Tissue Banks Now Under Heightened Regulation

According to Victoria Stagg Elliott in the February 5, 2001, issue of American Medical News, the Food and Drug Administration (FDA) will now require all tissue banks and their products to be registered within the next two years.

Until the new policy was announced in January, the tissue banking industry had largely been unpocked—a situation that had raised concerns from advocates, donor families, and physicians. Many have rarely—or ever—been inspected, and there is no complete list of tissue banks in the United States. This step will help the FDA fill knowledge gaps regarding companies that provide eyes, bone, heart valves, and skin as well as reproductive tissue and stem cells. Only two states—New York and Florida—required tissue banks to be licensed and inspected.

"The process is becoming more formalized, and that's good because it forces the tissue banks who might be marginal to go through the whole process," says ophthalmologist Ronald E. Smith, medical director of the Eye and Tissue Transplant Bank in Los Angeles.

The FDA's action came after a report from the Office of Inspector General, which, among other things, noted that families felt that items derived from donated tissue were not treated with as much respect as donated organs. "That 'screw' is not a screw to me—it came from somebody's loved one," said the report, quoting the mother of a tissue donor.

The FDA will now require that products derived from tissue will be clearly marked as "donated" in order to engender more respect.

Physicians were generally supportive of the FDA's regulations. "It's very important to have high standards for tissue banks to protect patients," said Dr. Russell Kridel, president of the American Academy of Facial, Plastic, and Reconstructive Surgery. "Most of us are appreciative of the donation because those are the best tissues to use and much better than artificial."

AMA Fights “Encroachment”

Physicians are increasingly concerned about what they see as "encroachment" on their professional turf by other health care workers, writes Jay Greene in American Medical News.

Last year, more than 30 state legislatures considered bills to grant various "scope-of-practice" rights to nonphysicians, including psychologists, pharmacists, and nurse practitioners. In Georgia, for example, a measure would have expanded the number of medications optometrists are allowed to prescribe. That bill was defeated, partly as a result of efforts by the state medical association. Among "scope" combat zones this year are:

- Florida, where nurse practitioners have asked the legislature to let them prescribe controlled substances
- Maryland, where nurse psychotherapists want to prescribe medication, pharmacists want the right (in collaboration with physicians) to change or modify prescriptions, and certified nurse midwives want hospital staff privileges
- Illinois, where pharmacists want the right to conduct drug therapy

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GENETICS AND ETHICS

Avoiding the Pitfalls of Genetic Testing

The first ethical principle physicians should follow when first confronting the rocky terrain of genetic testing is to seek help from other professionals, writes Faith Lagay, PhD, a fellow of the Institute for Ethics, in the February 5, 2001, issue of American Medical News.

The biggest ethical pitfall of genetic testing is physician misinterpretation of test results and patient misunderstanding when receiving the results. Help is available, however, through genetic counselors, who have the knowledge and proper ethical and clinical training to assist both caregivers and patients.

Lagay proposes a set of five ethical guidelines for physicians to follow and patients to be aware of after reviewing family history and the request for genetic testing.

• Pursue testing only when there is a need to know. Testing should only be performed when the results will alter the actions a person takes in the interest of his or her health. Family prevalence of colon, breast, or ovarian cancer is an example in which behavior can be modified based on test results.

• Children and embryos should be tested only for serious diseases that manifest in childhood. Testing for carrier status and conditions that do not pose health problems is not ethically acceptable.

• Inform patients that physicians have a duty to share information with patients under certain circumstances. If the genetic test results show a disease or risk that can be treated, managed, or prevented, family members who carry the gene should be informed.

After these guidelines have been met, patients and their caregivers should begin genetic counseling to determine future actions in an ethical manner.

TECHNOLOGY

Just Say “No” to Technology

Just because we have the most modern technological tools at our fingertips doesn’t mean we need to overuse them to communicate, writes Michael Schrage in the December 18, 2000, edition of Fortune. Organizational benefits of certain forms of high-tech communication are often outweighed by their costs, as some companies are realizing. Computer Associates, a multibillion-dollar software firm, blocks internal e-mail communications for several hours a day so that managers can get work done. And Procter & Gamble is well known for insisting on one-page memos—longer ones are just not read.

Ever-present technology makes it easy to generate more “information” in less time. The relative simplicity of creating spreadsheets, color slides, and organization-wide e-mail updates engenders a culture in which employees often feel an artificial need to communicate. Does the company truly need a 47-slide PowerPoint presentation to teach employees about the new pension plan? Does every manager in the organization need to see the 17th project update memo in a month? As some point, organizations have to say “no!”

Sometimes the smartest way to use a resource is to create guidelines for its use, which forces employees to be more creative and judicious. For example:

• Limit voice mail messages to one minute to encourage focus
• Suggest a maximum of 10 e-mails per employee per day
• Have employees note on every e-mail whether the communication requires a response
• Limit presentations to no more than 10 slides

Xerox chief scientist John Seeley Brown once insisted that presenters only use New Yorker cartoons to make their business case. The result was entertaining and forced the presenters to structure their presentations without the overuse of numbing technology.

Organizational media without discipline and forethought breeds wastefulness of time, effort, and money. Companies concerned about their employees’ time will put as much thought into the use of technology as they do in the technology itself.

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