

Medical Devices: Should They Be Cleared before Marketing?

There are an estimated 12 million medical devices on the market in the United States. A lot of them don't work.

As things stand now, there is nothing much the government can do to protect the public from defective devices until after they have appeared on the market and injured unsuspecting patients. For several years, there has been legislation before Congress to remedy the situation, but it has never gotten very far. This year, however, it looks as if a medical device bill will get through, once congressmen work out their disagreements over what the bill should say and how tough it should be.

It is impossible to produce accurate records of how many devices are faulty and how much injury they have caused—there is no requirement for reporting and, therefore, no way of knowing how many device accidents are covered up. Nevertheless, there are some figures on the subject and they are disconcerting, to say the least. For example, a Food and Drug Administration (FDA) survey of the literature from 1963 through 1970 revealed that there had been 676 reported deaths and more than 10,000 injuries from medical devices. The data included these specifics:

- 512 deaths and 300 injuries associated with artificial heart valves.

- 89 deaths and 186 injuries from cardiac pacemakers.

- More than 8000 injuries associated with intrauterine devices.

A glance at the list of medical devices that have been subject to FDA recall once defects had been spotted is also revealing. One brand of oxygen cylinder was recalled for leaking. A portable cardiac defibrillator was recalled for what the FDA describes as a "self-discharge hazard." Even tongue depressors made the recall list; one brand was cited for "suspected bacterial contamination."

Medical devices are big business. According to FDA estimates, retail sales—to hospitals, physicians, and directly to individuals—total more than \$3 billion a year and are expected to double by 1981. There are approxi-

mately 5000 different types of devices, ranging from highly sophisticated equipment employing ionizing radiation to routine operating-room machines to contact lenses to simple steel pins.

There seems to be a consensus among FDA, congressional, and industry people that regulations governing medical devices must be flexible for a couple of reasons. One is that different classes of devices should be treated differently; procedures covering steel pins should not be as complex as those applying to nuclear powered, fully implantable pacemakers. Another reason is a desire not to cut off research in the field, much of which is conducted by relatively small companies that, theoretically, would go out of business were the government to subject their products to months or years of delay while forms are filled out and passed around bureaucratic channels. But how one creates regulations that are both flexible and yet worthwhile as far as protecting the public interest is concerned has yet to be demonstrated.

The Kennedy, Rogers Bills

The bills that are receiving the most attention in Congress at the moment are two nearly identical pieces of legislation that have been introduced by Edward M. Kennedy (D-Mass.) in the Senate and Paul G. Rogers (D-Fla.) in the House. [An administration bill, introduced by Senator Jacob Javits (R-N.Y.), is also receiving consideration by the Congress.] Apparently, the FDA, which will have to administer the medical device law once it is passed, can live with the provisions in these bills. In fact, sources on Capitol Hill claim that Peter B. Hutt, chief counsel of the FDA, had a hand in drafting the Kennedy legislation—an allegation he emphatically denies. Of course, as a member of the Administration, he was involved in preparation of the bill Javits introduced.

The basic argument surrounding the various device bills has to do with the matter of premarket clearance and the presumption that legislation which does

not require FDA approval of certain categories of devices before they are marketed is soft on industry. In the Senate, Gaylord Nelson (D-Wisc.), who has been introducing medical device legislation since 1969, is adamant about premarket clearance and intends to fight to get some of his language in the Kennedy bill when it is taken up by the Labor and Public Welfare Committee.

Nelson wants the law to require premarket clearance of any medical device that:

(A) is intended to be secured or otherwise placed, in whole or in part, within the human body or into a body cavity, or directly in contact with the mucous membrane, and is intended to be left in the body or such cavity, or in such direct contact, permanently, indefinitely, or for a substantial period or periods (as determined in accordance with regulations issued after notice and opportunity to present views), or (B) is intended to be used for subjecting the human body to ionizing radiation, electromagnetic, electric, or magnetic energy (including, but not limited to, diathermy, laser, defibrillator, and electroshock instrumentation), or heat, cold, or physical or ultrasonic energy, or is intended for physical or radio or electronic or electric communication in either direction with any part of the human body or with a device placed within or connected with the human body.

Thus Nelson, who has the support of several consumer groups in this matter, is explicit about what he wants to be subject to premarket clearance—virtually any device that touches the body or emits energy. In testimony before the health subcommittee, he explained how his premarket clearance proposal varies from those in the Kennedy, Rogers (by implication), and Administration bills. "The Kennedy and Administration bills require 'scientific review' [which amounts to premarket clearance], but with restrictive caveats," Nelson said. "In the Kennedy bill, only those devices which the Secretary [of Health, Education, and Welfare] determines pose 'unreasonable risk of illness or injury' would have to have 'scientific review.' In the Administration bill, only those 'intended for use in life threatening situations' would require such review." Nelson does not want to leave that much up to the discretion of the Secretary or the FDA.

Dissatisfaction with the premarket clearance provisions of the Kennedy and Administration bills was also expressed in testimony before the health subcommittee by Sidney M. Wolfe, an M.D. with the Health Research Group,

a Washington, D.C., consumer organization. He claims what the Kennedy bill calls scientific review of a product can only be initiated after an outside panel of experts meets and decides that a certain product should be cleared before marketing and after a further determination by FDA that scientific review is really necessary. Said Wolfe, "These determinations could be made by FDA only if it had extensive evidence about the device. But it could not have extensive evidence about the device unless testing had already been conducted. This is the Kennedy bill Catch-22." And he argues that scientific review panels "cannot make recommendations for premarket testing because there is no mechanism to call their attention to the existence of recently developed or developing devices before they are on the market." Wolfe calls premarket clearance "an elementary mark of human decency."

The Kennedy and Administration bills emphasize standard setting as the pri-

mary means of regulating medical devices. A major issue here arises over the question of who should set standards—Nelson wants the bill to state that persons who have financial interests in medical devices are excluded from standard-setting panels—and whether standard-setting itself is reasonable in a field in which technology is rapidly changing. The inevitably cumbersome procedures, involving scientific panels and committees for establishing standards, could not possibly keep up with device technology, it is argued. Standards could be out of date before they are set.

Therefore, Nelson is adamant about wanting premarket clearance, although he is willing to leave the details of its implementation to the discretion of the FDA, largely to allow for the measure of flexibility that is said to be essential to workable device legislation. Indeed, none of the bills spells out just what premarket clearance should be, in contrast to the Food, Drug, and Cosmetic Act, which is quite explicit in set-

ting forth requirements for new drugs.

FDA lawyer Hutt is not sympathetic to the scope of Nelson's premarket clearance amendment. "If it comes down to whether we should do premarket testing on all dental devices marketed during the last 50 years, or on all implantable steel pins, rather than on more sophisticated devices," Hutt says, "it is not hard to imagine where I stand." The FDA, he believes, simply is not able to undertake such a massive venture. Nor does he believe it necessary.

Whatever the final nature of the legislation, FDA will have to gear up in order to even attempt to implement it and forecasts of what will be required in terms of manpower and money have already been made. FDA figures it will have to take on 330 people and have a device budget of more than \$12 million in 1975. By 1979, the agency anticipates needing 500 people and \$15 million to carry out the medical device law.

—BARBARA J. CULLITON

Microbiology: Hazardous Profession Faces New Uncertainties

Since the turn of the century, some 3500 cases of laboratory-acquired infections have been reported, more than 150 of which resulted in death. Although with this accident rate it may still make more sense to be a microbiologist than a steeplejack, the profession is not entirely without risk. The risks are, if anything, increasing as more people take up work with viruses, including viruses suspected of causing cancer in man. Besides the risk to scientists themselves, there are also dangers posed by the new kinds of virus that can now be created in the laboratory and which, if they escaped, might constitute a threat to public health.

The degree to which people have become infected with the agents they work with depends on the care they take and the nature of the agent, but even under the most stringent safety conditions that can be devised, such as those at the former biological warfare laboratories at Fort Detrick, Maryland,

infections do occur. During the quarter-century that the Fort Detrick laboratory was in operation, there were 423 cases of infection and three deaths. Since the cost of building even a moderate-sized laboratory to the same standards of safety is about \$125,000, most civilian laboratories have to make do with less. One experienced virologist reckons that, when working with agents which infect man, about 5 percent of the laboratory staff may become infected each year. "Every microbiologist has inhaled or absorbed significant amounts of any organism he has worked with," says A. Wedum, former safety director at Fort Detrick.

Bacteria were once the most common cause of laboratory infections, a role that has now been taken over by viruses. According to Wallace Rowe of the National Institute of Allergy and Infectious Diseases (NIAID), the hazards to laboratory workers are probably on the increase. One reason is

that many of the people now coming into virology are, for example, biochemists who do not have the safety instincts of the trained microbiologist and tend to regard viruses simply as another chemical reagent. Another is the trend to use viruses in more and more highly concentrated forms. Infection depends on the dose of virus to which a person is exposed, and solutions now in common laboratory use contain 100 to 1000 times more virus than they did a few years ago. A third kind of hazard is the creation of hybrid or otherwise new viruses, which pose unknown risks both to scientists who work with them and the population at large.

According to Wedum, about a quarter of all laboratory infections can be traced to accidents, such as self-inoculation with a syringe. For the rest, a precise cause is usually hard to find, but inhalation is often the reason. Many common laboratory operations, such as blending, sonicating, or simple spillage, can lead to the formation of an aerosol containing viral particles.

Probably the most dangerous single source of viruses is monkeys, in which occur a number of agents fatal to man. There have been 20 suspected cases of human infection with herpesvirus B, with only three possible survivors. Another monkey agent, Marburg virus,