tions that can have the effect of repairing the original defect. What it amounts to is that in the presence of a mutagenic chemical, the bacteria begin to grow again, forming colonies that show up as white spots. A particularly handy feature of the test is that powerful mutagens will cause a larger number of bacteria to revert than will less potent ones, thereby providing at least some indication of how potentially hazardous a suspect chemical may be. The test is cheap—it costs only $200 per chemical—and fast—it can be completed in 3 days.

Other quick assays for mutagenic chemicals are based on yeast, fruit flies, and mammalian cells grown in culture. At present, no other assay is as widely used as the Ames test, but each is being studied extensively.

Commercial laboratories report that the recent interest by industries in quick tests has provided them with a substantial increase in business. David Brusick of Litton Bionetics in Kensington, Maryland, says that his firm has had some contracts to screen chemicals for the past 2 years but that the vast majority of its clients have been signed up in the past few months. Now Litton Bionetics does the tests for about 50 companies. Clients include pharmaceutical companies, manufacturers of agricultural chemicals, producers of pigments and dyes, and other companies that may be marketing toxic substances.

Litton Bionetics, like most other commercial laboratories, offers its clients a range of quick tests, including the Ames test, which is almost always performed first. In many instances, a firm is told that its chemical is mutagenic in the Ames test and will then request other quick tests of the chemical before deciding what course of action to take. The cost of a whole battery of tests is less than one-tenth of the cost of a cancer test in which laboratory animals are used.

The widespread use of the Ames test is a tribute to the decade of work put in by Ames and his associates. They have

Medical Devices Law Is on the Books at Last

Congress has finally given the Food and Drug Administration explicit authority to regulate medical devices in a law signed by the President at the end of May. The event concluded 15 years of intermittent congressional efforts to fill a regulatory gap that was becoming ever more evident with leaping advances in medical technology.

Efforts to pass a devices law began in earnest following a 1970 report by a study group at the Department of Health, Education, and Welfare, which revealed that medical devices had been implicated in 10,000 injuries and 731 deaths between 1963 and 1969. Most of the deaths resulted from malfunctioning heart valves and pacemakers.

The new amendments to the Food, Drug and Cosmetic Act for the first time empower FDA to review and approve high-risk devices before they go on the market. The law puts all medical devices from tongue depressors to artificial organs into three categories. Classification, to be done by outside panels appointed by the secretary of HEW, will be made according to the potential danger of each device and the availability of information sufficient to formulate safe standards governing its design, manufacture, and use.

Devices put in class III, the most stringent category, will require FDA clearance before they are marketed. This applies to devices that are deemed to be life supporting or life sustaining or are implanted in the body. Class II devices must conform to standards to be promulgated either by groups from outside the government or by the government. Class I devices are subject to "general controls," which means they basically won't be regulated any more than they are now. This is equivalent to the "generally recognized as safe" designation for food additives.

Until now, the only explicit statutory authority the FDA has had to regulate devices has come from the 1938 drug law which permits the agency to take action against any device found to be "misbranded" or "adulterated." In 1969 the concept that devices could be regulated as drugs within the law was elaborated by a Supreme Court decision which ruled that Bacto-Unidisk, a paper disk used for testing bacterial sensitivity to drugs, should be classified as a drug. But since then, only a handful of devices, such as copper IUD's and soft contact lenses, have been regulated as drugs.

According to a lawyer on the staff of Senator Gaylord Nelson (D–Wis.), who is largely responsible for strengthening the bill from its earlier versions, what the new law does is shift the burden of proof that a device is safe and effective from the FDA (which only had the power to intervene after a device was on the market) to the manufacturer. The law requires that every "new" device—that is, every one that is introduced after passage of the law and is not "substantially equivalent" to something already in use—must be automatically put in class III. From there, panels have 6 months to decide whether to approve it and whether to reclassify it in class I or II. All "old" devices—those already on the market—that are implantable or life sustaining also go into class III. Their manufacturers are given 3 years from the date of the law's enactment to get marketing approval. Devices now covered by new drug applications would also probably go into class III.

Passage of the law has taken a remarkably long time considering the fact that some sort of legislation has been widely thought to be not only desirable but inevitable. Even device manufacturers have supported it as being far preferable to alternative and even more stringent regulatory procedures. Their main complaint about the new law, according to a spokesman from the Pharmaceutical Manufacturers' Association, is that class III is unnecessarily broad and that the restrictions in this class will impede the flow of new devices onto the market.

As for consumer advocates, the chief problem, according to attorney Anita Johnson of Ralph Nader's Health Research Group, is that the major classification decisions are to be made by committees of nongovernment personnel. Johnson believes outsiders are more lax and subject to conflicts of interest, and that the only way to ensure accountability is to keep all responsibility on the backs of public servants. "We must decide whether we want outsiders to be making basic public health decisions," she says. Johnson also calls the standards-setting procedures "a Rube Goldberg machine" that offers numerous opportunities for industry interests to create obstructions and delays.

The new law covers about 12,000 devices, products of a more than $3-billion-a-year industry. According to an FDA official, about 10 percent of all devices would go into the premarketing approval category and half would be allowed to stay under general controls.—C.H.