

POLICY & PRACTICE

Proposed Cuts to Mental Health

Mental health and substance abuse programs took a funding hit under President Bush's budget request for fiscal year 2007. The request calls for \$698 billion for the Department of Health and Human Services—\$58 billion more than fiscal 2006—but contains a number of cost containment measures that would either whittle down or cut certain programs entirely. Proposed funding for the Substance Abuse and Mental Health Services Administration is set at \$3.3 billion, a net decrease of \$67 million from last year. This includes \$849 million for mental health services, which is \$35 million less than last year. That decrease is occurring because even though the Center for Mental Health Services will not cut any programs in 2007, "there are a number of grant cohorts within programs that will come to their natural end" and no new grants will be awarded, although grants in mid-cycle will continue, according to center director Kathryn Power. The budget request freezes funding for children's mental health programs at last year's level of \$104 million. The request also includes a proposal to reform the Community Mental Health Block Grant designed to make the mental health system more consumer- and family-driven, and to promote early mental health screening. Substance abuse prevention programs "of regional and national significance" would receive \$181 million in 2007, \$12 million less than in 2006. As the budget request noted, one possible reason for the decrease is that illicit drug use among teens has dropped nearly 19% since 2001.

Primary Care Drug Testing

Pediatricians and other primary care physicians often don't use the right urine sampling techniques and validation procedures when they perform drug tests on adolescents, according to a study that appeared in the February issue of the Archives of Pediatric and Adolescent Medicine. Dr. Sharon Levy of Harvard Medical School and colleagues surveyed 359 physician members of the American Academy of Pediatrics, the Society of Adolescent Medicine, and the American Academy of Family Physicians and found that only 23% of physician respondents used an effective collection procedure (patient provides identification, empties pockets, and uses the bathroom without running water; blue dye is placed in standing water; and specimen temperature is checked immediately). Only 7% of respondents said they routinely checked both urine creatinine level and specific gravity to prevent patients from cheating on a test by providing diluted urine. Most respondents also did not know that Ecstasy, oxycodone, and nitrous oxide are not detected by routine screens, the authors noted. "The primary care workforce is not prepared to provide guidance to schools, parents, or pa-

tients with questions regarding drug testing," they wrote, adding that physicians who do these types of drug screens in their offices frequently should seek further training.

Depression Prevails in Teens

Earlier interventions are needed to address childhood onset of mental health disorders, Missy Fleming, Ph.D., program director for child and adolescent health with the American Medical Association, said at a meeting of the National Institute for Health Care Management Foundation. "We need to develop a stronger infrastructure and policies to promote and support healthy psychological development," she said. This includes increasing access to interventions that are likely to reduce the burdens of untreated mental disorders; linking assessment services to prevention and treatment, especially those that are sensitive to cultural needs; and enlisting primary care physicians, schools, and community resources to meet adolescent and young adult mental health needs. Major depressive disorder is common during childhood, with an estimated prevalence of 2%-5% for adolescents aged 13-18 years. This problem increases through young adulthood, she said. "At least 14%-25% of youth experience one episode of major depression before adulthood." One in five adolescents ages 9-17 experiences symptoms of mental health problems that can cause some impairment in a given year, she said, citing the Substance Abuse and Mental Health Services Administration's 2004 National Survey on Drug Use and Health.

Lester Crawford, Lobbyist

Former Food and Drug Administration Commissioner Lester Crawford, D.V.M., has taken a position at Policy Directions Inc., a Washington, D.C.-based lobbying and consulting firm. Mr. Crawford will be senior counsel to the organization, which counts pharmaceutical manufacturers and biotechnology and food companies among its clients. By law, he will be barred from directly lobbying Congress for at least a year. Policy Directions declined to make him available for an interview. Mr. Crawford resigned abruptly from his FDA post in September, just 2 months after he was confirmed by the Senate. In the 5 years of the Bush Administration, the FDA has had a permanent commissioner for only 18 months. (Mr. Crawford served in an acting capacity for 16 months without Senate confirmation.) In early February, Sen. Chuck Grassley (R-Iowa) wrote to White House Chief of Staff Andrew Card asking that a permanent commissioner be nominated, adding that the agency was adrift without such leadership. For now, Dr. Andrew von Eschenbach is the acting Commissioner, but also continues to hold his previous job as head of the National Cancer Institute.

—Joyce Frieden

FDA Guidance Backs Early Clinical Studies

BY MARY ELLEN SCHNEIDER
Senior Writer

Researchers now have a pathway for conducting early clinical testing of drugs in a small number of human subjects under new guidance from the Food and Drug Administration.

Officials at the FDA finalized guidance on exploratory investigational new drug (IND) studies which allows researchers to move forward with small human studies before beginning traditional phase I safety testing in humans. The guidance, published in January, makes recommendations on safety testing, manufacturing, and clinical approaches in these early studies.

The FDA also published draft guidance and a direct final rule in January that outlines new standards for the manufacture of drugs solely for use in phase I studies. The rule is aimed at making it easier for scientists to produce small quantities of drugs for small-scale, early-phase human testing.

"This is about saving lives and about building medicine's future," said Dr. Andrew von Eschenbach, acting FDA Commissioner of Food and Drugs.

Currently, less than 10% of IND applications for new molecular entities progress beyond the investigational stage, according to the FDA. These changes will remove some of the hurdles from very early drug development, Dr. von Eschenbach said during a media teleconference sponsored by the FDA.

But critics of the approach say it relaxes needed human subjects protections at a time when the safety of clinical trials is already being questioned.

In guidance on the exploratory IND, FDA officials outline their thinking that drug sponsors have not taken full advantage of the flexibility in the existing regulations and often provide more supporting information than is required.

Exploratory IND studies involve administering either a subpharmacologic dose of a product or doses that are expected to produce a pharmacologic but

not a toxic effect, so the risk to human subjects is considered lower than in a traditional phase I study, FDA said in its guidance documents. Since exploratory IND studies pose fewer risks, they can be initiated in humans with less, or different, preclinical support than what is required for traditional IND studies.

Previously, one of the major obstacles in the development of new drugs was that the requirements for beginning early experimental studies were the same as those for large pharmaceutical companies who are making drugs for thousands of patients, Dr. Steven Rosenberg, chief of surgery at the National Cancer Institute, said during the teleconference.

"We've been at the mercy of large biotech and pharmaceutical companies who have the resources to fulfill the very stringent regulations that exist for taking these new products to very large numbers of patients," he said.

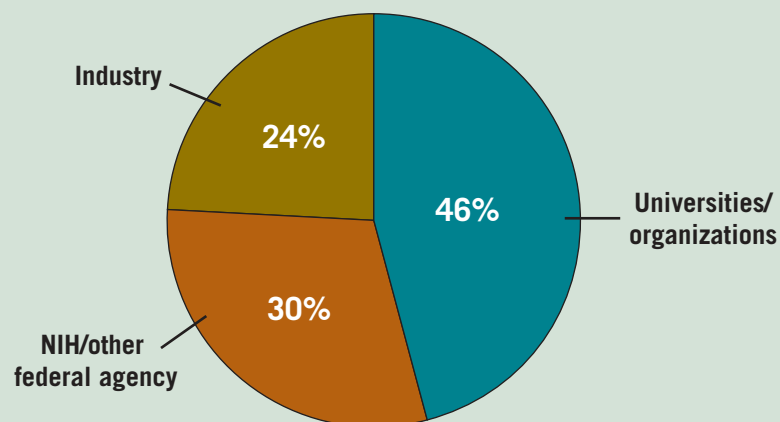
The changes made by the FDA will make it possible for scientists to take new ideas to small numbers of patients with desperate diseases and test those agents in ways that weren't possible before, he said.

But Dr. Sidney Wolfe, director of Public Citizen's Health Research Group, said he remains concerned that the usual protection for human subjects has been "watered down." Under the new process, a safety problem that might have been detected through more extensive animal studies now may be missed, he said.

And he is doubtful of the benefits. Dr. Wolfe said the types of studies described in the exploratory IND are already being done but with the previous protections in place for human subjects.

Sen. Charles Grassley (R-Iowa), chairman of the Senate Committee on Finance, which has been conducting oversight of the FDA's consumer protections, also expressed safety concerns: "At a time when new questions are being raised about whether participants in clinical trials are protected and treated ethically, the FDA is loosening the reins on drug companies." ■

DATA WATCH

Who Sponsors Clinical Trials?

Note: Based on nearly 14,000 international clinical trials currently recruiting as of Dec. 1, 2005.
Source: Clinicaltrials.gov, National Institutes of Health