between devices and diagnostics unless clearly supported. This view stems from the law itself which also treats devices and diagnostics without distinction.

III. Initial Concerns

Despite the forthcoming changes which may be expected in the IVD regulations, the initial concerns for diagnostic product manufacturers are the same as those for medical device manufacturers. If one initial concern could be singled out for special attention, it would have to be the additional authority in the area of product misbranding. The new law clarifies FDA authority to enforce adequate product labeling. Thus, Section 501 of the Act, as now amended, can be viewed as removing any hesitancy on the part of the FDA to pursue misbranding actions. Considering that there is already an extensive FDA regulation on IVD labeling, manufacturers would be well advised to audit their labeling compliance programs. The view of a responsible FDA official suggests that data to support labeling claims must be of the same caliber regardless of the product classification. In other words, the amount of data as between Class I and Class III will vary substantially but should not vary with respect to its sufficiency to establish the validity of the performance claim(s).

IV. Classification

Preliminary classification results from FDA diagnostic panels indicate a wide preference for Class II. FDA officials have indicated that there will be some migration out of Class II into the other two classes as a result of the additional inquiries into all products stemming from the passage of the law. Classification of in vitro diagnostic products has lagged behind that for medical devices. However, it is anticipated that a comprehensive list of the panel recommendations will be available by late summer of 1976. Following the FDA plans for classification in general, manufacturers of products with high standards priority (e.g. glucose, calibrators, hemoglobin, etc.) can expect to see *Federal Register* publication for comment on classification well before the bulk of all diagnostic products.

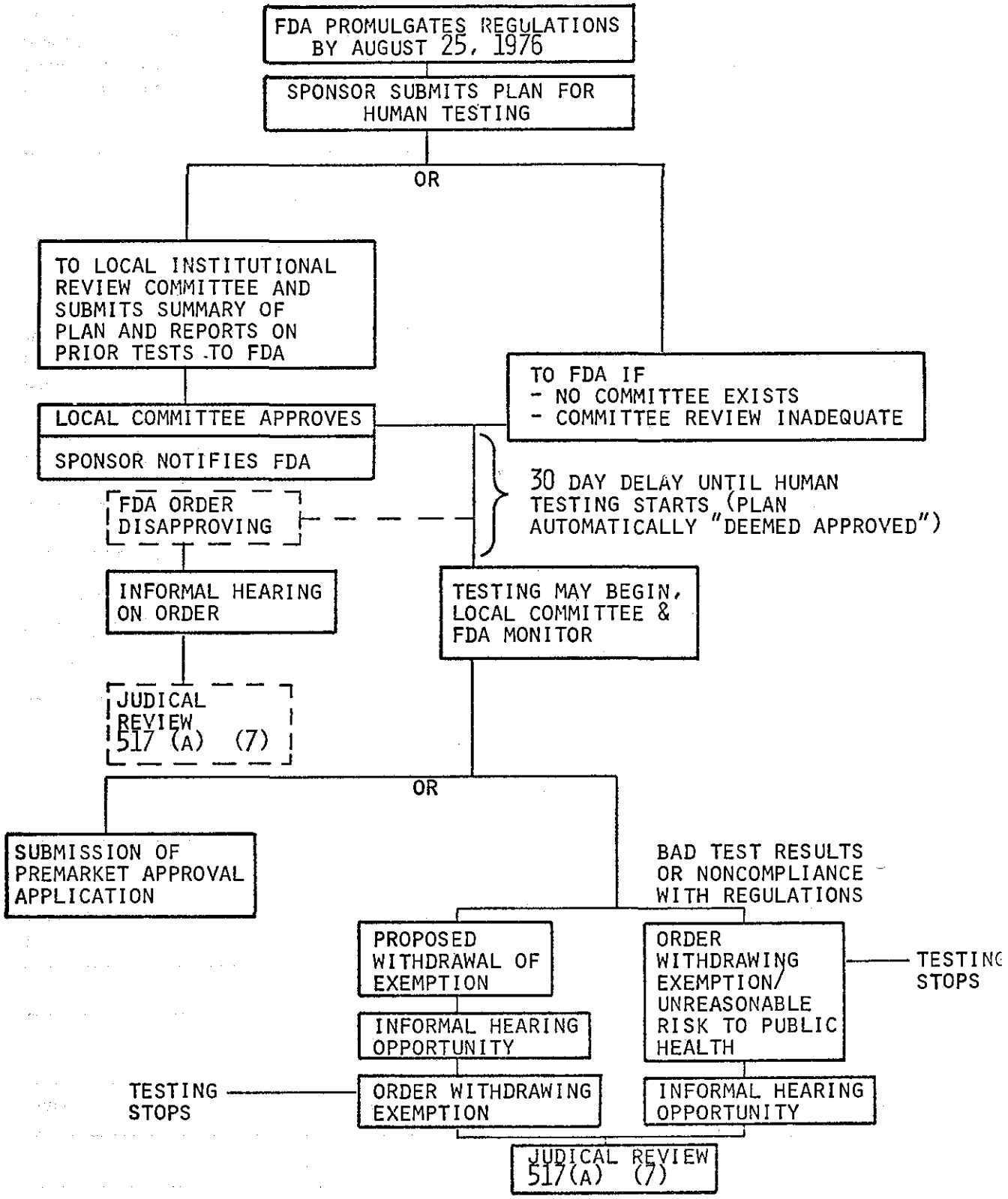
Manufacturers of general purpose reagents and equipment which appear to fall in Class I (General Controls) would be wise to pursue the statutory exemptions for Class I before the panels. With panel recommendation and FDA concurrence, any Class I product can be exempted in whole or part from registration and listing, good manufacturing practices and records and reports requirements. A number of general purpose reagents and equipment seem to be good candidates for these exemptions especially in view of labeling requirements already in force.

V. General Controls - Manufacturer Compliance

Major interest in this area is the 90-day advance notice of product introduction. Characteristics of diagnostic products important to the substantial equivalency test are unknown as yet. Manufacturers of diagnostics must carefully review the forthcoming regulations for Section 510(k) to assure that they do not foreclose introduction of substantially equivalent new products by over emphasis on safety and effectiveness related to therapeutic medical devices. The performance of diagnostic products should be the principal index of equivalency in contrast to patient exposure, hazards and the like which are of lesser importance in the application of the product.

It is understood that substantial equivalency to products already manufactured by the same manufacturer may be more easily established at least during the period before regulations are issued. Although performance and claims comparisons need not be exhaustive, it has been suggested by FDA officials that intra-company data submissions may carry more weight than comparisons to competitor's products.

INVESTIGATIONAL USE EXEMPTION PROCEDURES



c. I am required to prepare and maintain adequate case histories designed to record all observations and other data pertinent to the clinical investigation. ZIMMER · USA will provide all case record and study forms which I agree to use.

d. I am required to furnish my reports to ZIMMER · USA which is responsible for collecting and evaluating the results. ZIMMER · USA is responsible for presenting any progress reports that may be required to the Food and Drug Administration at appropriate intervals. Any adverse effect which may reasonably be regarded as caused by, or is probably caused by, the new device shall be reported to ZIMMER · USA promptly; and if the adverse effect is alarming it shall be reported immediately. An adequate report of the clinical investigation will be furnished to ZIMMER · USA shortly after completion.

e. I will maintain the records of disposition of the device and the case reports described above for a period of 3 years following the completion or suspension date, or longer as may be required by compliance with the Food and Drug Administration. Upon the request of a scientifically trained and specifically authorized employee of ZIMMER · USA or the Food and Drug Administration, at reasonable times, I shall make such records available for inspection and copying. The names of the subjects need not be divulged unless the records of the particular subjects require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual studies or do not represent actual results obtained.

f. I certify that the device will be used only on subjects under my personal supervision or under the supervision of the following investigators responsible to me: *(to be completed by investigator with supervised investigators' curriculum vitae attached)*

_____

_____

and that the devices received by me for this clinical protocol will not be supplied to any other investigator or to any clinic for use in humans or for other study.

g. I certify that I will inform any patients or persons used as controls, or their representatives, that the device is being used for clinical investigation, and will obtain the written informed consent of the subjects, or their representatives, except where there exists a life threatening situation involving the subject and it is not feasible to obtain consent from the subject and there is not sufficient time to obtain such consent from his representative. Where it is a life threatening situation and it is not feasible to obtain informed consent, I certify I will document the circumstances in writing and have it concurred in, in writing, by a licensed physician not involved in the study, before using the device. Only if immediate use of the device is necessary to save the life of the human subject and there is not sufficient time to obtain concurrence, may I use the device on a human subject without his (or his representative's) informed consent or the concurrence of a licensed physician not involved in the study, and certify that I will fully document any such circumstances. I agree to use the informed consent forms supplied to me by ZIMMER · USA, and to adhere to any Federal Law concerning informed consent or the investigational use of devices on humans.

h. I agree to follow the clinical testing protocol for this investigation (attached). If I feel, in my medical judgement, that reasonable alternatives and deviations from this protocol are required, I will document these alternatives and deviations and the reason(s) required.

i. It is understood that I retain the right of publication of the clinical work I perform, though I am encouraged to cooperate jointly in publications with the other investigators in this study in order that the data and results may be as complete and statistically significant as possible. I agree that ZIMMER · USA has the standard right of review and comment on any proposed publications, and that I will not submit any articles for publication on this investigation prior to my completion of this protocol. Protocol completion period for each subject is _____.

c. Teaching or research experience: Dates, institutions, brief description of experience.

Institution	Date	Experience

d. Experience in medical practice or other professional experience: Dates, institutional affiliations, nature of practice, or other professional experience.

Affiliations	Nature of Practice or Experience	Date

e. Any additional education and training that qualifies me for clinical trials is:

2. The name and address of the medical school, hospital, or other research facility where the clinical trial will be conducted is: *(to be completed by the investigator)*

Name _____

Address _____

PLEASE PRINT OR TYPE

NAME OF INVESTIGATOR_____

ADDRESS_____

CITY_____

STATE_____

NAME OF STUDY_____

DATE_____

Return to:

ZIMMER · USA
727 North Detroit Street
Warsaw, Indiana 46580

Att: Clinical Affairs Dept.

_____
(Name of assigned ZIMMER® monitor)



ZIMMER·USA
Warsaw, Indiana 46580

EXEMPTION FOR DEVICES FOR INVESTIGATIONAL USE

My final topic of discussion is Section 520(h), The Investigational Use Exemption. What is the Investigational Use Exemption?

It is provision in the law which permits the testing of medical devices which would otherwise be a violation of the Act. The provisions to which the Exemption relate are:

- Section 502 (Misbranding)
- Section 510 (Registration and Listing)
- Section 514 (Standards)
- Section 515 (Premarket Clearance Approval)
- Section 516 (Banned Device)
- Section 519 (Records and Reports)
- Section 706 (Color Additives)
- Section 520(e) (Restricted Devices) and
- Section 520(f) (GMP's)

When is the Exemption effective and what conditions apply?

The law requires FDA, within 120 days of enactment, to promulgate regulations establishing procedures and conditions under which an Investigational Use Exemption may be granted.

While such regulations do not currently exist, the law does specify requirements which must be included in FDA's regulations. The requirements are to include a submission of an application to the Secretary and the maintenance of such records and the making of such reports as are necessary to enable FDA: to assure compliance with the conditions of the Exemption; to review the progress of the investigation; and, to evaluate the safety and effectiveness of the device.

FDA procedures and conditions may vary depending upon: the scope and duration of clinical testing to be conducted; the number of human subjects to be involved in the testing; the need to permit changes to be made in the device subject to testing; and whether the device is being tested for the purpose of developing data to support its commercial distribution. It is my understanding of the legislative history, that in instances in which proposed investigations do not involve human subjects, Congress anticipates that such procedures and conditions would be addressed principally to adequate recordkeeping, reporting, and assurances that a device is not diverted for human use.

The legislation also contains special requirements with respect to exemptions for devices intended to be tested using human subjects. For such testing, the person seeking the exemption must submit a clinical protocol and a report of any prior investigations to a local institutional review committee for review. If such committee does not exist, or if the process of review by a committee is determined to be inadequate, then the full protocol and report are to be submitted to the Secretary for approval. If an institutional review committee is to be utilized to supervise the research, a summary protocol and report must be submitted promptly to FDA rather than a full protocol and report.

The legislation further requires that if the device is to be distributed to investigators for testing, the person applying for the exemption must obtain a signed agreement from each investigator stating that testing involving human subjects will be under the investigator's personal supervision and that informed consent will be obtained from each human subject. Such agreements must be submitted to the Secretary.

Informed consent is required in all testing involving human subjects with one exception. If the investigator conducting or supervising the proposed testing determines that there is a life-threatening situation which necessitates the use of the device, and it is not feasible to obtain informed consent from the patient or his representative, informed consent need not be obtained. The circumstances of the exemption must be documented in writing and concurred in by a physician who is not involved in the clinical study.

While the law does not set forth detailed requirements for informed consent, the legislative report on the bill strongly indicates language which FDA should require by regulation. These requirements are:

1. A fair explanation of the procedures to be followed, including an identification of any procedures 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;

interpretations of the term "adequate directions for use" or utilized prescription labeling purely for marketing or product liability reasons. Considering the regulatory burden associated with "Restricted Device" controls you should strongly consider the more prudent choice of labeling your product for non-prescription use.

In my opinion, unlike prior law, if adequate directions for use cannot be written for a particular product, "Restricted Device" classification is not automatically required or permitted. Device attributes which do not permit adequate directions for use by the layman simply reflect a threshold finding that the device has a potential for harm. To designate a device a "Restricted Device", the Legislation requires the Secretary to publish findings that limitations on the use, sale, or distribution of the product, and the added controls regulating "Restricted Devices", are necessary to reasonably assure protection from the potential harm and that other reasonable and lesser controls cannot provide such assurance.

Among the factors which should be taken into consideration by the Secretary in determining whether a "potentially harmful" device should be subject to "Restricted Device" controls are:

> The extent to which the other provisions in the Law minimize the potential for harm, (e.g., the labeling, standards, premarket clearance, misbranding, and adulteration provisions); the likelihood that the product will be demanded by consumers, or untrained or inexperienced health professionals, and; the extent to which State licensing results in limited use by consumers.

If restricted device status is not appropriate and "adequate directions for use" may not be written, the Secretary should, pursuant to authority granted under Section 502(f), exempt the device from the "adequate directions for use" requirement.

Thus, for example, the safe and effective control of surgical instruments, and ancillary surgical equipment (e.g., rongeurs and bone screws) which can only be utilized safely and effectively for their intended use by a physician, may be reasonably controlled by appropriate labeling and State licensing of practitioners.

In closing on this subject I would like to emphasize that FDA's approach to categorically designate as "Restricted Devices" all prescription devices is, in my opinion, not permitted by the legislation and inappropriate. "Restricted Devices" must be designated on the basis of the criteria found in Section 520(e). Regulations must be proposed and finalized on an individual or a category of device basis. Such regulations must identify unreasonable risks associated with such devices and indicate why restricted device controls are necessary to remedy or minimize such risks. Industry's review of its products labeled as prescription devices against the Section 520(3) criteria would be an important initial step toward surfacing those factors and considerations which would be instrumental in determining whether a device should be designated a "Restricted Device".

CUSTOM DEVICES

My second topic of discussion is Custom Devices. What is a Custom Device and why is it controlled differently?

As you know, the Medical Device Amendments provide for the classification of products into three categories: Class I, General Control; Class II, Performance Standards; Class III, Premarket Clearance.

Medical devices are often ordered from manufacturers by health professionals to conform to their own special needs or to those of their patients. In many instances, health professionals, through manufacturers, develop or alter devices to serve such needs. This practice is especially prevalent in the orthopedic and dental industries.

Congress recognized that the standards and premarket clearance provisions of the law would have an adverse impact upon such "Custom Devices". Consequently, an exemption provision is contained in the law which permits manufacturers to provide physicians or other health professionals with medical devices which do not comply with standards or premarket clearance criteria.

The exemption, which is found in Section 520(b) of the Act, applies only to devices which:

> necessarily deviate from an otherwise applicable performance standard or premarket approval requirement 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).

The exemption, however, has additional limitations:

Section 502(q) designates a "Restricted Device" misbranded 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).

Section 502(r) states that a "Restricted Device" is misbranded if its *advertisements* or *labeling* do not contain:

1. A true statement of the device's established name as defined in Section 520(e) printed prominently in type at least half as large as that used for any trade or brand name thereof,
2. A brief statement of the intended uses of the device and relevant warning, precautions, side-effects, and contraindications and, in special instances to protect the public health, a full description of the components of the device or the formula showing quantitatively each ingredient of such device.

Section 502(4), however, expressly prohibits the Secretary, except in extraordinary circumstances, to require prior approval of the content of any advertisement.

Section 510(j) requires every registrant, including foreign manufacturers of devices imported into the United States, to file with FDA a list of all devices manufactured, processed, compounded or prepared by him for commercial distribution. The devices must be listed by their established name and proprietary name, if any, and the reason why the registrant believes each device included in the list is a device rather than a drug. Extensive additional data are required to be included in the submission for "Restricted Devices". Such data must include:

- copy of all labeling for the device, and
- representative sampling of advertisements.

Upon request, for good cause, the Secretary may require a copy of all advertisements for a particular device to be submitted rather than a sampling.

Finally, Section 704 expands FDA's inspection authority for "Restricted Devices". Inspections of facilities in which "Restricted Devices" are manufactured, processed, packed or held, may extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether the "Restricted Device" is adulterated or misbranded or otherwise in violation of the Act.

What is the effective date for "Restricted Device" controls?

June 4th Regulations

On June 4, 1976, FDA published in the *Federal Register* a notice relating to the implementation of the Medical Device Amendments. The notice, in part, stated that statutory and regulatory requirements having an immediate impact upon passage of the bill on May 28th include:

- The duty to comply with the new disclosure requirements for advertising of "Restricted Devices" (Section 502(r) of the Act), and
- The duty to permit duly authorized FDA representatives to inspect records concerning "Restricted Devices".

In addition, the notice expressed FDA's opinion that:

"Restricted Devices" include all prescription devices as now defined in 21 CFR 801.109.

From a practical point of view, the June 4th regulations reflect an FDA posture to sweep under rigid controls all medical devices currently labeled as prescription devices by manufacturers. The regulations also indicate that FDA will be adopting as a reference point drug prescription labeling, advertising and promotional controls for "Restricted Devices". It will be incumbent upon industry to demonstrate that such an approach is legally unauthorized, and/or inappropriate for medical devices. FDA's posture on "Restricted Devices" should not come as a surprise, since "drug type controls unless proven otherwise" reflects the pattern of legislative development for medical devices as a whole.

From a legal point of view, it is extremely important to note that the notice published by FDA is a statement of interpretation and not a regulation. In my opinion, the notice is clearly inconsistent with the language of the Medical Device Amendments for two reasons.

First, Section 520(3) requires the Secretary to initiate regulatory proceedings before designating a device or certain category of devices as "Restricted Devices". Unquestionably from the plain meaning of the law, regulations such as those proposed by FDA for labeling and distribution of hearing aids on April 21, 1976, are required.

Secondly, such regulations, according to Section 520(e) must be based upon findings:

With respect to the PDP process, FDA approval of a proposed PDP constitutes final Agency action which entitles adversely affected third parties to judicial review under §515(f)(4) and 5 USC §702; while, with respect to the premarket approval process, FDA approval of an application for premarket approval entitles interested third parties to either a formal hearing or an advisory committee review pursuant to §515(d)(3). Note the distinction between the two processes with respect to the persons[5] entitled to a procedural remedy—interested persons with respect to a PDP vs. adversely affected persons with respect to premarket approval—; the process stage[6] at which the procedural remedy is available—approval of a PDP vs. approval of an application for premarket approval—to these persons; and the procedural remedy[7] available—judicial review with respect to a PDP vs. formal hearing or advisory committee review with respect to premarket approval—to these persons.

In sum, there are differences in the third-party procedural remedies provided under the PDP and premarket approval processes, but it is difficult to state which is preferable to the applicant. This may be a subject on which it will be worthwhile for you to consult long and hard with your food and drug law attorney.

[5]Are competitors or consumer interest groups interested parties? Are they adversely affected parties?

[6]Is there any time limit within which these third party procedural remedies must be used or they will be lost? Is the risk of having a third party avail himself of a procedural remedy a perpetual risk to the applicant?

[7]What is the review standard to be applied with respect to each procedural remedy? Is the very tough arbitrary, capricious and abuse of discretion review standard used with respect to judicial review under 5 USC §702? Is the less tough substantial evidence standard used with respect to formal hearings, advisory committee reviews and judicial review under §517?

Complication 1

The FDA, by order, disapproves the application for an investigational use exemption. [§520(g)(4)(a)]

Complication 2

The FDA, by order, withdraws an exemption for investigational use granted under §520(g) upon making a determination that the conditions for obtaining such exemption are not met. Note that the FDA may issue such an order before holding an informal hearing if a determination is made that continuation of testing will result in an unreasonable risk to the public health. [§520(g)(5)]

Complication 3

The FDA determines that the application does not meet the statutory requirements and does not refer such application to the appropriate classification panel for study and recommendation respecting approval of the application. [§515(c)(2)]

Complication 4

The FDA denies approval of an application for premarket approval upon finding 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 proposed labeling thereof or that there are other difficulties of the type set forth in §515(d)(2).

Complication 5

The FDA issues an order withdrawing approval of the application for premarket approval upon finding that the conditions for withdrawal set forth in §515(e)(1) apply with respect to the device.

F. **Appeal and Remedial Mechanisms**

In the event that complications are encountered in the PDP or premarket approval processes, certain appeal and remedial mechanisms are available to the applicant. These mechanisms include: (a) an informal hearing; (b) a formal hearing; (c) advisory committee; and (d) judicial review.

1. *Informal Hearing*

Persons adversely affected by action taken or proposed to be taken by the FDA are provided an opportunity for an informal hearing in certain circumstances. Such "informal hearing" is defined at §201(y) and serves as an appeal mechanism for the applicant. The Report of the House of Representatives indicates that the informal hearing is designed to balance the need for oral presentation of different views with the need to avoid procedural delays encountered in trial-type hearings with respect to taking action on matters essential to health.

The applicant has an opportunity for an informal hearing in the following instances:

a. with respect to a PDP;
   (1) before the FDA issues a final order revoking a PDP [§515(f)(6)(A)],
   (2) before an order declaring a PDP not completed becomes effective [§515(f)(6)(B)], and
   (3) before issuing an order revoking completion of a PDP [§515(f)(7)];

b. with respect to an application for premarket approval;
   (1) after issuing an order disapproving an application for an investigational use exemption [§520(g)(4)(B)],
   (2) (i) before issuing an order withdrawing an investigational use exemption [§520(g)(5)],
   (ii) after issuing an order withdrawing an investigational use exemption where continued testing under the investigational use exemption will result in an unreasonable risk to the public health [§520(g)(5)];

c. before issuing an order withdrawing approval of an application for premarket approval [§515(e)(1)].

2. *Formal Hearing*

A "formal hearing" in accordance with the requirements of the Administrative Procedure Act—specifically set forth at §554 of Title 5 of the United States Code—shall be held in those instances set forth in §515(g)(1).

months and perhaps, in some instances, a year or more. Once the notice of completion is submitted, the FDA has 90 days to declare by order the PDP completed or not completed. [§515(f)(6)(B)]

Event 6

The FDA issues an order declaring the PDP completed. [§515(f)(6)(B)]

As indicated above, the PDP approach is a new approach, one that has no equivalent in drug law. Therefore, an initial delay in getting FDA approval of the first PDP submitted for a particular device or type of device may be experienced for several reasons: (a) the PDP format and approach has yet to be developed; (b) the FDA is not experienced with respect to proposed device investigational and clinical and testing programs; (c) the FDA may have very limited experience or knowledge about that particular type of Class III device; and (d) the FDA has an inborn reluctance to give its stamp of approval to any new item. Accordingly, filing the first PDP application for a type of device may be a frustrating experience, as well as a challenging one.

C. **Premarket Approval Sequence of Events**

The sequence of events (assuming no complications) for the premarket approval approach is as set forth in the bottom portion of Chart I. Again, as with the PDP approach, the premarket approval approach is encompassed within the Amendments which were enacted May 28, 1976, and, so that is the sequence of events' starting points.

The first three events relate to the investigational use exemption and will be covered in more detail by the following speaker. However, they are an integral part of the premarket approval sequence of events, and for that reason, are included and briefly discussed at this time.

Event 1

Within 120 days of the enactment date, the FDA is required to promulgate regulations prescribing procedures and conditions under which devices intended for human use may be granted an exemption to permit the investigational use of the device. [§520(g)(2)(A)]

Event 2

An application is made for an investigational use exemption. Such an application shall be deemed approved on the thirtieth day after the submission unless on or before such day, the FDA by order disapproves the application. [§520(g)(4)(A)]

Event 3

The application for the investigational use exemption is approved. [§520(g)(4)(A)]

Event 4

An application for premarket approval is filed with the FDA. [§515(c)(1)] The FDA shall approve or deny approval of an application for premarket approval within 180 days from its receipt. However, with respect to "old devices" and devices "substantially equivalent" to "old devices", the 180-day period may be extended by agreement between the parties, in cases in which the continued availability of the device is deemed necessary for the public health. [§515(d)(1)]

Although there is no required waiting period between the approval of an investigational use exemption (Event 3) and the filing of an application for premarket approval (Event 4), there is a requirement that the application meet the requirements of §515(c)(1) before it will be referred to the appropriate §513 panel for recommendation respecting approval. Since one of the §515(c)(1) requirements is a full report of all investigations which relate to whether or not the device is safe and effective, this, in essence, means that the time from the first human use of the device until the requirements of §515(c)(1) are met will likely be several months, in most cases, and, in some cases, a year or more. However, please note that the requirements of §515(c)(1) can be fulfilled by use and experience with a device other than device use and experience under an investigational use program pursuant to §520(g). In fact, in the case of an "old device", the device use and experience will be obtained from having the device in commercial distribution.

Event 5

The FDA—upon receipt of an application meeting statutory requirements—refers the application for premarket approval to the appropriate §513 panel for study and for submission of a report and recommendation respecting approval of the application. [§515(c)(2)]

ever, as a practical matter, it's likely that the difference in emphasis between the two sets of criteria will result in more devices being placed in Class III under the "critical device" criteria[2] than under the "non-critical device" criteria.

As a practical matter, it appears that it will be more difficult to get a "critical device" than a "non-critical device" reclassified from Class III to Class I or II pursuant to §513(f)(2)(B). The reason: In the case of a Class III "critical device", but not in the case of a "non-critical device", the classification panel is required to recommend the denial of a reclassification petition unless it determines that classification in Class III is not necessary to provide reasonable assurance of safety and effectiveness.

E. Devices Regulated As Drugs—§520(1)

"Drug devices" are products which are devices under the Amendments' new definition of "device", but which were regulated as drugs as of the date of enactment. "Drug devices" are placed into comparable regulatory status as devices to that which they had as drugs under the provisions of §520(1). All such "drug devices" are classified into Class III, unless they are classified into Class I or II pursuant to a petition under §520(1)(2).

III. PREMARKET APPROVAL/PRODUCT DEVELOPMENT PROTOCOL (PDP) PROCESS

Premarket approval or the PDP equivalent for Class III devices may be obtained as follows:

(1) by obtaining an order approving an application for premarket approval pursuant to §515(d)(1); or

(2) by obtaining a notice of completion of a product development protocol ("PDP") pursuant to §515(f)(6)(B).

An approved new drug application (NDA) must be in effect for a new drug before it can be introduced into or delivered for introduction into interstate commerce. To show that a new drug is safe for use and effective in use, an exemption from the NDA requirements may be obtained for the investigational use of a new drug by experts qualified by scientific training and experience to investigate the safety and effectiveness of such new drug. Like drug manufacturers, device manufacturers may obtain an exemption to investigate the safety and effectiveness of a Class III device. This investigational use exemption is basically equivalent to the investigational new drug (IND) exemption.

Although the premarket approval process for Class III devices is analogous to the new drug premarket approval process, the language spelling out the approval process would appear to be somewhat more comforting in §515 with respect to Class III devices than is the language in §505 with respect to new drugs. That is, the language of §505(d) directs the FDA to not approve a new drug application unless that application includes "adequate tests by all methods reasonably applicable to show whether or not the drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof"; whereas, the language of §515(d) directs the FDA to not approve an application for premarket approval, in the case of a Class III device, unless that application provides a showing of reasonable assurance that the device is safe and effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling. These differences in language would appear to make it more difficult for the FDA to disapprove an application for premarket approval in the case of a Class III device than in the case of a new drug.

The product development protocol ("PDP") approach was designed as an alternative to the premarket approval approach for Class III devices. The PDP approach has no equivalent in drug law.

The original purpose for which the PDP alternative was developed was to reduce the expense and administrative entanglements involved in bringing certain new medical devices to market. However, the PDP approach has undergone significant changes from the form in which it was originally conceived, and, whether or not the PDP approach, as enacted, will fulfill the purpose for which it was originally conceived remains to be seen.

Under the PDP approach, the manufacturer and FDA agree upon the proposed product development protocol ("PDP"); i.e., they agree in advance upon what constitutes appropriate preclinical and clinical testing, and what the appropriate results of such testing will be. In theory, the FDA will be more in-

[2]See ¶513(f)(2)(C) for critical device criteria.

diagnostic, and therapeutic devices. Accompanying these major advances in medical device technology came the potential for increased hazards and risks to public health.

The increased risks to public health associated with sophisticated medical devices coupled with the expanded authority to regulate drugs, under the 1962 amendments to the Food, Drug and Cosmetic Act, encouraged the FDA to regulate as drugs some products generally regarded as devices. In the first case [*AMP, Inc. v. Gardner,* 389 F. 2d 825 (1968), Cert. Denied, 393 U.S. 825 (1968)], the United States Court of Appeals for the Second Circuit held that a product consisting of a disposable applicator, a nylon ligature hoop, and a nylon locking disc used to ligate severed blood vessels during surgery was a drug. The court observed that since the product (a suture) could fall within either the "drug" or the "device" definition, a liberal interpretation of the Federal Food, Drug and Cosmetic Act justified classifying the product as a drug to better protect the public health through the premarket clearance procedure. In the second case [*United States v. Bacto-Unidisk,* 394 U.S. 784 (1969)] the United States Supreme Court sustained a determination of the FDA that a cardboard disc impregnated with antibiotics and used to determine antibiotic sensitivity was a drug. The court held that the legislative history of the Act ". . . read in light of its remedial purpose, directs us to read the classification 'drug' broadly". This liberal interpretation allowed the FDA to regulate as drugs certain diagnostic products, various weight reducing kits, hydrophilic contact lenses and intrauterine devices.

4. *Recommendations for Comprehensive Medical Device Legislation*

In late 1969 the Secretary of Health, Education and Welfare convened a medical device study group, composed of experts in medicine and technology, to evaluate the alternatives and devise the best approach to comprehensive medical device legislation. This group (the Cooper Committee) held meetings with representatives of the medical profession, industry, consumers and governmental agencies. The Cooper Committee recommended that medical devices be classified into three distinct regulatory categories: (1) those not subject to standards and premarket review; (2) those for which standards are necessary and adequate to assure safety and reliability; and (3) those requiring premarket approval.

B. The Medical Device Amendments of 1976 (the "Amendments")

After lengthy hearings and careful consideration, a regulatory program designed to protect the public from unsafe and ineffective medical devices, and, also to keep unnecessary regulatory restrictions from stifling advances in medical device technology was developed and enacted as the Medical Device Amendments of 1976 (the "Amendments"). The Amendments make distinctions between those devices which represent little risk to the public health and those devices which are more sophisticated and potentially more hazardous to the public health. These distinctions are made via three regulatory categories: Class I, General Controls (the lowest regulatory level); Class II, Performance Standards; and Class III, Premarket Approval (the highest regulatory level).

II. PREMARKET APPROVAL/CLASS III

Premarket approval is required for each Class III device. Three categories of devices which may be classified into Class III are: (1) "old devices", (2) "new devices", and (3) "drug devices". These terms are not used in the Amendments, but are adopted here to facilitate reference to these categories of devices. An "old device" is a device in commercial distribution before the date of enactment of the Amendments. Any such "old device" may be classified into Class III by the FDA following the receipt of recommendations for classification by the classification panel. A "new device" is a device not in commercial distribution prior to the date of enactment and not "substantially equivalent" to, and of the same type as, an "old device". A "drug device" is an item which is generally considered as a device but which has been regulated as a drug. "Drug devices" are to be transferred to the device regulatory scheme in Class III, unless placed in Class I or II under Section 520(1)(2).

A. *General Requirements—§515(a)*

A Class III device, unless exempt under the investigational use exemption [§520 (g)], is required to have an approval of an application for premarket approval, or alternatively, a product development protocol ("PDP") which has been declared completed pursuant to §515(f).

B. *"Old Device" Requirements—§515(b)*

An "old device" is not required to have an approved application for premarket approval until the la-

FDA Establishes 71 Standards as "Priority List"

FDA advisory panel chairmen have established a priority list for 71 standards as follows:

INTER-PANEL PRIORITY LIST FOR DEVICE STANDARDS DEVELOPMENT

Group 1

Aneurysm clips/devices
Arterial grafts and vascular prostheses—1
Cardiac monitoring systems—1
Defibrillators—FDA 1
Electroconvulsive therapy devices
Electrosurgical units and coagulators—FDA 1-3
Emergency ventilators and resuscitator units—9-11
Endoscopes—1
Ethylene oxide sterilizers—1
Fluoroscopic X-ray direct viewing
Gas anesthesia machines (include anesthesia breathing systems)—13—9—12
Hand driving controls—8
Hearing aids—4
Hip implants—8
Infant warmers-incubators (mobile & permanent)—FDA
Internal shunt assemblies
Intra-oral X-ray machines—11—3
Knee prostheses—8
Medical gas supply and vacuum systems—13—12
Ophthalmic lasers—1
Respirators and breathing machines (all types)—9—12
Short wave electromagnetic diathermy
Tracheal and tracheostomy tubes and cuffs—9
Ultrasound diathermy—1
Uterine suction devices (abortion)
Vacuum devices—12

Group II

Cryosurgical apparatus and accessories—1
Electrocardiograms—FDA 1
External cardiac compressor
External transcutaneous cardiac pacemaker—1
Finger joints—8
Hard contact lenses—1
Heart-lung resuscitator
Hypothermia/hyperthermia devices/systems
Withdrawal-infusion pumps
Intra-aortic balloons and balloon pumps—1 & 7 (Joint)
Intra-uterine catheters
Nursery apnea monitors
Oxygen monitors, depletion alarms
Pacemaker batteries, electrodes and lead adapters—FDA 1
Proximal femoral devices—8
Sorbent hemoperfusion apparatus
Spectacle lenses—5
Surgical lasers—1
Wheelchairs—8

Group III

Artificial shoulder implants—8
Auditory impedance testers—2
Autoclave sterilizers—1—3
Automatic gas furnaces—3
Beta radiation units—11
Compressed gas cylinders—16
Dental casting machines—3
Fixation screws—8
Fetal vacuum extractors
Foley catheters
Foot-ankle assemblies
Intermedullary rods—8
Inductively coupled implanted neurostimulator—1—8
Internal prostheses and mesh
Knee units
Microwave electromagnetic diathermy
Nystagmographs—2
Ophthalmic photocoagulators
Paracervical anesthesia sets—13
Perineural nerve stimulators (i.e. facial)—1-8
Transcutaneous electronic nerve stimulator—1—8
Uterotubal insufflators. CO 2
Anesthetic jet injectors—13—3
Therapeutic X-ray collimators—11
Therapeutic X-ray generators—11

ing the product in standards. The panels for the most part haven't done that to date, but recently the Panel Chairmen discussed a supplementary data sheet calling for the listing of indications, a general identification of any risks, specific hazards to health identified, along with the characteristic or feature of the device associated with the hazard. When the panels make these determinations, it should be much easier for the Agency to detail what it feels a performance standard should include.

Assuming the process of risk identification is accomplished, we'll be at the point where the drafter and then the Agency must decide what provisions of those available are necessary to control the risk. As I mentioned earlier, the pitfall to avoid here is indiscriminate application of all the possible provisions. So what criteria should be applied to pick the necessary provisions?

The industry viewpoint on this issue is summarized in a position paper drafted by an industry study group.

The paper states that the following principles should always be applied in determining the need for a standard, in developing a standard, or evaluating an existing standard for possible adoption:

1. Standards are only one mechanism which can help assure safety and effectiveness. Everyone involved in developing standards should be familiar with other regulatory provisions in the Food, Drug, and Cosmetic Act and specifically with the many general controls set forth in the new medical device legislation.
2. The standard should not require that the device or its performance exceed the current state-of-the-art.
3. Standards should represent a consensus of cognizant medical specialists and should avoid responding to a particular industry or professional preference relative to the requirements set forth in the standard.
4. A standard should not be developed for performance characteristics of the device where these characteristics would be adequately regulated by general controls.
5. The standard should encourage rather than restrict the application of new technology and innovation.
6. The standard should try to exclude requirements that connote a specification or define standardization unless there is no other practical method to describe the performance of that characteristic.
7. The standard should avoid incorporating design specification for those nonessential characteristics which pertain to convenience, aesthetics and the like.
8. The standard may include a test requirement section in order to ascertain that the essential characteristics of the device conform to the requirements set forth in the standard. Every test requirement section should include a referee test method by which the FDA may test compliance. Changes proposed for reference or referee test methods should be subject to the procedures set forth and appropriate for amendments to a performance standard. A standard might also contain a recommended test method. To the maximum extent possible, performance standards should not require the use of particular test methods by the manufacturer or certification by nongovernmental entities, the absence of which would preclude the manufacturer from distributing its product.
9. The standard should not include material limitation except when no other method is available to describe the performance of that characteristic.
10. Performance standards should be drafted with a recognition that, historically, standards reflect a minimum level of acceptable criteria or performance not in the sense of the lowest level but in the sense that they reflect reasonable practice, reasonable care, reasonable requirements, and a consensus agreement that the required criteria are attainable and are feasible when weighed against cost factors, manufacturing capabilities and the performance characteristics desired by a significant portion of the medical community. Caution should be exercised to avoid drafting a performance standard whereunder the result would be that a device would have to reflect the highest

PERFORMANCE STANDARDS

Michael Cole
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We've been concerned to this point in the program with the problems faced by a manufacturer immediately upon enactment of the Amendments. Let's shift our focus farther out into the future for a few moments and discuss the performance standard.

In the materials distributed to you is the HIMA/PMA Study Paper entitled "Summary of Major Provisions." Pages 16 and 17 of that summary set forth in detail the six steps in the procedure to promulgate a standard and the steps to amend or revoke a standard. This is a procedure you'll want to understand, but there's little I can add, so we won't spend time on it here. Instead, I'd like to describe for you standard-drafting activity that was in progress before enactment, which may cause problems if it continues as it has.

It concerns a very fundamental question—what should a regulatory standard try to accomplish? The Agency apparently has one view and industry another, and I want to discuss those views with you.

To put the discussion in context, let's review a few points quickly.

According to Section 513(a)(1)(B), a product is placed in Class II, Performance Standards, when the General Controls that have been discussed by earlier speakers on the program would by themselves be insufficient to provide a reasonable assurance of the safety and effectiveness of the device in question, and for which

> . . . there is sufficient information to establish a performance standard to provide such assurance . . .

Section 514(c), the notice inviting proposed standards, provides that when proposing a standard, an identification must be made of:

> . . . the nature of the risk or risks associated with the use of the device and intended to be controlled by a performance standard.

This notion that the performance standard is intended to control the risk associated with the use of the device is reiterated in Subsection (g)(2), which requires as an essential element of a Notice of Proposed Rulemaking:

> . . . 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.

The Regulatory Performance Standard, then, is a document which is intended to provide a reasonable assurance that the device subject to the standard is safe and effective by identifying the risks associated with the use of the device and providing means to control, reduce, or eliminate that risk.

The means available to control this identified risk are set out in the statute as the provisions which a performance standard can contain. We'll discuss each of these in turn. The important thing to keep in mind is that the statute says they should be included, *where necessary*. It doesn't say to the Agency, "Here's a checklist of all the things to cover in a performance standard; make sure you get them all."

So the decision as to whether to draft a performance standard involves two key steps. First the Agency must identify the risk. Then they must identify the means they feel are necessary to control that risk. To control the risk, FDA may direct that a standard contain provisions relating to many phases of a product—where those provisions are necessary to reasonably assure safety and effectiveness.

The regulatory standard may include provisions respecting the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to such systems. The House makes it clear in its report that where necessary these provisions include design-related requirements.

Next, the standard can include a provision for testing the device to insure conformity with the standard. The House Committee indicated that this testing could include both clinical testing and testing rele-

in the FDA's armamentarium has now been filled by a provision relating to temporary detention—or as the Act euphemistically calls it—"administrative restraint".

The new provision provides that, at any time during an inspection of a facility or a vehicle, any device which the FDA investigator "has reason to believe is adulterated or misbranded" may be detained by the FDA for up to 20 days or, in some cases, up to 30 days. During that period, of course, the FDA will compile whatever data are necessary to determine whether or not the device should be formally seized.

RISK NOTIFICATION AND COMMERCIAL REMEDIES[19]

The last new remedy given to the FDA by the device amendments is one of the controversial provisions of the new device legislation.

(Slide 5) The device amendments give the FDA the additional authority to order risk notification and the "3R" remedies of repair, replacement and refund.

The new law provides that if the FDA determines that a medical device "presents an unreasonable risk of substantial harm to the public health" and "notification . . . is necessary to eliminate the risk," the FDA may *order* "that adequate notification is provided in an appropriate form, by the persons and means best suited, . . . 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". There is an additional provision permitting FDA to require that health professionals give notice to their patients who have been exposed to the risk.

Ironically, we have felt over the years, that we were making some progress in limited situations where we were able to get the FDA to approve the use of "Dear Dr." letters as a substitute for device recalls. We didn't realize that we were only laying the ground work for this notification provision. On the one hand, I suppose the new provision is a recognition that notification has a role to play when device problems occur. On the other hand, we are now in a position where the FDA is going to tell us when, how, and to whom notice shall be given.

The commercial remedies are of particular concern since, for the first time, they give the FDA direct authority over the commercial relationship between the device manufacturer and its distributors and customers. The FDA has the authority to require a manufacturer to repair, replace, or refund the purchase price of a defective device, but only after making four specific findings. The FDA must first find that the device in question " . . . presents an unreasonable risk of substantial harm to the public health" (a phrase found throughout the Act). Secondly, it must find " . . . that the device was not properly designed and manufactured with reference to the state of the art as it existed at the time of its design and manufacture". Next, the FDA must find that the risk was not caused by the failure of someone other than the manufacturer, importer, or distributor—e.g., the installer, a maintenance man, or a repairer. Finally, the FDA must find that the notification which I have just discussed "would not by itself be sufficient to eliminate the unreasonable risk" and that use of the commercial remedies "is necessary to eliminate such risk".

If the four finds are made, the FDA can order the manufacturer, distributor, or importer to submit a plan for taking one or more of the commercial remedy actions. The FDA can either approve the plan submitted or disapprove it and prepare its own plan. The plan ultimately approved will be embodied in an order directed to the manufacturer, importer, distributor, or retailer, or one or more of them.

This plan may require one of these persons to do one or more of the following:

> Repair the device so that it does not present the unreasonable risk; replace the device with a like or equivalent device which is in conformity with the Act; or refund the purchase price of the device less a reasonable allowance for use, if the device has been in the possession of the user for a year or more.

A special provision states that the order may require a manufacturer, distributor, or importer to reimburse any other manufacturer, importer, distributor, or retailer of the device for any expenses incurred in connection with carrying out the order.

Finally, for those who had any hope that this provision might be in lieu of the present product liability responsibilities, this Section provides: "Compliance with an order issued under this section shall not relieve any person from liability under Federal or State laws."

What will this mean to us? I am sure you are aware that before the device amendments, the FDA en-

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[19] 21 USC 518

Penalties[6], including fines and imprisonment, can follow the commission of a *prohibited act.* You have most likely heard of the *Park* decision in which the President of a supermarket chain was found guilty of allowing products to be stored in a warehouse under unsanitary conditions which resulted in their being deemed adulterated. The case was appealed to the Supreme Court of the United States[7], and the Chief Justice in upholding the conviction said:

> "The Act imposes not only a positive duty to seek out and remedy violations where they occur, but also, and primarily, a duty to implement measures that will insure that violations will not occur. The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well being of the public that supports them."

Thus, I think you can see that the enforcement portion of the statute is really built upon the definition of *adulterated* and *mislabeled* devices.

With this background, let's see what changes have been made in these definitions by the device legislation.

(Slide 2) Before the Amendments, a device was deemed to be adulterated if it was composed of any filthy or decomposed substance or if it was prepared, packed, or held under unsanitary conditions whereby it may have been contaminated, or been rendered injurious to health. In addition, a device would be deemed to be adulterated if its strength or quality differs from or falls below that which its labeling set forth.

Under the device amendments, a device will be deemed to be adulterated in the following additional situations:

1. If it is subject to a performance standard and does not meet that standard[8],
2. If it is a Class III device and does not have the required premarket approval[9];
3. If it is a banned device (which I will discuss in a moment);[10]
4. If it was not manufactured, packed, stored, and installed in conformity with good manufacturing practices; or[11]
5. If it fails to comply with an applicable investigational use exemption.[12]

(Slide 3) Turning to misbranding, a device, under the prior law, was deemed to be misbranded if its labeling was false or misleading, if its labeling did not bear required language, or if it was dangerous to health when used as indicated in its labeling.

In addition to the ways in which a device could be deemed *misbranded* under prior law, a *restricted*[13] device may now be *misbranded* if its advertising is false or misleading, or if its advertising does not contain required information concerning warnings, precautions and contraindications. Prior to the device amendments, the FDA did not have jurisdiction over device advertisements. The FDA now not only has that jurisdiction as to restricted devices, but has full enforcement powers, through the mislabeling provision, for the agressive exercise of the jurisdiction.

A device will now also be deemed to be *misbranded* if it is subject to a performance standard[14] and its labeling does not bear any language required in the performance standard, or if the manufacturer has failed to keep the required records and make the reports which relate to the device. Finally, under the Amendments, a device will be deemed to be misbranded if its label does not bear the established name[15] for the device in type size at least 1/2 as large as the proprietary name used. FDA is given authority to set the established name of a device. Also regarded as misbranded under the Amendments are devices produced

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[6]21 USC 303
[7]United States v. Park 95 S. Ct. 1903 (1975)
[8]21 USC 501 (e)
[9]21 USC 501 (f)
[10]21 USC 501 (g)
[11]21 USC 501 (h)
[12]21 USC 501 (i)
[13]21 USC 502 (q) and (r)
[14]21 USC 502 (s)
[15]21 USC 502 (r) (1)

Slide 1
GENERAL CONTROLS

1. ESTABLISHMENT REGISTRATION
2. PRODUCT LISTING
3. 90 DAY NOTIFICATION
4. GOOD MANUFACTURING PRACTICES
5. RECORDS AND REPORTS
6. INCREASED INSPECTION AUTHORITY FOR "RESTRICTED DEVICES"

Slide 2
GENERAL CONTROLS

1. ESTABLISHMENT REGISTRATION
   a. Existing facilities annually
   b. New facilities immediately

Slide 3
GENERAL CONTROLS

2. PRODUCT LISTING
   a. At time of initial establishment registration
   b. Up-dated semi-annually (June and December)

Slide 4
MEDICAL DEVICE LISTING

A. Class II and III Devices
   —Drug/Device Statement
   —Reference to Marketing Authority
   —Copy of all Labeling
B. Restricted Devices
   —Drug/Device Statement
   —Copy of all Labeling
   —Representative Sampling of Advertisements
   —FDA may Request Copy of all Advertisements
C. All Other Devices
   —Drug/Devices Statement
   —Label
   —Package Insert
   —Representative Sampling of Other Labeling

Slide 5
GENERAL CONTROLS

3. 90 DAY NOTIFICATION [§ 510 (c)]
   a. Statement of determination
   b. Action taken to comply with standard or PMA

Slide 6
GENERAL CONTROLS

4. GOOD MANUFACTURING PRACTICES
   a. Advisory committee
   b. Exemption of variance

Slide 7
GENERAL CONTROLS

5. RECORDS AND REPORTS
   a. Regulations to be promulgated
   b. Necessary to assure safe and effective and not adulterated or misbranded
   c. Not to be "unduly burdensome"

Slide 8

1. Unpublished reports of clinical experience as well as reports in the scientific literature;
2. Unpublished reports of animal experience as well as reports in the scientific literature;
3. Experience involving physical or other properties of your product;
4. Copies of mailing pieces and other labeling as well as advertisements;

Slide 9

5. Information from which estimates of the incidence of adverse effects can be calculated;
6. Information concerning any previously unreported changes in the conditions of your premarket approval application;
7. Adverse experience reports; and
8. In certain limited situations, requirements for continuation of long-term studies.

Slide 10
GENERAL CONTROLS

6. INCREASED INSPECTION AUTHORITY FOR "RESTRICTED DEVICES"

Slide 11
ALL MEDICAL DEVICES

1. Facilities and Equipment
2. Materials
3. Containers
4. Labeling
5. Records required by Law [§ 519]
6. Records required by an IND [§ 520 (g)]

Slide 12
RESTRICTED DEVICES

Inspection Authority Extended to:

1. Records
2. Files
3. Papers
4. Processes
5. Controls

Slide 13
LIMITATION ON INSPECTION AUTHORITY

1. Financial data
2. Sales data
3. Pricing data
4. Personnel data
5. Research data

substantial outlays of capital and therefore plan accordingly. Third, you should begin to develop a quality control manual consisting of your standard operating procedures, in other words, "put it in writing." And fourth, you should develop both master product and product history records. Remember, the concept of GMP goes well beyond "end product testing" alone; rather, it seeks to build in product integrity at each phase in the manufacturing process. Although it appears unlikely that FDA will be able to promulgate final regulations by year-end, it is certainly not too soon to plan. It is well to remember that a failure to comply with Good Manufacturing Practices renders your products adulterated, subjecting them, as well as responsible corporate officials, to enforcement action.

SLIDE 7—RECORDS AND REPORTS

Another general control contained in the new Amendments permits FDA to require manufacturers, importers and distributors to establish and maintain records and reports necessary to assure that a device is not adulterated or misbranded and is otherwise safe and effective *(Section 519)*. This provision will not become effective, however, until FDA promulgates specific regulations.

Both the legislative history and statutory language recognized the need to eliminate unnecessary recordkeeping and report requirements consistent with the need to protect the public health.

As a result the new law places several limitations on FDA's authority to promulgate record and report regulations. First, FDA may not impose requirements which are unduly burdensome, balancing the cost of of compliance against the need to obtain information. Second, each request for the submission of a report must state the reason for the request and identify the requested information. Third, a manufacturer, importer or distributor of a Class I device may not be required to maintain records or submit reports not in his possession unless necessary to determine if the device should be reclassified or is adulterated or misbranded. These restrictions should not be construed as limiting otherwise necessary records and reports. For example, the House Report indicates that reasonable reporting requirements may include "reporting defects, recalls, adverse reactions, patient injuries and clinical experience" at least with respect to Class III devices.

With increased recordkeeping and reporting requirements, manufacturers may well anticipate a rise in regulatory actions and civil product liability litigation. Many of the documents furnished FDA will be available to plaintiff's attorneys and other interested parties under the Freedom of Information Act.

If record and report requirements now imposed upon holders of New Drug Applications is any indication of the Agency's thinking on this matter, manufacturers of at least Class III devices may expect to be required to maintain records and make reports with respect to:

SLIDE 8—(Anticipated Report and Recordkeeping Requirements)
First Half of Subject Matter

1. Unpublished reports of clinical experience as well as reports in the scientific literature;
2. Unpublished reports of animal experience as well as reports in the scientific literature;
3. Experience involving physical or other properties of your product;
4. Copies of mailing pieces and other labeling as well as advertisements.

SLIDE 9—(Second Half of Subject Matter)

5. Information from which estimates of the incidence of adverse effects can be calculated;
6. Information concerning any previously unreported changes in the conditions of your premarket approval application;
7. Adverse experience reports; and
8. In certain limited situations, requirements for continuation of long-term studies *(21 CFR 310.300)*.

Much of this information will be required to be submitted to FDA on a periodic basis. However, you may expect to be required to immediately report information concerning labeling mixups with other devices; significant deviations from specifications established in a premarket approval application or performance standard; and information concerning unexpected side-effects, injury, toxicity or sensitivity reactions.

In addition to requiring this information, FDA is authorized to inspect, copy and verify all required records and reports *(Section 704(e))*. This is true regardless of the classification of your device and regardless of whether or not the device has "restricted" status.

SLIDE 3—DEVICE LISTING

At the time of establishment registration, applicants must submit to the Agency a list of all devices which are being manufactured or processed for commercial distribution at that facility and which have not been included in any prior listing (Section 510(j)). Device lists will be required to be up-dated semi-annually in June and December. Lists for medical devices will be required to include a brief statement of the basis for believing that *each* product is a device rather than a drug. It would appear that a reference to the new definition of "device" contained in Section 201 of the Act indicating that the particular device does not achieve its principal purpose through chemical action nor is it dependent upon being metabolized may suffice.

SLIDE 4—MEDICAL DEVICE LISTING CHART

In addition to the statement on why a device is a device, the device listing will have to include the following:

A. In the case of medical devices subject to a *performance standard or premarket approval,* a reference to the authority for marketing the device and a copy of all labeling for such device;

B. In the case of a *restricted device,* a copy of all labeling, a representative sampling of all advertisements, and upon request for good cause, a copy of all advertisements;

C. In the case of *all other devices,* the label and package insert and a representative sampling of any other labeling.

If you have not already done so, it would seem wise for your company to prepare an up-to-date inventory of all medical devices that you manufacture or process and review all labeling and advertising pieces which you will be required to furnish FDA with your device listing. For some companies, this may be a substantial undertaking. Although registration and listing requirements are effective immediately, they will be implemented according to a time schedule established by the Agency.

SLIDE 5—90-DAY NOTIFICATION

One of the most significant and perhaps controversial provisions of the new law, since it is a provision which became effective immediately, is the notification requirements contained in Section 510 (k). In essence, that Section requires manufacturers proposing to begin the commercial distribution of a medical device to notify FDA at least 90 days before going to market in such form and manner as the Agency prescribes. The notice should include:

1. The class in which the device has been classified or if the device has not been classified, a statement of that determination. This statement should refer to the device's tentative classification until such time time as the classification becomes finalized by formal regulation; and
2. Action taken by such person to comply with any performance standard or premarket approval requirements applicable to the device.

Several interpretations of the intent of Congress have been advocated concerning both *when* this provision becomes effective and *which* device introductions require advance notification. FDA has already indicated its position as to *when* the provision becomes effective. On June 4, the Agency published in the *Federal Register* its Notice that manufacturers are under an immediate:

> **"Duty to notify the FDA 90 days before a person begins the introduction or delivery for introduction into interstate commerce for commercial distribution of a device for Human use."**

Others have questioned the legal authority of FDA's Notice. They argue that the provisions cannot become effective until either regulations requiring advance notification are promulgated or until manufacturers have filed their first Establishment Registration Form. I will not attempt at this time to resolve which position is right or wrong, but only will point out that a conflict exists and that the issue should be followed closely.

Perhaps of even more significance is the issue of *which* device introductions require advance notification. This is likewise subject to several interpretations. Many contend that a manufacturer should provide 90 days' advance notice when introducing a product not previously marketed by *that company,* whe-

panels will be meeting to review their efforts to date. In the past, few manufacturers have actually been represented at classification meetings and even fewer have submitted data or made presentations to the panels. Those who have done so will attest to the willingness of the panels to consider data or respond to presentations. The law gives the manufacturer the right to participate in the classification process; I suspect that more manufacturers will do so in the future.

While I have just recommended that more manufacturers should make presentations and should submit data to the panels than in the past, I have some concern whether the panels will reopen full deliberations on the many hundreds of devices which they have already reviewed. Certainly if all of us approach the panels with the scientific and field experience data we have, including large amounts of labeling, the panels would by necessity have to remain in session for long periods of time. On the other hand, as I previously mentioned, can we conclude that, in the absence of such full and lengthy evaluation, determinations of the safety and effectiveness are being made in compliance with legal requirements? It would appear that FDA might have jumped the gun in the entire classification procedure and caused the panels to rush into an extremely important task and to make critical determinations where an adequate data base was and still is in large part lacking.

Perhaps classification efforts should have awaited the enactment of the law, principally because only now does FDA have access to records, reports and other information which are absolutely essential if the panels are to make their determinations on the basis of existing clinical evaluations and other scientific evidence. Let us not lose sight of the fact that once devices and diagnostics are fully classified, the products are essentially locked into a permanent control category. For that reason alone, it would be well for FDA to re-examine the weight it contemplates giving to all past classification efforts.

in preventing impairment of human health; or (2) the device presents a potential unreasonable risk of illness or injury.

Let's talk about Class III for a moment, because it has one unique feature—and that is a special emphasis on inclusion of certain types of devices in premarket approval. Late in the game when the legislative conferees were meeting, the legislators decided that certain limitations should apply to the classification of devices intended to be implanted in the human body and those considered to be life-sustaining or life-supporting. When one of these devices is referred to a classification panel, the panel is *required* to recommend Class III unless the panel finds that the classification is not necessary to assure safe and effective performance. If the panel does not recommend Class III, it must state its reasons for *not doing so.* Likewise, when the FDA acts on the panel's recommendation, it must propose and ultimately classify the device in Class III unless that classification is not necessary.

By now, it should be obvious to you that a high percentage of implants and life-supporting/life-sustaining devices are likely to be classified in Class III. This situation could arise by default. In other words, the burden of establishing safety or effectiveness through Classes I or II will be too great or time consuming for the panels or the FDA to cope with.

The statute does not define implantable devices or life-sustaining/life-supporting devices. However, the Conference Report is of some help until the FDA provides some guidance or the panels establish some rules by actual classification practice. The Conference Report indicates that the Congress believes that devices which do not remain in the human body for 30 days or more should not be considered as implants for purposes of classification. Further, the Report notes that the FDA should "consider devices which are essential to the restoration or continuation of bodily function important to life to be life supporting or life sustaining".

The panels must provide the FDA with recommendations for classification of devices on the market before enactment within one year of the date when a funding appropriation is approved for the new law. When the FDA receives these recommendations, it will publish them (or a revision as noted below) in the *Federal Register* along with a proposed regulation assigning the device to an appropriate class. For the most part, the Agency will follow the panel's recommendations but is not legally required to, and it could propose a higher or lower classification for a certain device. The *Federal Register* notice will invite public comments on the classification of the devices. After these comments are received and reviewed, the FDA will publish a final regulation classifying the products, and perhaps revising some classifications based upon the comments received.

Officials of the FDA have indicated that they will accelerate the panel actions and publication of proposed classification for those devices already included in a pre-enactment priority list for standards. The panels have established tentative priorities for approximately 70 types of devices and included 26 devices in a highest priority listing. Those who manufacture or import these devices should expect to see their classification appear in the *Federal Register* much before the majority of other devices.

The other matter of note about *Federal Register* classification regulations is their application to devices in Class III. As of the date of the final order, the clock begins to run on the time limit to secure premarket approval for devices on the market before enactment and certain other Class III devices introduced after enactment. The manufacturer or importer will have at least 30 months to obtain an approved application or product development protocol. The House Report offers some cogent advice about final classification when it states - "classification into Class III does, however, serve the important purpose of providing notice to manufacturers or importers of such devices that they must begin preparation for submission of applications for premarket approval".

In all the discussion up to now, we have talked about the classification of devices which were on the market prior to enactment. ~~This inventory of medical devices and diag~~nostic products on the market prior ~~to May 28, 1976, are collectively referred to as "old de~~vices". This is a convenience term which is not found in the statute. Neither are the next two terms I will use to describe devices introduced after enactment found in the law. When we talk about devices introduced after enactment, the terms - "me-too device" and "new device" may be conveniently used for interpretative purposes.

A *me-too* device is any product introduced to the market after the enactment date which is of the same type and substantially equivalent to an old device. Further, a me-too device may also be a product similar to another device brought to market after enactment where that first device, which I call the *pioneer,* has been classified in Classes I or II.

I would like to offer a final comment on the *Federal Register* notice. In the notice, there is only a brief discussion of when panels shall meet in open or closed session. Prior to 1976, these classification panels, with few exceptions, conducted their classification in closed session. This year, we have seen a dramatic reversal of that procedure so that device classification meetings are generally open to the public. Concerning attendance at these classification meetings, I will offer some additional thoughts in a few minutes.

Addressing just the most important subsections of Section 513, I would like first to reference the discussion of medical device classification in the HIMA/PMA Study Papers on the Medical Device Amendments of 1976. You will find a general review of classification in the summary paper (pages 5-11) and an analysis of new product classification in the paper on new product introduction (pages 39-43). Discussions of the classification process can be confusing so you may want to refer to the references just cited along with the sections of the Act itself.

A word or two about the philosophy of the classification process will be helpful. Each of the three classes of devices under the new law is designed to provide the public, through FDA enforcement of certain controls, with the degree of regulation necessary to provide a reasonable assurance of safety and effectiveness. As you all will recognize, the term "reasonable" involves a value judgment which is in turn influenced by one's education, training, experience and, in some cases, prejudice. The dictionary defines reasonable as "not extreme or excessive". If we use that definition as part of the classification philosophy, then the next issue is how to arrive at reasonableness in the classification process. In the first instance, the law requires that reasonableness be the conclusion of experts on the classification panels. Thus, a reasonable assurance of safety and effectiveness entails thoughtful consideration by a group who can arrive at a collective and informed judgment about the device in question.

The legislation provides rules which these experts are required to keep in mind when making a classification decision. Under subsection (b), the law states that safety and effectiveness are to be determined by taking into account three elements of device use or experience. These are: (1) the *persons* for whose use the device is intended or represented; (2) the *conditions* of use prescribed, recommended or suggested in the product labeling; and (3) *weighing* any probable benefit to health from the use of the device against any probable risk of injury or illness from that use.

Besides these general rules, Section 513 provides additional guidance on how to reach conclusions on device safety and effectiveness. The safety of a device is really determined by the amount of information known about the product and whether it is represented for a critical use in therapeutic or diagnostic health care.

The supplemental rules for device effectiveness are concerned with the extent of clinical investigations upon, or the experience recorded with a particular device. The law correctly recognizes that some medical devices may not have had nor require the "well-controlled investigations" which are familiar to new drug studies. Thus, subsection (b) states as a general premise that device effectiveness will be determined through FDA regulations to require well-controlled investigations including clinical investigations where appropriate. However, the panels may consider what is being called "alternate evidence of effectiveness". This is *valid scientific evidence* other than that derived from well-controlled investigations. This type of evidence, according to legislative history, could be evidence derived from well-documented case histories or evidence in lieu of well-controlled investigations where unnecessary patient risk should be avoided.

When the FDA considers allowing the panels to use alternate evidence of effectiveness, it must satisfy itself on two counts; obviously, in the first instance, the alternate evidence must be sufficient in scope and documentation to make a judgment upon. Secondly, the evidence must be in a form so that the panels can fairly and reasonably make a finding on effectiveness as represented in the product's labeling. Assuming these two tests are met, the Agency should authorize the effectiveness of a device to be determined by alternate evidence of effectiveness.

While not required by the legislation, FDA has developed the "logic tree" which is a series of logic questions which, if answered properly, would aid the panels in reaching better classifications and would also provide more uniformity between the classifications of all panels. FDA has considered it necessary to have the medical device panels complete a supplementary data sheet to provide information not previously generated by the logic tree questions. Some of the new information was required by late changes in the legislation.

date. Although what I have just stated is true, that is, a premarket clearance device similar to a device on the market on May 28 may be first marketed after May 28 and if it is, is subject to the same rights and privileges; there is a provision in the new law which must be considered as it relates to these devices. The provision to which I am referring is one requiring manufacturers who propose to begin the introduction of a device into commercial distribution to notify FDA at least 90 days *in advance of* marketing. FDA takes the position that the 90-day requirement is effective immediately *and* applies to *all* devices sought to be commercially introduced except devices similar to devices previously marketed by other manufacturers. That is, if you want to market for the first time a device similar to one previously marketed by a competitor, you are subject to the 90-day rule.

The purpose of the 90-day rule is to give the FDA a 90-day opportunity to decide whether the product is, in fact, similar to one on the market as of May 28. If it is, a manufacturer is free to go to market but if it is not, the device is automatically subject to premarket clearance and cannot be marketed. The problem created for industry by the 90-day rule, and more specifically by FDA's interpretation of it, are twofold. First, the effects of a 90-day delay when shipping and promotional arrangements on the introduction are well underway; and second, the effects on a manufacturer of a disagreement between the manufacturer and the FDA as to whether a product is similar to a device previously on the market or is one which must be kept off the market because it is subject to premarket clearance. It is, of course, very risky to introduce a product in the face of an FDA claim that it is not similar to a device previously on the market.

FDA's conclusion that the 90-day notification rule is immediately effective and applies to most products and variations of products introduced on the market after May 28 is not necessarily compelled by the wording of the statute. It says that the advance notification requirement applies to manufacturers who are required to register and that the notification shall be in such form and manner as FDA shall prescribe by regulation. It can be argued that no manufacturer is required to register until the due date of the first registration. Further, FDA has not promulgated any regulations setting forth the form and manner of the notification notice. There are other factors to be considered. The notification provision requires notification by a manufacturer "who proposes to begin the introduction . . . of a device". If the device is substantially equivalent to, or of the same type as, a device that the same manufacturer had on the market on May 28, an argument can be made that the bringing of that device to market is not the beginning of the introduction of a device within the notification requirement but is merely marketing of a different version of the previously marketed device. There is indication that FDA shares this view.

Depending on whether the term device is used generally or not, the argument could be made that the same conclusion could be reached with regard to the bringing to the market for the first time a device substantially equivalent to, and of the same type as, one marketed only by your competitor as of May 28. As was the case with regard to the prescription device-restricted device issue, careful consideration must be given to your own situation before deciding how to apply the 90-day notification provision to your products. In PMA's and HIMA's letters to FDA I mentioned earlier, we also conveyed our concern about what we consider to be the unlawful conclusions reached by FDA on the 90-day notification provision. Congressman Rogers in his letter also stated that the 90-day notice rule could not be made effective absent a regulation setting up its implementation.

This concludes a description of the major provisions which manufacturers must consider immediately now that the law is passed. As time goes on, FDA will be promulgating regulations on such subjects as: manufacturer and product registration; requirements for the maintenance of records and submission of reports; good manufacturing practices; provisions governing the import of medical devices; regulations setting up the investigational use requirements for medical devices; the release of safety and effectiveness data submitted by manufacturers; regulations on restricted devices; and regulations providing for administrative detention of devices.

I'll close by repeating an observation I made earlier. It is important for the public and the industry that industry cooperate with FDA whenever possible. Even when we disagree on a legal question, we should not, without more, confront the Agency. It is also important to object when the Agency attempts to sidestep legal requirements to our disadvantage. When that happens, the appropriate course of action should be taken only after careful consideration.

devices have always been subject to prohibitions against their containing unsuitable substances or being packed under dirty conditions; and of course, the quality of a device has for some time been required to be maintained at the level at which it is represented. Similarly, devices have not been allowed to be described by false or misleading labeling. A package containing a device has had to bear the name and place of the manufacturer, packer, or distributor and a statement of its quantity of contents since 1938. Prominence of required labeling statements and adequate directions for use and adequate warnings have been requirements applicable to device labeling for some time. Of course, a device cannot be dangerous to health when used as recommended. It is the labeling requirements that probably need the most attention.

The new law adds some new requirements relating to the adulteration and misbranding of devices. They are effective immediately. Device containers are not permitted to be composed of any poisonous or deleterious substances and the device may not contain any unsafe color additive which would come into direct contact with the body for a significant period of time. If in fact you have a product containing a color which does have such body contact, you must check the status of the color. Some colors are limited to certain uses in certain amounts as set forth in final regulations. These final regulations have been issued only after submission of extensive animal tests and other data. Other colors are allowed either for general or special use in products pending the promulgation of final regulations.

Under the new law, devices must be labeled with their common and usual name (in addition to any trademark or brand name) until an official name is designated by FDA, at which time the official name will have to be used in place of the common or usual name. The common and usual name is the name most persons would consider most descriptive of the type of device involved.

Special provisions in the new law concern devices which, before the new law was passed, were marketed as drugs. As many of you know, as a result of two court decisions over six years ago, FDA was permitted to regulate some devices as drugs pending passage of a new law. Examples are: antibiotic sensitivity discs and some instruments used to tie sutures. Such products are now devices and, if marketed under an approved new drug application on May 28, are automatically considered to be legally on the market now pursuant to an approved device application and no further action need be taken at this time by a manufacturer. There were some devices in commercial distribution as of May 28 which are of the same type as, and are substantially equivalent to, devices subject to approved new drug applications on May 28. Some of them were neither subject to approved or pending new drug applications nor to investigational exemptions on that date. Such products are automatically placed in a premarket clearance category and must be taken off the market by July 27 unless one of two actions is taken. The affected manufacturer must either file a petition within 60 days to classify the device in the standards or general controls categories or file a completed application for premarket approval. In most cases, if data for an application have not yet been compiled, an application will not be able to be completed by the due date. Consideration should be given to the filing of a petition to reclassify. Although intraocular lenses are among the products included in the drug-device category, they are afforded special treatment. They are given 18 months to secure premarket approval. Special rules are also effective immediately for devices such as antibiotic discs which contain antibiotics subject to certification requirements. They will continue to be subject to antibiotic certification until such time as an approved device application or an effective standard supersedes that requirement. If a device containing an antibiotic is classified in the general controls category, antibiotic certification requirements will no longer apply once the effective date of the classification into general controls has been reached.

Other provisions of the new law effective immediately are sections requiring FDA to maintain the confidentiality of trade secrets and other confidential information and a general prohibition against states having in effect laws or regulations inconsistent with those placed in effect by the Federal Government. It might be a good idea to note those portions of documents you submit to the Agency which you consider to be trade secrets or otherwise confidential information. Agency officials would be running a risk of incurring criminal liability if, in spite of such notification, they released the data. The confidential information other than trade secrets is that protected from mandatory disclosure under the Freedom of Information Act. That Act should be consulted to see what categories of information are included. With regard to state laws, certainly consult your legal counsel if states attempt to impose requirements on you inconsistent with Federal law.

Devices in commercial distribution on May 28 which were considered prescription devices under the Federal law in existence at that time generally are afforded the same treatment as other devices commer-

INITIAL CONCERNS ON ENACTMENT OF THE MEDICAL DEVICE AMENDMENTS OF 1976

Rodney R. Munsey
Vice President
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Pharmaceutical Manufacturers Association

I am pleased to be here today to talk to you about requirements set forth in the new devices law which manufacturers must consider immediately. As you know, the word is "immediately" because the Amendments were signed on May 28. You probably noticed Frank Samuel and I were careful, as program co-chairmen, to assign ourselves topics that would require little thought. A general overview can usually be composed quickly from easily obtainable sources and a statement of what provisions are effective immediately can be derived from a quick glance at the effective date portions of the Act. We leave to others on the program the job of telling you what these provisions mean, how they will affect your business, and what you should do about them.

One of your handouts for this conference is an informational piece prepared jointly by HIMA and PMA entitled "The Medical Device Amendments of 1976". Part II of that handout is "First Concerns Upon Enactment". It contains much of the substance of what I will be talking about as well as additional information. As you know, copies of my remarks as well as those of the other speakers will be forwarded to you later. Some of the comments made by the various speakers today will be repetitive and overlapping. This is intentional. In our view, the complexity of the provisions requires both repetition and approaches from different directions.

A logical first consideration of immediate concern to manufacturers under the new law is the new definition of medical devices. Some products may now be devices that were not devices as of May 28. For example, some products that were drugs will now be devices as will be products that were formerly in limbo as *in vitro* diagnostic products. Also, products in the Official Compendia that are not drugs are devices as are all instruments and apparatus used to diagnose bodily conditions whether or not disease or specific body structure or function is involved. A careful review should be made of all products used in the health field which were not previously thought of as medical devices to ascertain if they now are. A good rule of thumb is that if they are used directly and specifically for health care and are not now drugs, there's a good chance they are devices.

Before discussing other immediate concerns and actions of manufacturers under the various provisions of the new law, I'll mention the new enforcement provisions which can be applied immediately to any device in general distribution. If a device in commercial distribution which is intended for human use presents substantial deception or serious risk, FDA in some circumstances may *remove* or ban that device from the market without *any formal* administrative hearing and indeed, in advance of any opportunity of the manufacturer to go to court. If the deception or risk, in addition, presents a direct and substantial danger to the health of individuals, FDA can in some circumstances remove the device from the market in advance of even granting any informal hearing. Similarly, if a determination is made by FDA that a device in commercial distribution presents an unreasonable risk of substantial harm to the public health and certain other conditions are met, it may require notification to all parties involved. In some cases, manufacturers may be required to repair or replace such devices or refund the purchase money paid for them. These FDA sanctions are in addition to the court actions which have *traditionally* been available to the Food and Drug Administration to enforce the Food, Drug, and Cosmetic Act. The traditional actions are: the bringing of a criminal action for violation of the Act, proceeding to court for an injunction against future or continuing violations of the Food and Drug Act, and the obtaining of a writ from a court to seize devices that do not conform to the Act. A seizure action is a court action in which the Government seeks to condemn a particular product or batch of product rather than proceeding against the offending individual personally or against the company. Incidentally, under the new law, some previously existing limitations on the circumstances under which devices can be made subject to a seizure action have been removed. Thus, under the new law, if a device is adulterated or misbranded, it is subject to seizure whether or not the device has been or will be shipped in interstate commerce. In seizure actions involving other products under the juris-

- *Section 516* contains the standards and procedure for banning a device from the market in both conventional and emergency situations.
- *Section 517,* primarily the concern of the lawyers, deals with the procedure for and standards to be applied when court review of various FDA actions is sought. It will not be dealt with during these meetings.
- *Section 518* details the procedural requirements and determinations which need to be made when FDA wishes to order that users be notified of hazards or the repair, replacement or refund of a device.
- *Section 519,* potentially one of the most far reaching sections of the bill, sets forth the requirements and limitations of FDA authority to require recordkeeping and reporting.
- *Section 520* contains many significant features in the bill including, for example, the authority to issue device good manufacturing practice regulations.
- *Section 521* provides for the preemption of state laws on the subject of devices but allows, with the permission of the FDA, fairly significant exemption from that preemption authority.
- *Section 3* is what might be called the fine print in the Amendments. And, as usual, the fine print has many key changes, ones which tie device and diagnostic product regulation into the pre-existing provisions of the Food, Drug and Cosmetic Act. For example, here (see page 37) can be found the new definition of "device" and amendments to the prohibited acts, misbranding, adulteration and export provisions of the Act as well. I should note here that the term "device" is defined to include *in vitro* reagents and instruments. The use of the word "device", therefore, should not lull IVD manufacturers into a false sense of security. Most of what will be said today applies to you as well as manufacturers of devices in the trade sense.
- *Sections 4 through 10* of the Amendments set forth significant general controls and other aspects of FDA authority.

The table of contents does not reveal two of the most significant features of the legislation. The first is the wide-spread use of advisory committees. This has been a feature of FDA's implementation of its responsibilities under the Food, Drug and Cosmetic Act in recent years. Here, for the first time, it is written into the statute. You will hear about the utilization of these advisory committees during various other presentations today, but surely the statutory requirement for their utilization distinguishes these Amendments from others. By law, non-voting industry representatives are required on almost every advisory panel established by the Amendments. Thus there is an opportunity for direct input into the advisory process.

Secondly, the Amendments set forth in great detail procedural steps which must be taken by the Agency in regulating our industry and other steps which may be taken by representatives of manufacturers or others in either pursuing or protecting a right under the Act. Mastery of these procedural steps is absolutely essential for any company with a product to which they apply.

But the text of P.L. 94-295 and the committee reports are only the beginning. The extent and complexity of the new law demand that the manufacturers keep well informed on its implementation. This means that you should pay attention as never before to published material from several sources: your trade associations, whether PMA,HIMA, or others; the FDA through the *Federal Register;* and the trade press. The extent and complexity of the new law also require that management decisions about specific products or situations should be made only after careful consultation with counsel competent in FDA law. Industry and FDA opinions which you will hear and read about are no substitute for this consultation.

D. *The Outlook for Implementation*

Let me close my remarks with speculating about what will happen now that the law has passed.

First of all, I think there will be a substantial period of uncertainty during which FDA sorts out its priorities for action and provides interpretations of the provisions of the Act. In some respects, this process of interpretation and implementation will never end.

The period of uncertainty means that manufacturers will be at risk from decisions which they will be forced to make on their own to interpret the intent of the law and the range of permissible FDA administrative action. In one sense, this is a wholly irrational situation: manufacturers will be given no real guidance on what FDA expects, but they will be held responsible for the results of well-informed and well-intentioned decisions which turn out later to be different from what FDA decides should have been done. On the other hand, the opportunity is there for the industry to make thoughtful, well-considered decisions

OVERVIEW OF MEDICAL DEVICE AMENDMENTS OF 1976

Frank E. Samuel, Jr.
Vice President and General Counsel
Health Industry Manufacturers Association

A. *Purpose of HIMA/PMA Meetings*

During the four HIMA/PMA conferences, we expect that nearly 1,000 representatives of the device and diagnostic product industry will hear the presentations which you will hear today. We have three major purposes for holding these meetings.

First, we are beginning the educational process in the *law*. Even for those of you who have been involved with the *legislation* for some time, today is a beginning. We now have a "law", not competing bills, various amendments, several possibilities. We now know what the law says, and we must turn our attention to trying to figure out what it means.

Consequently, the second purpose of these meetings is to give you some idea of the implications and problems of P.L. 94-295. This will build upon explaining the terms of the legislation itself and can only be suggestive, not definitive. The real meaning of the statute will become clear only as it is implemented by FDA. Nevertheless, you will gain insight today into the number of issues posed by the legislation, as well as the fact that rarely is there only a single way to deal with many situations. That may leave you more frustrated and confused than when you came; if so, you will not be alone. It should leave you skeptical of certainty, whether it comes from FDA or one of the speakers on this platform.

Third, our sessions should help make the sessions with the Food and Drug Administration more useful. That is why we scheduled our meetings to precede the FDA's. Because you will have a better understanding of the terms of the bill, we hope you will be able to put FDA's presentations and their answers to your questions in better perspective.

B. *Historical Background*

Most of our attention today will focus on the Medical Device Amendments of 1976, but the legal context for the regulation of the medical device and diagnostic product industry dates back much farther than that. There are five dates which will suggest this context.

1. **1906:** Congress passed the Pure Food and Drug Act which gave to the agency which is now the Food and Drug Administration authority to remove adulterated or misbranded foods or drugs from the marketplace.

2. **1938:** The Federal Food, Drug and Cosmetic Act was enacted, significantly modifying the 1906 Act and including medical devices for the first time within FDA's jurisdiction. The authority over devices, however, extended basically only to those devices which were adulterated or mislabelled.

3. **1962:** Congress passed significant amendments to the Food, Drug and Cosmetic Act, the Kefauver-Harris Amendments, giving FDA greatly expanded authority over determining the effectiveness of new drugs.

4. **1970:** The Cooper Commission submitted its report on the regulation of medical devices and diagnostic products.

5. The final date is, of course, May 28, 1976, the date that President Ford signed into law the Medical Device Amendments of 1976, Public Law 94-295. These are the first device-related amendments to the Food, Drug & Cosmetic Act since 1938.

These five dates, then, suggest the historical context for the new legislation. I would like to make five points with it in view.

1. At least since 1962, vastly increased regulation of the medical device and diagnostic product industry has been virtually inevitable because of two factors: the increased public and Congressional concern with health care and health care products (as evidenced by passage of the 1962 drug amendments), and the significant growth in the number, complexity and visibility of products which we manufacture. The only real question after 1962 was whether increased regulation would take place through judicial or legislative means.

2. The Cooper Commission findings and recommendations articulated a consensus that was to be reflected in all serious, subsequent legislation on the subject. This consensus lives on, virtually unchanged,

Frank E. Samuel, Jr., Esq.

Mr. Samuel is Vice President and General Counsel of the Health Industry Manufacturers Association. He previously served as deputy assistant secretary for health legislation of the Department of Health, Education and Welfare where he had major responsibility in developing and presenting the department's legislative programs in the area of health.

Mr. Samuel holds a BA from Hiram College in Ohio and received his JD from Harvard Law School.

George F. Smith

Mr. Smith joined the Pharmaceutical Manufacturers Association as Manager of Medical Devices in 1974. He has spent over 22 years in the development and production of guided missile and aerospace systems and is experienced in nuclear safety planning for DOD weapon programs.

Mr. Smith received his BS from West Point and his MS in Electrical Engineering from Johns Hopkins University.

Donald R. Stone, Esq.

Mr. Stone is Senior Vice President, Product Assurance and Regulation, Medtronic, Inc., with responsibility for the company's efforts to ensure product safety, efficacy, reliability and regulatory compliance.

Mr. Stone earned a BS in physics from the University of Wisconsin in 1960 and a JD from the University of Wisconsin Law School in 1963 where he was elected to the Order of the Coif and was a member of the *Wisconsin Law Review* Board of Editors.

Timothy M. Wendt, Esq.

Mr. Wendt is Group Counsel, Pharmaceutical, Dental, and Dietary Groups, American Hospital Supply Corporation. Previously he was a law clerk in the U.S. Court of Appeals, Sixth Circuit, then an Assistant Professor of Law at Vanderbilt University, and most recently an attorney with Miles Laboratories.

Mr. Wendt graduated cum laude from Carroll College in 1967 and received his JD from the University of Wisconsin where he was elected to the Order of the Coif and was a member of the University of Wisconsin *Law Review*.

He has been an active member of the HIMA Legal and Regulatory Section.

Jaxon A. White, Jr., Esq.

Mr. White is Assistant General Counsel and Director of Diagnostic Regulatory Affairs for the Health Industry Manufacturers Association. He has served as a staff attorney for the American Society of Hospital Pharmacists and as the Assistant Director of Medical Regulatory Affairs for the Scientific Apparatus Makers Association.

Mr. White holds a BS in Pharmacy and a JD degree from Catholic University's Columbus School of Law. He is a Registered Pharmacist and a member of the Virginia and District of Columbia Bars.

Maynard Youngs, Esq.

Mr. Youngs is Senior Attorney, Regulatory Affairs, Travenol Laboratories, Inc. From 1962 to 1975, he served as Vice President and General Counsel for Lakeside Laboratories in Milwaukee, Wisconsin.

He received his BS in Chemistry from Kalamazoo College in 1954 and his LLB From George Washington University in 1959. Mr. Youngs is a member of the Virginia, District of Columbia, Wisconsin, and Illinois State Bars, as well as of the American Bar and American Patent Law Associations.

The Speakers

G. Marshall Abbey, Esq.

Mr. Abbey is Vice President, Secretary, and General Counsel at Baxter/Travenol Laboratories, Inc. He received a BA degree with high distinction in 1954 from the University of Rochester where he was elected to Phi Beta Kappa in his junior year. He received a JD with distinction in 1957 from Cornell Law School where he was elected to the Order of the Coif and was a member of the *Cornell Law Review* Board of Editors.

Mr. Abbey was engaged in the private practice of law from 1957-1965 with the law firm of McLane, Carleton, Graf, Green and Brown in Manchester, New Hampshire. In 1965, he joined Baxter/Travenol Laboratories and was named General Counsel. He was elected Secretary of the Corporation in 1972 and made a Vice President in 1975.

Michael Cole, Esq.

Mr. Cole joined Johnson & Johnson in 1969 as General Attorney and currently has responsibility for device legislation in the United States and Canada and product liability matters for most of the Johnson & Johnson companies. He has also been an active member of the Legal and Regulatory Section of HIMA.

Mr. Cole graduated Magna Cum Laude and Phi Beta Kappa in Political Science from Vanderbilt University and was a Root Tilden Scholar at the New York University Law School.

Timothy R. Craig, Esq.

Timothy R. Craig is Assistant General Counsel for the Health Industry Manufacturers Association. Mr. Craig joined the HIMA staff in April, 1975. Formerly, he was Manager of Governmental Affairs for Smith, Bucklin and Associates, a trade association management firm with offices in Chicago and Washington, D.C. Mr. Craig assumed his position with Smith, Bucklin upon completion of law school in 1973. While attending law school, he served as staff assistant to the Honorable J. Edward Roush (D.-Ind.) and was involved in both legislative and administrative affairs.

Mr. Craig holds a bachelor's degree in political science from Northwestern University, having graduated in 1970 with departmental honors, and a JD from Georgetown University Law Center. He is a member of the State Bar of California.

Thomas E. Hubbard, Esq.

Mr. Hubbard is Director of Clinical Affairs, Zimmer-USA, Inc. He served as a regulation writer for the Food and Drug Administration from 1974 to 1975, working extensively on the draft for medical devices and diagnostic products.

Mr. Hubbard received his BS in Biomedical Engineering in 1970 from Duke University and his JD in 1973 from the University of North Carolina. He is a member of the North Carolina State Bar, the Association for the Advancement of Medical Instrumentation, and the American Society for Testing Materials.

James W. Hulse, Esq.

Mr. Hulse is Corporate Director of Regulatory and Industry Affairs at Becton, Dickinson and Company. In his position, Mr. Hulse is responsible for identifying product regulatory requirements and coordinating compliance programs and policies throughout the Company and its subsidiaries. He also represents the Company's position before governmental agencies and various trade and professional associations in the health care industry.

Experienced in Food and Drug Administration affairs, he is active in the Health Industry Manufacturers Association, Pharmaceutical Manufacturers Association, and the Scientific Apparatus Makers Association.

Mr. Hulse joined the Law Department of Becton, Dickinson in 1970. Previously he was an attorney with Esso Research and Engineering Company; Chas. Pfizer & Co., Inc.; and with the U.S. Department of Justice.

He received his BA and JD degrees from Rutgers University and has been admitted to practice before the District of Columbia, New Jersey and New York bars.

D. House Report No. 94-853 - Medical Device Amendments of 1976

E. Conference Report No. 94-1090 (Joint Explanatory Statement of the Committee on Conference)

F. Medical Device Amendments of 1976 - Study Papers (May 28, 1976)

G. "Premarket Clearance, How and When Products Get There and What Must be Done About Them" (Speech by Rodney R. Munsey, PMA, at the AAMI Clinical Evaluation of Medical Devices Conference on April 28, 1976)

H. FDA Key Officials

I. Implementation of the Medical Device Amendments of 1976, 41 *Federal Register* 22620, June 4, 1976

J. Tools of Compliance (Publication of the Bureau of Medical Device and Diagnostic Products, Food and Drug Administration)

K. FDA's Initial Registration Instructions

L. Premarket Approval/Product Development Protocol Sequence of Events, Complications and Remedies

