

## Tracking medical devices

Within a period of about 40 years creative pioneers, often working under difficult conditions, have saved countless lives by developing a whole host of artificial organs and implantable devices. They built these devices however they could, often facing great obstacles. Their progress was slow, they had successes but even more disappointments, and although the profit motive did not rank high in their minds, they soon discovered that eventually industry had to become involved to effect the final transition from the workbench to the bedside. Their eventual success, it is fair to say, can be attributed to an environment that helped unleash the creative energy of a generation of such ingenious investigators.

This creative energy is now sadly being stifled to death. Witness the Safe Medical Devices Act of 1990, passed by Congress with the laudable intent of protecting the consumer. Apparently enacted in response to problems with the generic drug industry, it requires a tightening of the manner in which the Food and Drug Administration (FDA) reviews new medical devices before approving them for marketing.

This new measure puts increased responsibility on manufacturers to demonstrate the

safety and effectiveness of their products. Though passed in 1990, it has been implemented slowly because of staffing shortages at the agency and complaints from industry. But sometime in 1993 according to recently published regulations, the FDA will require manufacturers to track millions of pieces of foreign material implanted into human bodies. For each device the manufacturers will need to develop a system to keep track of the lot number, the batch number, the serial number, the date it was shipped, the name, address, phone number, social security number of the prescribing physician, the surgeon, the physician regularly following the patient, and the patient.

There are pages of additional "requirements and responsibilities," rules for distributors, requirements about notification if the devices are 'explanted,' if they are returned to the distributors, if the patient dies, and detailed records will need to be kept for the government inspectors. All vascular graft prostheses fall under these rules, as do heart valves, pacemakers, infusion pumps, nerve stimulators, and breast, tracheal, and testicular prostheses, though mercifully not tracheostomy tubes and peritoneal dialysis catheters.

The whole thing promises to be a night-

mare—just keeping track of perhaps 50 000 dialysis patients with prosthetic vascular grafts, let alone some 10 million other devices, boggles the mind. Nor is it clear what the manufacturers will do with all this paper or the FDA with the information, most likely they will just file it away. Yet despite a storm of protests the agency seems determined to press on regardless. It will impose an enormous burden on manufacturers and distributors, on hospitals and physicians, and the cost will eventually be passed on to the patients and the taxpayers. That such a law should have been passed in the first place goes a long way to explaining why American industry has lost its competitive edge. It may account for the public's disenchantment with its politicians and its interest in an alternative to the two main presidential candidates—*GEORGE DUNEA, attending physician, Cook County Hospital, Chicago, USA*

