TESTIMONY OF SIDNEY M. WOLFE AND ANITA JOHNSON
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ON
MEDICAL DEVICE LEGISLATION
BEFORE
HOUSE SUBCOMMITTEE ON HEALTH
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Chairman Rogers and members of the Subcommittee, thank you for the invitation to present testimony on the pending medical devices legislation.

The ability of the government to control medical devices now, in 1975, is largely comparable to its ability to control drugs in 1906. The public is justifiably outraged by the endless succession of medical devices such as IUDs, pacemakers, cardiac resuscitation equipment and the like which, not having been adequately tested before marketing, fail to work properly and kill or injure thousands of people each year.

This need to bring medical devices from the earlier to the later part of the 20th century by regulation comes, however, at a time when many are questioning the need for certain kinds of regulation.

The experiences with the ICC and CAB, in which cartels are being protected from the public should not be confused with consumer protection statutes such as the Food, Drug & Cosmetic Act, Occupational Safety and Health Act, Consumer Product Safety Act and other legislation which more clearly intend to prevent harm to the public.

In considering this legislation, then, the question needs to be asked, will it significantly reduce the mounting toll of medical device-caused injuries and deaths or will it simply further the cartel status of the largest companies which control this multi-billion dollar per year industry? Will we continue to see dozens of deaths, hundreds of injuries and thousands of units "voluntarily" recalled as with pacemakers, IUDs and other devices -- the extent of whose dangers have not yet been made known to the public? Will this legislation prevent these tragedies or will it merely institutionalize and even legitimize their further occurrence?

I will cite several examples of serious problems associated with medical devices which illustrate the need for mandatory authority to regulate devices more like drugs than like office furniture, as the present bill might allow.

INTRA-OCULAR DEVICES

Intra-Ocular Devices (IODs) are plastic lenses which are surgically implanted in the eyes of people whose natural lenses have had to be removed, usually because of cataracts. Although these lenses have been in use for more than 20 years as an alternative to wearing glasses after cataract surgery, many ophthalmologists think they have never been properly tested in animals or clinically investigated by multiple ophthalmologists under carefully controlled protocols.

As a result, the implantation of IODs has resulted in serious damage to the eyes of many patients including glaucoma, severe corneal disease, inflammation and infection. In a large number of cases, many known to the FDA, it has become necessary to re-operate to remove the plastic lens because it has become displaced forward or backward from its original location.

More alarming are a very large number of cases, mostly never published -- or reported to the FDA -- of people who have had to have their entire eye removed because of complications resulting from the lenses. The one published study of such complications reports on 17 people whose eyes had to be removed because of IOD-induced glaucoma, severe corneal damage and other complications.[1]

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1. Arch. Ophthal. 82, 726, 1969

At a recent meeting (April 3-4, 1975) of the FDA Ophthalmic Devices Advisory Committee, Dr. Richard Troutman, a noted ophthalmologist from the Manhattan Eye and Ear Hospital in New York, revealed the following:

> 1) One of the earlier lenses, the "Strampelli" lens, was eventually discontinued because 80% of those implanted had to be removed, 20% of these causing sight-destroying complications.
>
> 2) 10-15% of a series of 261 patients who had a "Copeland" IOD implanted suffered retinal damage (cystoid maculopathy) which may be irreversible and lead to decreased vision.
>
> 3) The placement of lenses in younger (than 67) patients results in uniformly poor results.
>
> Conservative ophthalmologists* do not implant lenses in patients under 67 years of age or in more than 10% of cataract patients and then only in one eye (because of the possibility of serious bilateral complications).
>
> Two West Coast ophthalmologists, on the other hand, place the lens into about 90% of their cataract operation patients, often in both eyes, in young patients and at a rate that may be as high as 100 lenses per week.

Dr. Troutman further told the FDA advisory committee about his concern that "in the United States lenses were used which had not been clinically proven" and that "statistically significant results on implants which had been placed for 5 to 7 years were not available."

He expressed serious concern about the bioincompatibility between the plastic lens and the eye which he felt to be the primary cause of the problem.

Finally, in response to being asked if he would have an intra-ocular lens implanted, Dr. Troutman stated

> "If I were more than 75 years of age and if I had a signed death certificate indicating that I would die in seven or less years, than I would have it."

We have subsequently learned, via sources in the industry, that the Copeland lens alone is being produced at a rate exceeding 3,000 in 1974 and estimated at over 5,000 for 1975. At more than $1,000 per operation, this amounts to a $50 million dollar annual industry.

Like the IUD, the IOD, or intra-ocular lens is a plastic device for long-term implantation in the human body without adequate pre-market testing before what was and is mass-marketing for both. Both have yielded millions of dollars for their producers and for the doctors who put them in. Both have had severe adverse effects on health with death from septic abortions from the IUD, loss of eyes and vision from the IOD.

In the absence of mandatory pre-market testing for all such devices, more disasters are bound to occur.

CARDIAC PACEMAKERS

In April of this year, Senator Ribicoff made public the HEW response to his inquiry about defective pacemakers. It was learned that more than 23,000 pacemakers had, by that time, been recalled with approximately 29 deaths due to pacemaker failure. (See recalls number 1 thru 7 in table below).

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* The most conservative ophthalmologists do not use the lens at all since it has not been properly tested yet.

Since then, there have been 4 more "announced" recalls (8-11) with 2 additional deaths.

In addition to the more than 24,000 announced recalls as of today, Biotronik, in a document never released by Sen. Ribicoff, refers to a large failure rate (8.9% in 2 years) in a Medtronic pacemaker which was never recalled. As we have observed before, Medtronic, the pacemaker market leader, seems to enjoy a favored position with FDA top officials. Thus, despite the numerous problems that have occurred with its pacemakers, there has only been one small official recall. (several weeks ago)

Pacemaker Recalls

	Date	/Company	Number /Defective Units	/Defect	/Deaths	
1.	April 1972[a]	GE	574	leakage of body fluids uncontrolled rate increase	8	
2.	July 1973[b]	Cordis	14,050	rate increase	18	
3.	Oct 1973[b]	Cordis	4,900	premature failure	?	not finished
4.	Feb 1974[c]	Biotronics	1,478	battery leakage	1	(+ 27 injuries)
5.	June 1974	GE	257	fluid leakage rate increase	?	
6.	June 1974[d]	Vitatron	506	leakage of body fluids rate increase	?	
7.	Feb 1975	GE	2,239	leakage of body fluids	2	
8.	May 1975	Vitatron[e]	256	leakage of body fluids	?	
9.	May 1975	Pacesetter	47	fracture of wire & failure to pace	2	
10.	May 1975	GE	17	leakage of body fluids premature battery depletion	?	
11.	July 1975	Medtronic	3	failed test for electrical current leakage	?	

As can be seen from the table, the problem in most of the defective pacemakers was leakage of body fluids into the implanted instrument.

We have received a copy of an unpublished paper, recently submitted to the Journal of Thoracic and Cardiovascular Surgery by cardiac surgeon and pacemaker researcher Dr. Frank Tyers, Associate Professor of Surgery at Penn State and his co-worker, electrical engineer Robert Brownlee. It discusses the problem of non-hermetically sealed pacemakers:

> "The publicly reported loss of life from pacemaker rate changes and the recall of pacemakers within the last few months represents just the latest in a series of problems related directly to inadequate protection from moisture.... The intrusion of body fluids into epoxy encapsulated pacemakers can and has resulted in lethal pacemaker "runaway".... Premature battery depletion and other circuit

a) FDA learned of this recall through the news media
b) FDA learned of recall in August 1974, 10 months after it occurred, during a plant inspection
c) FDA learned of recall August 1974, 1/2 year after ot occurred, from an M.D.
d) FDA learned of recall in Dec. 1974, 6 months after it occurred, from an M.D.
e) Originally thought monitoring could detect defect, (see d above)

deterioration with resultant pacemaker malfunction or total failure can also occur from the gradual entrance of the caustic implant environment into the pacemaker unless means are devised to provide long-term protection from moisture...."

"The real problem is the industry reliance upon epoxy encapsulation for sealing body fluids out of pacemakers when the inadequacy of this material as an absolute moisture barrier has been known for years. Non-hermetic metal coverings over epoxy encased units have proven to be equally inadequate as moisture barriers in both Biotronik and Medtronic pacemakers. In fact, fluid entrance into metal encased Biotronik units has resulted in encapsulant rupture with poisoning and gas formation in the tissue of the host patient and tissue ingrowth resulted in early failure of sheathed Medtronic Units."

"In 1969 the Navy proposed standards for hermetically sealing electronic components but they were rejected by the FDA. In the interim, over 22,000 pacemakers manufactured by Biotronik, Cordis, General Electric and Viatron have been involved in class one or two recalls, 26 sudden deaths have occurred in patients with defective pacemakers and several hundred patients (5% of our own series of over 200 implants) have been subjected to additional surgery because of moisture related pacemaker malfunction. It therefore seems readily apparent that the pacemaker industry over the last 10 years and unfortunately with continuing practice, has absolutely proven that hermetic encapsulation of implanted electronic devices is essential to insure patient safety and as a requirement for any significant extension of device functional life. Why then would Secretary Weinberger of Health, Education and Welfare, in a hand delivered 11-page letter to Senator Ribicoff, recently state that 'to require the hermetic sealing of all implanted pacemakers is not necessary or wise' but 'would adversely affect the present utility of pacemakers' and in addition 'the entire unit can't be sealed because gas must be released.' Each of the Secretary's assertions is incorrect and we are surprised that he did not go on to recommend that the Navy instead go along with the FDA and make epoxy torpedoes."

Dr. Tyers concludes his paper by stating that:

"A continuation of the development and sales of non-hermetic pacemakers beyond a reasonably brief phase-out period should be considered malpractice on the part of the device manufacturers."

In discussions last week with Dr. Tyers and his co-worker, Robert Brownlee, I learned that the pacemaker standard presently being developed -- with major input from industry -- completely omits requirements for hermetic sealing. They went on to question whether or not it would really be possible to ever work out an adequate pacemaker standard and both thought that pre-market testing would probably be more appropriate for pacemakers. (and many other such devices)

If 31 deaths, 1,300 cases of emergency surgical removal, and 24,000 defective pacemakers don't convey sufficient urgency to require pre-market testing, what will it take?

According to Dr. Tyers, virtually all the defects which have occurred after the mass-marketing of now over 150,000 pacemakers could have been predicted by proper pre-market testing. Industry was and is too eager, however, to get their goods to the market first (competitive spirit) to do adequate pre-market testing unless required by law.

ANESTHESIOLOGY DEVICES

More than 100,000 persons die each year in the U.S. during or shortly after surgery, with a disproportionate number of these deaths being associated with the use of general anesthesia.[1] In many cases, faulty anesthesiology devices have been responsible for the deaths.

Although device manufacturers would have the public believe that device-associated hazards are almost always the fault of medical personnel rather than the device itself, the large number of recalls due to defective equipment argues to the contrary.

During the past 2 months alone, the following device recalls have occurred just for anesthesiology equipment:

Device	/Company	/Problem	/Units Distributed
gas evacuator	Ohio Medical Products	valve sticks with possible bursting of patients lungs	4,887
air/oxygen mixer	Bendix	valve sticks; incorrect amount of oxygen delivered	208

At its most recent meeting, April 7, 1975, the FDA Anesthesiology Device Panel was especially concerned about assigning a high priority for setting standards for those devices with "urgent" problems associated with their use.

The following list, obtained from the minutes of the April 7th meeting, contains a description of those anesthesiology devices in "urgent" need of standards and a brief description of the basis for this need:

APPENDIX B

Flow meters, anesthetic gas. The loss of vital gas flow to the patients through a leaking, broken, cracked or through misassembly of unmarked components of a flow meter may result in serious problems or even death.

Alarms, oxygen concentration. These devices have inadequate and unreliable performance. They have a high incident of use and the failure to operate properly can cause severe problems for the patient.

Monitors, breath oxygen. The misconnection or misapplication of this device can cause serious problems for the patient. They have a high incidence of use, with many problems reported.

Anesthesia breathing circuit, with adapters and connectors. These devices are universally used and are life-supporting. There are a wide variety of components that may be misconnected or misapplied.

Breathing machines for medical use. This means all ventilators. These devices are widely used on critically ill patients. They are considered to be a primary therapeutic modality. There are a large variety of designs which are easily misassembled and misapplied. These devices do not always function as advertised. There are many probelms with both ease of use and the operating instructions.

Gas-machines, anesthesia/analgesia. These devices are a life-supporting system when properly applied. There are a variety of designs which are frequently misassembled, misapplied and not easily interconnected. They are a dosage meter for potentially toxic agents and must be accurate and reliable.

1. Clin Anaesth. 1, 127, 1967; J. Am. Med. Ass'n. 178, 261, 1961

Emergency ventilators, manual. These devices have a wide variety of designs, and have wide spread use with numerous citations in the literature of failure to perform as expected.

Emergency ventilators, powered. These devices have a wide variety of designs, and have widespread use with numerous citations in the literature of failure to perform as expected.

Tubes, endotracheal. These devices have extremely widespread application in critically ill patients. Many documented complications from use can be cited. There is a wide range of material, sizes and shapes.

Tubes, tracheostomy. These devices have extremely widespread application in critically ill patients. Many documentated complications from its use can be cited. There are a wide range of materials, sizes and shapes.

Valves, resuscitator (manual and/or demand). These devices have a variety of designs, and have widespread use with numerous citations in the literature of failure to perform as expected.

Central pipeline systems and vacuum. These devices have widespread use and there are some building standards available at this time. It is well documented that there are many problems which exist with these particular devices. These problems are almost always concerned with new installations or repair of old installations. There are many considerations; the sizes of the pumps and of the compressors, the materials used in all components, and in the distribution and placement within the facility.

Hyperthermia devices/systems. The use of these devices is widespread and frequently used in critically ill patients. There are numerous citations of problems in the literature. They are poorly controlled systems with poor monitors and transducer functions.

Hypothermia devices/systems. The use of these devices is widespread and frequently used for critically ill patients. There are numerous citations of problems in the literature. They are poorly controlled systems with poor monitors and transducer functions.

Incubator, infant (including portable models). These devices have widespread use in the nursery or neonatology intensive care units. There are not always built-in fail-safe systems for the use of the U.V. light or the heat source. Some designs do not have proper edges. Other designs the babies can fall off and out. There is also a problem with excessive noise in some designs.

Defibrillators, D.C., portable. These devices mainly have a problem in the failure mode, that is, they will not work. Several groups are working on standards for these devices at the present time.

Electrosurgical equipment and accessories. These devices fail in nearly every mode. They have failed in terms of current selection and control; they have failed in terms of inadvertent grounding or lack of ground and the electrode systems at all times have been constantly implicated in failure. They also interfere with other equipment such as ECG machines. It is the unanimous recommendation of the panel that this item be given first priority among all anesthesiology devices.

It can be seen that this "urgent" list includes most of the anesthesiology devices which are used during surgical procedures such as flow meters for anesthetic gas, alarms for oxygen concentration, ventilation (breathing) equipment, defibrillators, and electro-surgical equipment and accessories. Despite the extreme hazards to which this equipment subjects patients, the panel's own "urgent" classification of these devices allows as long as five years before a standard is developed. How many people will die or be injured un-necessarily in the interim?

In summary, medical devices are, in many cases, more like drugs than like office furniture. Thus, it is necessary to maximize the amount of pre-market testing and minimize the amount of risky, senseless and prolonged standard-setting that may be appropriate for consumer products but not for medical devices.

SCIENTIFIC REVIEW AND STANDARD-SETTING

FDA should not set standards on most medical devices. It should not legitimize standards developed by the regulated industry. The Rogers Bill sets up FDA to do both. Instead, FDA should require premarket testing.

We have three objections to the standard-setting provisions of the Bill: (1) standards are guarantors of device safety and efficacy only in the relatively rare case where complete information is in; (2) standards are time-consuming and difficult to develop; these difficulties are exaggerated by labrynthine procedural requirements imposed by the Rogers Bill; (3) standards developed by industry associations are consensus standards and will justify the status quo rather than improve safety.

(1) Standards do not generate safety data (In fact, the Rogers Bill prohibits standards from requiring safety data. All that can be required is compliance data.) They are appropriate only when there already exists a substantial body of scientific data, through which one knows that the device is safe and effective, how it is most safe and effective, and when there is enough certainty about which version is vest, that barriers to alternate versions must be erected. Standards should be set only if development in the area has pretty much ended, since their capacity to freeze technology is well known. As Dr. Joel Nobel, director of the Emergency Care Research Institute, a device testing and evaluation organization, testified to the Senate, standards "institutionalize last year's technologic state of the art, and the last decade's belief about pathophysiology. They thus inhibit improvement and innovation and reduce the inclination to take fresh looks at old problems."

For most medical devices, such solid evidence is not available. Most medical devices have been accepted on the basis of testimonial evidence --i.e., someone's opinion--rather than controlled scientific studies of safety and efficacy. Since the medical devices field as a whole is in a developing and dynamic state, even devices with solid science grounding them, may be unsuitable atpresent for standards because they are still undergoing constant change. Pacemakers are not appropriate for standards, both because the scientific information is undeveloped and because they are still undergoing rapid innovation. Pacemakers should undergo testing to prevent further human injury.

The FDA medical device advisory committees are currently setting the majority of devices into the standards category, as the Rogers Bill would have them do. It will not improve marketplace safety to have standards set in the absence of clear knowledge of what design and materials are best.

(2) The Rogers Bill procedures for setting standards are cumbersome and obstructionist. First, a committee of outside advisors determines that the device is appropriate for a standard. An industry representative must sit on this committee, with full freedom to participate and submit documents. Then, FDA must publish the determination, called a "classification," in the Federal Register, open it for public comment, and then classify the device finally by publishing again in the Federal Register. Upon final publication, the Bill provides that industry may go to court to demand that FDA provide "substantial evidence" to support the classification. FDA must have substantial evidence that "general controls" (which is a category where neither testing nor standards are required) are insufficient to assure safety, that there

is sufficient information to establish a standard and that the standard is necessary. This defense must be made at the stage where the device is merely classified as appropriate for a standard. And this is only the beginning. FDA then publishes a notice in the Federal Register that it intends to develop a standard. Then there is another opportunity to submit further comments and to make another request for a change in classification of the device. If FDA receives another request for a change in classification, the matter must go back to the advisory committee, the same advisory committee that classified the device originally. If FDA denies the request for a change in classification, this denial is also subject to court review under a substantial evidence standard.

Then the FDA must publish a notice in the Federal Register inviting any person to offer to develop a standard. If a person offers to develop the standard, FDA cannot develop the standard itself, unless FDA determines, by notice in the Federal Register, that the offeror is unqualified or technically incompetent. FDA then accepts an offer and publishes the name and address of the offeror in the Federal Register. The standard is then developed by the outside party, most likely an industry-dominated organization.

Then when the standard has been developed, the FDA must publish the standard in the Federal Register and give opportunity for comment. After opportunity for comment, FDA apparently must either accept the standard developed by the offeror en toto or publish a notice to reclassify the device out of the standards category. (Although common sense would dictate that FDA have the right to make alterations in the developed standard as deemed in the public interest, the Rogers Bill does not provide this right.) The final standard is subject to court review once again.

Among other things, FDA would have to provide at this point substantial evidence that the standard would eliminate a specified degree of risk, together with the benefit to the public from the device. Industry has already served notice that it will contest standards it doesn't like on the basis of this provision. Harold Buzzell, a former high-level HEW health official who went directly over to an industry trade association this year, objected July 15, 1975 to an FDA implant materials standard on this basis: "Risks are merely recited, not documented. Mere bibliographic recitation of articles in professional and scientific journals are not a legitimate basis" for requiring a standard. He also stated that FDA must legally have evidence that a mandatory standard set by FDA entails less risks than a consensus standard developed by industry. The type of precise risk quantification required by the Rogers language here, is rarely, if ever, available to FDA or anyone else in any situation.

These standard-setting procedures are like a Rube Goldberg machine, comical, laughable if human lives were not at stake. In our view the procedures are designed to ensure that once a device is freed by the advisory committee from the requirement to test, good standards will never or rarely be set.

In the words of an April, 1975, evaluation of the Rogers Bill prepared by the Bureau of Medical Devices staff [hereinafter "staff memo"], these provisions, together with mandatory use of advisory committees, will result in a "costly, time-consuming bureaucratic snafu."

What this Bill does is take the traditional value of providing opportunity for public comment before final governmental regulation

and blow it up to absurdity. Industry is in on every step of the way. Not only does the industry participate in the advisory committee decisions on classification--as it must under the Bill--but there are seven opportunities to object and delay to standards, including three opportunities for a substantial evidence court review, two of which FDA could rarely or never meet, and should not be required to meet.

Industry lawyers will argue that this is simply "due process." Due process does not demand that industry handcuff the agency at every step. These procedures will ensure that industry is happy with the result, since if it is not happy it can paralyze the process. We submit that when it comes to public health matters, the most important value is not whether industry is happy.

Even under the best conditions--which the Bill does not provide--standards are difficult to devise. Dr. Joseph Davis, an FDA official, prepared at the request of the Senate subcommittee a personal statement on the viability of using standards for health matters. He stated:

> Standards for medical devices have, unfortunately and impractically, been seen as the beginning and end point for the solution of the many problems related to medical devices. Such concept is highly impractical. Those standards which are in existence would be useful in the scientific evaluation of a device for which the standards were applicable. Unfortunately, no single standard for a medical device will cover all those aspects related to safety and efficacy that should be considered in such a scientific evaluation. Further, it is economically and scientifically not possible to write all the necessary standards that would be required. I have repeatedly made the statement (and no one knowledgeable in standard making has disagreed) that if all the scientists in the United States who are knowledgeable and informed as to what is involved in writing a standard were to work 24 hours a day for the next 10 years, they still would not have written the required standards for the some 20,000 or more medical devices presently existing. Since such standards will require a re-review and up-dating every 3 to 5 years because of technological changes, the problems are further complicated as to the time and effort required.
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> I have based this projection on the fact that the DOD Defense Personnel Support Center estimates it takes three man years to write one of its specifications for a particular type or class of medical devices. DPSC has some 7,000 specifications for the approximately 10,000 medical devices they purchase for the military. They further estimate that these 10,000 items represent only about 50% of what the individual military hospital purchases on the open market. Since, obviously those devices purchased by the military as standard items, plus that fraction of what is available on the open market that is purchased directly by the hospitals, would not represent the total number of devices available. The total number could exceed 30,000. at 962-3.

Dr. Nobel agrees: "Many individuals underestimate the difficulty of creating appropriate and effective standards. Standards writing is an extraordinarily complex and time-consuming task."

April 7, 1975 the FDA advisory committee on anesthiology devices estimated it would take 15 years to develop standards on the devices that single committee had classified in the standards category.

Reflective of the difficulty in developing standards is the fact that under the Consumer Product Safety Act, effective January 1973, no consumer product safety standards have been issued. Under the diagnostics standards program of the FDA, begun in 1972, no standards have been issued.

(3) Under the Rogers Bill, standards will be developed by private offerors. Those offerors are almost certain to be industry associations, since there are no conflict-of-interest prohibitions, since development will cost well over $100,000 and since industry has much to gain by controlling what the standards say. As stated earlier, FDA cannot develop standards even if it wants to, unless no one responds to FDA's published invitation to develop standards (It is unlikely that FDA could as a practical matter disqualify an industry group on the basis that it was incompetent.).

On the basis of the well-known safety principle that the fox should not guard the chicken coop, we oppose industry development of standards. Manufacturers cannot be expected to develop standards that will put pressure on their own businesses. Traditionally, industry-generated standards have represented very close to the lowest common denominator of items on the market. The National Commission on Product Safety studied the safety standards produced by 48 private standard-setting organizations. It concluded:

> these standards are chronically inadequate, both in scope and permissible levels of risk (Final Report, 48).

The Commission concluded that safety itself has been a secondary consideration in the process of private development of standards. Decisions are reached by consensus. At the American National Standards Institute, for example, the guideline for approving a standard is "when at least 4/5 of those organizations substantially concerned have voted in favor of a standard."

The Senate Judiciary Committee held hearings on privately-developed product standards, March 1975. These hearings found that the standards developed by private organizations are used to bankrupt small competitors, to gouge consumers, and to obstruct inventors with better ideas. In other words, the "ins" use standards to exclude the "outs." This has recently been documented to have been the case with private development of the matches standard for the Consumer Product Safety Commission.

Some of the standard-setting organizations appear to be more independent than the outright trade associations such as the Pharmaceutical Manufacturers Association. However, according to the National Commission on Product Safety, there are few members free of financial conflict of interest. According to the Report, the "Consumer Advisory Committee" of Underwriters Laboratory includes such groups as the National Retail Merchants Association, R.H. Macy and Co., the Mail Order Association of America, American Hotel and Motel Association, Variety Stores Association, etc. This is typical of these groups' idea of consumer representation.

The Health Industry Manufacturers Association [HIMA], a medical devices trade association, has served notice that standards developed for FDA willbe essentially the same as the voluntary standards developed in the past. HIMA has announced guidelines for developing standards under the new law. The first guideline is: the standard should

represent a consensus of cognizant medical and technical disciplines and should avoid responding to a minority preference relative to requirements desired within the standard. Another guideline is: the standard should exclude requirements that connote a "specification" or "standardization" unless there is no other practical means to describe the performance. Another guidelines: unless absolutely necessary, a performance standard should not incorporate mandatory test methods to verify such test requirements.

If FDA employees have not been involved in the development of standards, it is as a practical matter, unlikely that FDA will stop a bad standard. According to the Senate Judiciary hearings, most government agencies simply accept standards developed by the industrial and professional societies for lack of technical knowledge and time to evaluate them. If FDA employees do take the time to learn the field and evaluate the standards, the result timewise will be nearly equal to developing the standard in-house--a much safer and more reliable procedure.

As Dr. Nobel has pointed out, if we choose to go the standard route, the public needs standards which push the state of the art, not standards which legitimize the way things are normally done today. The public needs much better safety, quality and performance--else the Congress would not be considering new legislation.

If the committee persists with the standards approach, the offeror provisions should be erased. FDA and its FDA-chosen advisers are technically capable of producing standards in the relatively few cases where they are appropriate, as the Over-the-Counter Drug review program has demonstrated. Should this Committee persist with the offeror provision, two provisions are needed: FDA should have the option of developing standards itself, and conflict of interest prohibitions for all members of offeror groups should be enacted.

Premarket approval

FDA should have the authority to require scientific tests for all devices, but the legislation should mandate premarket testing for devices which are life-supporting, life-sustaining, implantable, and energy-emitting.

William Goodrich, then FDA General Counsel, urged seven years ago that all devices implanted or inserted in the body for extended periods of time be classified as new drugs to bring them under testing requirements. Tests on implantable devices are especially needed because of their extended physical and possibly chemical interaction with the body. The same is true of devices which emit radiation or energy which is absorbed by the body. Here too, the effects of prolonged interaction, physical and chemical, must be tested before subjecting hundreds or thousands to possible harm.

According to Dr. Nobel, pre-market testing should be mandatory for two classes of products:

> a) Those which are implanted or contact mucous membrances for prolonged periods of time, e.g., over ten days. This would automatically include IUDs, heart valuves, pacemakers, artificial joints, and similar devices. It is in this area that most deaths and short-term significant injuries occur.
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> b) Those devices which emit energy, either ionizing or non-ionizing. This class of devices would automatically include ultrasonic and fetal monitors, electrosugical machines, radiotherapy equipment, and many quack devices such as the Diapulse. As a class, these devices rarely result in early deaths, often have short-term complications, and tend to be devices in which the long- term adverse effects or lack of efficacy are not easily perceived. They therefore deserve detailed study prior

to marketing.

> If the language that makes pre-market clearance mandatory is quite specific, as it tends to be in the Nelson bill, the obligations of both industry and the FDA will be clearcut. If pre-market clearance is discretionary for these two classes of devices, it is inevitable that a lack of basic technical data will be inappropriately accepted and perceived as the absence of adverse effects. The presence of adverse effects will then be established over a period of years -- and by patients paying for the privilege.

The 1973 House hearing record contains letters from two eminent cardiologists supporting mandatory premarket testing for all life-supporting, life-sustaining devices. The Senate-passed bill requires premarket testing for all devices which are life-supporting and life-sustaining, and requires premarket testing for all implantable devices unless FDA makes an explicit finding that they do not pose a health risk. It gives authority to FDA to require premarket testing in any situation where insufficient information exists to assure safety and efficacy.

Premarket testing is a flexible, not a rigid, concept. It may involve extensive testing or it may involve a single laboratory test, depending on the nature of the device. This is within the discretion of FDA and its advisers, depending on what the important gaps in knowledge are. Because the manner in which devices work is inherently less complex and easier to understand in relation to the conditions they are designed to affect, than drugs, and because so much more investigation can be conducted outside of the human body, the cost of device testing will be considerably below thatof the more complex of new drugs.

Where a device is classified for premarket testing, and scientific information already exists on the device, the manufacturer does not conduct tests, but merely sends in the extant information.

The Rogers Bill allows premarket testing for devices which are (a) of substantial importance in supporting, sustaining or preventing impairment of human life or health; and (b) devices which present an unreasonable risk of illness or injury. This provision is, in our view, totally inadequate. First, tests could not be required for devices such as surgical implants, biofeedback devices, trans-cutaneous nerve stimulators, contact lens, ultra-sound and IUDs because they are not life-supporting, etc.

The "present an unreasonable risk" requirement before premarket testing is virtually useless, since FDA would not know about risk until after testing had been conducted. The "unreasonable risk" standard requires FDA to prove the risks by substantial evidence before it can require testing. "Unreasonable risk" is the same standard used in the pesticide law, the Consumer Product Safety Act, and the pending Toxic Substances Act to ban a product after all the evidence is in. The Bureau of Medical Devices Staff memo puts it this way:

> One of the major problems with medical devices is the lack of well-controlled studies showing the safety and efficacy of devices or showing the degree of hazard from such a device. ...The wording of the Rogers Bill places the burden on FDA to establish the degree of risk to the patient and the benefit of the device before the Agency can even require premarket approval for that device. The Staff does not believe that this provision is in the best interest of the public.

ADVISORY COMMITTEES

One of the major flaws of the Rogers bill is its excessive reliance on committees of non-government advisers to make regulatory decisions. Advisory committees conduct the initial classification of devices into "general controls", "performance standards" and "scientific review." Another group of advisory committees, probably 14 in number, must be set up to review industry challenges to classifications of individual devices. A further advisory committee must be established to oversee the development and revision of good manufacturing practices. An advisory committee must review all product development protocols, and outside advisors develop standards.

It will be difficult to procure the number of advisers needed. The FDA Medical Devices staff memo states:

> "It is not unreasonable to predict that the Agency will need to support over 300 advisors and consultants to implement the Rogers Bill. Some Staff members have expressed doubt that the Agency can attract the large number of qualified medical device experts who have the time and desire to serve on panels.

Advisory committees are time-consuming and difficult to administer. As the Medical Devices staff stated:

> "The Rogers Bill impedes FDA's present rule-making authority by establishing cumbersome, multi-stepped procedures which require the agency to consult with numerous advisory panels and publish panel recommendations before FDA can even propose a regulation."

The benefits of this bureaucratic tangle will all accrue to industry, since the more difficult it is to take action on a medical device, the longer it will take and the less likely it will occur, leaving the industry just where it wants to be -- unregulated by the government.

Most advisory committees do relatively careless work compared to individual scientists. We believe that consumers want high quality scientific scrutiny placed on medical devices. Committees generally are valuable in deliberating on general policy decisions, but they are not good vehicles, for careful scientific analysis and evaluation of information. Furthermore, groups will often make decisions that individuals would never consider doing. For example, FDA committees for classifying devices as to pre-market testing, standards, etc. are making decisions on the basis of the opinions of the members, and inquiries are not made as to what controlled scientific evidence the opinions are based on. The committees are not even asking for literature searches to be conducted! Yet I don't think one single scientist as an individual would ever be responsible on this casual basis for deciding that there was adequate evidence of efficacy, etc. If consumers want critical scientific work performed -- and I say "critical" in the sense of healthy skepticism that all good science demands -- they will not get it from committees but from an individual working alone, whose name is on the line at the bottom and who is individually accountable later for the decision involved. Members of advisory committees are not individually accountable in that decisions can not be traced to individuals and individual jobs are not on the line.

In general, advisory committees have shown themselves to be less skeptical of industry claims and assurances on its products, than individual FDA scientists are. The Fountain sub-committee of the Government Operations Committee studied FDA advisory committees in superbly-detailed hearings last year. One case study was the approval by an advisory committee of the drug propanolol for heart pain. The hearings showed that the advisory committee approved this new purpose even though not one member identified a controlled clinical study which demonstrated effectiveness and four out of five members later said there weren't any (the fifth wasn't asked). The Food and Drug Act requires demonstration of effectiveness by controlled clinical studies. Essentially the same situation is occurring with Depo-Provera, a 3-month injectible contraceptive known to cause cancer in animals, and suspected of causing cervical cancer in humans,

where an advisory committee approved the drug without scrutinizing the scientific data submitted by the manufacturer (Upjohn), for either safety or efficacy. According to the transcripts of the committee meeting, the committee decided that the drug had an important benefit on the basis of a "gut feeling."

Another FDA advisory committee made a decision early this year about the use of phenothiazines for mentally retarded persons, on the basis of 41 studies which they called "substantial evidence" that the phenothiazines were effective in the management of the mentally retarded. Later analysis, by a non-member who looked up the studies cited, showed that of the 41 studies, only nine were controlled at all; some did not even involve phenothiazines, others did not involve mentally retarded persons. Only three contained evidence which could even conceivably support the effectiveness of the drugs; and three concluded that phenothiazines were not effective for this purpose.

A number of FDA medical officers, responding to a 1972 Health Research Group questionnaire on working conditions in the Bureau of Drugs, stated that advisory committees approved drugs and labels which did not meet legal evidentiary requirements.

Make no mistake about it -- an advisory committee making a decision usually means a less skeptical decision. In a scheme where the data are submitted by industry, decisions will be more pro-industry.

FDA Bureau of Drugs Director, J. Richard Crout, stated at the Fountain hearings April 30, 1974, that he could recall no instance where advisory committees recommended against approving or labeling new indications for a drug. Since then, an advisory committee has disapproved an indication on at least one occasion. However, the general rule remains: advisory committees are expected to impose less stringent safety demands than civil servants do.

Advisory committees are important organs for obtaining general advice by the agency. By nature, however, they are usually ill-suited for specific scientific decisions on individual products, since decisions are reached on the basis of general group discussion rather than critical review of data, and since everyone knows that no one is personally accountable if the decision is poor or wrong.

Remember also, that inspite of the Federal Advisory Committee Act, FDA closes to the public almost all advisory committee meetings. Transcripts of FDA medical devices meetings are not taken, so that even Congressional investigators cannot know how much care went into a decision.

The Rogers Bill requires each advisory committee to have an industry representative member. FDA medical devices committees now have such representatives, who are lobbyists for industry interests in minimizing regulation. Each industry representative has a "contact man" who immediately "de-briefs" him about what happens in each session. Pharmaceutical Manufacturers' Association has instituted "mirror panels" to consider the same questions as those the FDA committees consider, and prepare lobbying material for the industry representative on the committee to feed back to the other committee members at the next session. These activities are euphemistically called "assisting" the FDA committees.

In fact they are extremely successful in influencing committee policy, far beyond the merit of their views and data, in part because, unlike civil servants, the committee members are frequently inexperienced and naive in regulatory matters.

Dr. Nobel stated prophetically:

> [Advisory Committees] will be vulnerable not only to error, but if manipulated, can make a farce out of the entire process simply by classifying devices right out of the regulatory envelope. at 442.

These committees get little or no lobbying from the other side, the consumer point of view. There are consumer representatives, but though well-intentioned, they often lack technical expertise, support, money and other resources to prepare a lobby in the interests of conservative safety decisions.

The NAS-NRC advisory committees, which conducted evaluations on the efficacy of a large number of prescription drugs, were aware of the subtle influences of one-sided representation, banned all industry representations and presentations, unless they extended specific invitations. Input from industry was in written form. Certainly the NAS was far more sensitive to what actually can go on in advisory committees, than FDA has been, and than the Rogers Bill is.

Last, there is the danger that members of advisory committees will look after their professional interests rather than consumer interests. One senior Bureau of Medical Devices official states that this is already true of members on some committees.

The Fountain committee, which had access to transcripts of committee meetings in the Bureau of Drugs noted a particularly lurid example of this attitude. An advisory committee recommended that the warning on an anesthetic agent be removed because it was "duck soup for a lawyer." at 351.

Of course, no generalization about advisory committees is true of all. The four medical devices advisory committees which were selected by FDA -- the earliest committees -- are scrutinizing data and claims reasonably well. However, after these committees were chosen, FDA instituted, at the urging of Peter Hutt, a program whereby FDA would not select the advisory committees. Instead FDA now publishes a notice in the Federal Register soliciting nominations from various groups, and chooses the committees only from the nominations submitted. Naturally, the groups who submit nominations are the PMA, HIMA, the AMA, and specialized professional societies. Not surprisingly, for groups which work closely together -- the same person is nominated by both industry and professional societies. As a result of this procedure, these later committees tend to be strongly anti-regulation, as are the associations which nominated them. As pointed out at a recent American Association of Medical Instrumentation, these committees are classifying far fewer devices for testing, and far more devices for "general controls". So at FDA, not only are there the problems inherent in all advisory committees doing regulatory decision-making, but also the advisors are prescreened by the professional and industrial trade associations.

In summary, the Rogers Bill delegates key decisions to advisory committees which are by nature ill-suited to make decisions about consumer health. FDA should always be free to get advice from outside expert consultants, but the decision-making process, together with the decision, should be that of civil-servants, who are most free of conflict of interest, most savvy to the regulatory implications of their work, and most accountable to the public for what they do.

FREEDOM OF INFORMATION

The Rogers Bill should make safety and efficacy data on devices available to the public, but does not. In fact, it cuts back data availability. First, safety and efficacy data should be available to show the public the factual grounds on which FDA decisions are made. If they are secret, only the industry knows what the data are. Then, when a decision is made adverse to industry, and FDA is subjected to a barrage of anti-FDA publicity from the industry, no one can support FDA from the patient side.

In the new drug area, FDA is overwhelmed by drug industry publicity, since it secrets health and safety studies on new drugs, and industry is preeminently successful in training the public to believe that "miracle" drugs are withheld by FDA from the public. Were environmentalists, academics and doctors able to examine the

secret data in FDA files, the public would likely have a fairer view of the story on the value of many drugs industry promotes. As things stand now, Bureau of Drugs officials are isolated from all the world except industry.

The agency needs public sector scientists to help with data evaluation also. Some of the devices covered by this Bill may have a heavy impact on life and health. FDA has too few resources to make decisions of such important consequence, by itself. FDA scientists would not be free to talk with experts outside the agency no matter how complex the problem. Citizen-scientist input is shallow or meaningless unless the industry-generated data is available, since the chemical substances are often new and do not have a body of published scientific literature about them. Competent scientists would refuse to make judgments on the basis of statements by others of what the data show, but would need to analyze the primary data themselves.

Most humans perform best when their work is subject to scrutiny by others. Government officials, like all of us, will grow lazy and careless if there is no check on our work. For best performance by FDA, openness is needed. When safety and metabolism data and all other information is made public, the decision-makers have to be better, the decisions wiser. In the words of a Freedom of Information decision, Soucie v. David* ruling that data on the benefits and risks of the SST should be public:

> Congress recognized that the public cannot make intelligent decisions without such information, and that government institutions become unresponsive to public needs if knowledge of their activities is denied to the people and their representatives.
>
> ...The public's need for information is especially great in the field of science and technology, for the growth of specialized scientific knowledge threatens to outstrip our collective ability to control its effects on our lives.

Last, secret data means costly, duplicative tests within industry, which inhibits product development and innovation.

The Rogers Bill mandates FDA to withhold from the public trade secrets, information which contains or relates to trade secrets, and other matters referred to in 18 U.S. 1905. This latter includes "processes, operations, style of work, aparatus, and other items. The Rogers language would secret these matters even if they are not confidential. One extreme result would be that much of the material in the FDA library, now open to the public, will have to be secreted, such as standard reference works like the Merck Index, and books and journal articles on the device industry. The president of Medtronics may have stated on national television that body fluids leak into his pacemakers because the epoxy sealant is defective. Yet FDA could not, under the Rogers language, release this information.

The Rogers language goes far beyond the language of the Freedom of Information Act. It would exempt the material from important procedural provisions such as de novo court review, and destroy the agency's power to release material when necessary for the public health.

Congress carefully weighed the benefits and risks of withholding data when it passed the Freedom of Information Act in 1967, and overwhelmingly reaffirmed that balancing last year when it overrode a Presidential veto of strengthening amendments. In the House, that override was 370 to 7.

There are many industries in town that would like to be exempted from the Freedom of Information Act (just as there are many such

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* 449 $F._2$ 1067, 1080 (D.C. cir. 1971)

agencies). The medical device industry is at the head of a very long line. But Congress made the judgment that except for the narrow exemptions of the Act, the ultimate public benefit of disclosure overrides the inconvenience. Once this special favor is granted to the medical device industry, it will be very difficult to refuse the same favor for other industries, such as the drug industry, the chemical industry, and oil companies and the automobile industry.

In summary, we believe that FDA should have the power to withhold bona fide trade secrets such as secret formulas and secret manufacturing methods, but the Bill should mandate disclosure of health and safety data or publicly-known manufacturing information.

AUTOMATIC APPROVALS

Automatic approvals are a bad idea in any regulatory agency, since agency personnel are often over-burdened with work and do not always examine material before automatic approval occurs. In the drug area, FDA by regulation has created an automatic approval after 30 days for applications to investigate new drugs in humans. Under these regulations, the drug industry has experienced virtually no disapprovals, which is reflective not of administrative efficiency but probably of the fact that pre-clinical studies are not carefully reviewed -- regardless of the potential for harm. FDA has admitted publicly that examination did not occur in several cases where the potential harm was great. (See GAO report to the Senate Subcomm. on Executive Reorganization, Isoniazid Oct. 7, 1971; Drug Safety, Hearings before the House Subcomm. on Intergovernmental Relations, p. 1938). FDA staff people have told us of numerous other occasions where it did not occur. The Rogers Bill would require by law an automatic approval after 30 days of device investigation applications.

This mechanism originally appeared in the Food, Drug and Cosmetic Act of 1938 and in the Federal Insecticide, Fungicide and Rodenticide Act of 1947, for new product applications. In both it was found insufficient health protection and removed by Congress.

Moreover, the Rogers Bill puts a heavy burden on FDA to prevent tests, rather than on the manufacturer to justify them. The only way the application may be disapproved by FDA during the 30 days is if FDA has substantial evidence that the investigation does not conform to the regulations FDA has previously promulgated. Thus, FDA will have had to anticipate by regulation all the things that could be wrong with a device investigation in humans. Unless the situation was anticipated by regulation, the test cannot be stopped. For example, the device may have killed 50% of animals in which it was implanted. Yet if this situation were not anticipated by regulation, FDA could not stop the sponsor's investigation even when it had the evidence in hand.

Worse still, is an automatic approval mechanism for new device applications which have acquired a product development protocol. The product development protocol is a new invention, whereby a device manufacturer who is told he must test his product, may secure from FDA beforehand approval for test protocols, which if run without incident, will secure him marketing approval. Under the Rogers Bill, when the product development protocol is completed, the sponsor sends in the test data, and 90 days later the device is automatically approved unless FDA stops it.

In general, we think product development protocols are a very bad idea, since they will, by involving FDA in the innovation and development process, eventually undermine FDA's ability to be disinterested public health watchdogs. Industry supports these protocols strongly, as it rightly perceives that involvement in the development process will make FDA less able to critically examine the results and implications of safety and efficacy studies.

However unwise this system may be, the automatic approval mechanism at its end, greatly aggravates its disadvantages.

STATE LAWS

The Rogers Bill preempts state action on medical devices. For a Bill as weak as the Rogers Bill, the preemption provision would be a serious mistake. After years of FDA inaction on IUDs, the State of California has recently declared IUDs to be "drugs", so that manufacturers must conduct systematic studies. This move was supported by a number of women's organizations and health professionals. The Rogers Bill would wipe out this important step.

JUDICIAL REVIEW

Because of traditional principles of administrative law -- final agency action, and limited court scrutiny of agency decisions -- manufacturers normally bring a dispute with FDA to court only when FDA has made a final determination to ban or limit product sales. The Rogers Bill makes two major changes, both serious setbacks in terms of industry domination of the agency. First it makes the standard for judicial review for every agency move -- no matter how preliminary -- "substantial evidence on the record as a whole", whereas even if one could get into court under present law, the judicial standard of review would likely be less sweeping. "Substantial evidence" is an inappropriate standard of review for preliminary steps such as requiring data, etc. By contrast, it is an appropriate standard when FDA bans or limits product sales. At that time, of course, FDA should have the goods in hand to show with exactness why the product constitutes an unreasonable risk. But FDA should not have to demonstrate "substantial evidence" when it classifies a device, when it requires a device to undergo safety testing, when it disapproves an exemption for investigational testing, etc. The substantial evidence review in these circumstances demands of FDA a strong evidentiary documentation, at a time when by definition it is not available to anyone. The decision to require testing should not require extensive documentation because the hazards are by definition unknown. From a practical standpoint, the substantial evidence standard of review will paralyze FDA, leaving it with the same authority it has under present "device" law and considerably less authority than it has under "drug" law.

RECALLS

The Rogers Bill gives FDA authority to require notification of "all persons who should properly receive such information" about devices which present an unreasonable risk of substantial harm, if no more practicable means are available to eliminate the risk. It also provides an exemption to the notification requirement, so that the patient is not notified if FDA determines that the group of patients would suffer greater danger from the notification than from not being notified. We agree with the Bureau of Medical Devices staff memo that this provision is odious:

> The Staff objects to a procedure that permits a manufacturer to notify a patient's doctor without some assurance that the patient will ever learn of the problem. In the light of full disclosure and freedom of information requirements, the Staff does not believe that the Secretary should be a party to a procedure that permits important health information to be withheld from a patient. A patient has every right to know if their health is a risk because of a defective medical device.

CUSTOM DEVICES

The Bill would exempt from standards or premarket testing devices which are intended solely for use by one physician. This exemption is too broad. We call it the Harvey Karman exemption. As stated in our 1973 medical devices testimony before this committee, Harvey Karman habitually used the "supercoil" device, which was his invention, to induce abortion. This device was a plastic strip that was shoved in large numbers into the uterus until the fetus was forced out. It

was never tested properly for safety, and not unexpectedly, it caused complications in 60% of one group of abortions and 20% major complications.

NOTIFICATION

There should be mandatory notification by manufacturers and health professionals of adverse incidents associated with use of a device, since this is an important avenue for alerting FDA of hazards. The Bill gives FDA the authority to require this of manufacturers, but does not mandate it.

CONCLUSIONS

The Bureau of Medical Devices staff memo states:

> [T]he Rogers' Bill contains many burdensome and unnecessary provisions. These provisions will result in an avalanche of paperwork, regulation writing, and other bureaucratic procedures with no assurance that the public, industry, or government will realize any improvement in the quality, safety, or effectiveness of medical devices.

The Rogers Bill in its present form, is unlikely to result in anything other than an expenditure of the taxpayer's money, and will have the negative impact of making the public think that it is protected against unsafe and ineffective devices when it won't be.

Should the Committee wish to stay with the Rogers Bill, our major recommendations for a bill which would increase the safety and efficacy of devices are these:

1. Mandate pre-market testing for life-supporting, life-sustaining devices, implantable and energy-emitting devices, and all other devices which may pose a hazard to health.

2. Allow FDA to develop and set standards in the unusual case where they are useful.

3. Remove the "substantial evidence" judicial review opportunities for all preliminary FDA actions.

4. Remove all mandatory advisory committees, and remove all requirements for industry representatives on advisory committees.

5. Remove the product development protocols and automatic approval mechanisms.

6. Make safety and efficacy data available to the public.

The public is fortunate, however, in having an excellent drug law on the books, together with a Supreme Court decision which states that most important devices may legally be treated as drugs by FDA. 394 U.S. 784 (1969). Device standards, where appropriate, can be set under the misbranding provisions of that law. We recommend that FDA use the drug law to regulate medical devices, and that the Congress give it one new provision, a provision which would allow new device applications to be developed and sent to FDA in phases, perhaps according to priorities developed by FDA and its advisors, so that neither industry nor FDA would be deluged with applications all due at the same time. Otherwise, the public does not need legislation -- as Commissioner Schmidt has admitted -- and it certainly does not need H.R. 5545.