

## MEDICINE

# 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 been largely unpoliced—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."

## MEDICAL PRACTICE

## 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

and certified surgical assistants and lay midwives want the right to perform physical examinations on schoolchildren and bus drivers

Because nonphysicians receive less training than physicians, many doctors see "scope" legislation as a danger to public health. "These bills are prescriptions for disaster," said Randall Easterling, MD, a Mississippi family physician.

Other doctors focus on what they perceive as a threat to their profession. "These days we have forces at work to deconstruct our profession of medicine, break it down in little pieces and parcel it out for others to do," said James Skully, MD, a psychiatrist.

Robert Lyles, MD, PhD, a Maryland anesthesiologist, said "scope" legislation in his state was being encouraged by managed care organizations. "Nurse practitioners want to be defined as a provider for HMOs, just like physicians," he said. "HMOs support this because they see nurse practitioners as the cheaper provider."

#### 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*. 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



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 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 of possible discriminatory consequences of undergoing genetic testing. Prospective employers and insurers may 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 commu-

nicate, writes Michael Schrage in

the December 18, 2000, edition

of Fortune. Organizational bene-

fits of certain forms of high-tech

communication are often out-

weighed by their costs, as some companies are realizing. Computer Associates, a multibilliondollar 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 organiza-

tion-wide e-mail updates engenders a cul-

ture in which employees often feel an

artificial need to communicate. Does the

company truly need a 47-slide Power-

Point 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

Sometimes the smartest way to use a

resource is to create guidelines for its use,

which forces employees to be more cre-

· Limit voice mail messages to one

ative and judicious. For example:

Contraction of the second seco

 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.

have access to this information, and current legislation preventing discrimination is lacking.

minute to encourage focus

have to say "no!"

• Make sure patients return to the physician's office to receive and discuss the results. Communication is vital in order to decide on any medical treatment.

• 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. JOURNAL OF THE CATHOLIC HEALTH ASSOCIATION OF THE UNITED STATES

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# HEALTH PROGRESS.

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