

Hippocrates

Criminal investigation of dealers in used cardiac pacemakers

In the United States, several government agencies (Federal Bureau of Investigation, Food and Drug Administration, and Department of Health and Human Services) have begun looking into charges of criminal misconduct by brokers who buy and resell pacemakers. The investigation opened in early 1990 with the discovery of bloody pacemakers in a broker's office in Indiana.

The companies under investigation are Cardiotronics Inc., Corapace Inc., Coratronics Inc., Pulstar Inc., and Telepace Inc. All are operated from the same storefront address in Hammond, Indiana.

It is permissible to resell and reuse pacemakers, although it is a rare and highly unusual practice. Reputable pacemaker manufacturers condemn the market in used pacemakers. The lifesaving devices may be reused only within a specific time period following their manufacture. After that period, vital parts may fail. Before reuse, a pacemaker generally must be sterilized and revalidated using the same procedures employed during the initial manufacturing process.

The investigators believe that the companies in question were reselling used pacemakers beyond their recommended period, were altering the expiration dates on pacemakers, were not resterilizing them, and were not revalidating them. There also are suspicions that gifts were given to doctors and hospital aides in order to influence their decisions on what pacemakers to buy. Such gratuities might violate Medicare and Medicaid laws.

Some other questions have arisen about the resale of used pacemakers. Where do they come from in the first place? If they were taken from corpses, were they obtained legitimately? If they were taken from patients, is there a possibility that they were defective? When removed, were they intended for reuse? Have used pacemakers been directed into overseas markets, where it is especially difficult for the original manufacturers to track them and warn of any problems?

The best advice for any health care provider is to buy and install nothing but validated, new pacemakers. The medical and legal risks are substantial. If there is no choice but to buy a used pacemaker, check with the original manufacturer to establish its history. Insist on some verification from the seller of its expiration, its resterilization, and its revalidation. Be suspicious of any seller who offers gifts and otherwise fails to behave as a professional medical supplier.

Debate over abortion counseling by health care providers heats up

For years, 3900 hospitals, health clinics, and family planning centers in the U.S. funded by the federal government have advised nearly 5,000,000 pregnant patients on all their medical care options – including the availability of abortions. The courts, the Congress, the President, and the American Medical Association are in hot disagreement over whether these providers may continue to give such advice. There are significant medical and legal risks depending on the outcome of the debate.

The issue began to ferment in 1988 when the conservative administration of President Ronald Reagan promulgated rules prohibiting health care providers who receive federal financial support for family planning from counseling women on abortions. Most of the affected facilities continued to give abortion advice and continued to accept federal dollars.

Upset government officials quickly learned of this apparent violation of the rules and began legal action in the federal courts. After wending its way through the court system, the case finally reached the Supreme Court. In a decision announced in May 1991, the Court upheld the rule and said that providers who continued to give abortion advice could lose their federal funding.

The decision leaves health care providers in a difficult situation. If they counsel on abortion options, a major source of their funding may be cut off. Family planning facilities vary in their degree of dependence on federal government support. On the other hand, if a provider fails to recommend abortion when it is the medically advisable alternative, it may endanger the patients' health and expose itself to a lawsuit for malpractice. There seem to be risks either way.

The American Medical Association very quickly announced its opposition to the government ban. Its policymaking body urged the repeal of all laws and regulations that “prevent physicians from freely discussing with or providing information to patients about medical care and procedures or interfere with the physician-patient relationship”. Without mentioning the word “abortion”, the Association went on to strongly condemn “any interference by the Government or other third parties that causes a physician to compromise his or her medical judgement as to what information or treatment is in the best interests of the patient”.

One of the lawyers representing the medical profession in the case argued that the decision would require doctors to violate the ethical guidelines of their medical organizations as well as state laws on malpractice. A representative from the National Right to Life Committee, an anti-abortion group, countered that it would, in fact, be ethical for a doctor to act to prevent abortion from being used as a birth control method.

Where do the American people stand on the issue? A nationwide poll sponsored jointly by the Wall Street Journal and NBC showed that 64% of registered voters opposed the ruling while only 31% supported it. Even 50% of self-described conservatives were against the decision, with 40% in favor of it.

This national mood was reflected in the recent approval by the House of Representatives of a \$204 billion health and education budget bill which includes

an amendment barring the enforcement of the rules prohibiting abortion counseling. President Bush feels so strongly about the issue that he has said he will veto the bill if it reaches him. However, the 353-74 House vote on the bill suggests that Congress has a good chance of overriding such a veto. Even some of the more conservative members of Congress, traditional Bush supporters, have doubts about supporting the Supreme Court's decision. The leader of the House Republican Minority said: "Freedom of information, boy, that is one of our most cherished principles".

The odds are that, by the end of 1991, the Congress will have given veto-proof support to a new law authorizing abortion counseling by federally financed health facilities.

Unregulated tissue banks in the U.S. come under criticism

Six persons in Virginia recently were found to be infected with HIV as a result of their receipt of transplanted organs and tissue from a donor with AIDS. This sensationalized case has forced a re-examination of the operating standards of tissue banks. In the Virginia case, a 1985 gunshot victim was the source of five organs, two corneas, 54 tissue grafts, and several vials of bone marrow collected by one of the most reputable tissue banks in the country. He was tested twice for AIDS using the most sophisticated screening procedures known at the time. The tests showed, inaccurately, that he was free of the AIDS virus. His organs and tissues were distributed to hospitals throughout the U.S.A.

When the Congress in 1984 required the Food and Drug Administration (FDA) to develop regulations for organ banks, it failed to include tissue banks in the mandate. Left unregulated, some of these suppliers of bone, cartilage, tendon, and other tissues for around 300,000 surgical procedures annually have committed high-risk abuses. Some tissue banks have not collected their materials from the relatively safe environment of a hospital, but instead have gone to morgues where the risks of bacterial or viral infection are much greater. In an attempt to disinfect the materials, they are immersing them in ethylene oxide. This is a toxic chemical widely used with surgical instruments. It also is a known carcinogen. Its use with tissue shortly prior to transplant is criticised by many authorities. And a few banks are just performing generally poor quality work throughout their operation.

By most standards, the risks of infection through transplant of mishandled organ or tissue remains small. Since the initiation of HIV testing, more than 40,000 kidneys have been transplanted and several thousand patients have received heart, liver, and pancreas grafts. Cases of AIDS infection among this group are so rare that they attract national attention when they do occur. In a related area, the odds of AIDS infection through blood transfusion are about one in every 90,000 units of blood.

Despite the minimal risk, the few dramatic cases have prompted a review of the existing regulatory framework. Even organ banks are not under direct government

scrutiny. Instead, the FDA in 1987 delegated the responsibility to a private non-profit organization, the United Network of Organ Sharing (UNOS). This group has set standards for how organ banks must do business. It also keeps track of donors and recipients and asks to be notified of any AIDS-related death among donors or recipients. Banks that fail to meet UNOS standards can lose their membership in the group. In addition, the Department of Health and Human Services can withhold Medicare and Medicaid monies. Some health care officials are dissatisfied with even this level of control over organ transplants.

No one has the responsibility for overseeing tissue banks. Several non-profit agencies and private for-profit corporations operating tissue banks have begun to plead for some kind of government regulation. Their pleas are supported by many orthopedic surgeons and other physicians. An aide to Senator Albert Gore Jr., who sponsored the 1984 legislation imposing controls on organ banks, says that the Senator is considering either proposing new legislation or simply asking the FDA to extend its regulatory authority to tissue banks. Either way, it seems likely that such banks will be operating under strict government-enforced guidelines within at least two years.

In the interim, health care providers regularly using tissue transplants should become more curious about their origins. Determine whether the materials came from live patients or corpses. If the latter, ask what steps were taken to control infection. In either case, insist on evidence of thorough, accurate screening to determine the presence of infectious diseases in the donor. Conduct an on-site examination of the tissue bank's facility, equipment, and operations. These steps will minimize the chances of a successful legal action for professional negligence.
