

POLICY & PRACTICE

Stem Cell Support Drops Slightly

Most of the public supports the use of human embryonic stem cells for medical research, but that support may be faltering slightly, according to a new poll from Virginia Commonwealth University. The survey, which included 1,000 adults, found that 54% of respondents favored stem cell research in 2006, down from 58% in a similar VCU poll in 2005. The number of respondents who opposed stem cell research climbed from 32% in 2005 to 37% in the recent 2006 survey. However, when asked if they would support the use of embryonic stem cells to find a treatment for themselves or a family member with Parkinson's disease or spinal cord injury, 70% of respondents said yes. Only 21% would not support the use of stem cells in that situation, according to the 2006 poll. How people feel about stem cell research may also depend on their political affiliation. A recent survey by the Kaiser Family Foundation and the Harvard School of Public Health found that many more Democrats and Independents favor federal funding for embryonic stem cell research than do Republicans. In a national poll of 1,867 adults, the researchers found that 67% of Democrats and 61% of Independents favor broadening federal funding for stem cell research, compared with 37% of Republicans.

Expanding Autism Research

President Bush signed legislation that authorizes a major expansion of autism research, education, and early detection efforts. The Combating Autism Act of 2006 (S. 843) calls for spending nearly \$1 billion on activities and research related to autism spectrum disorders over the next 5 years. The new law also calls for research that would aid in developing and validating screening tools for autism spectrum disorders. "As the prevalence of autism grows, the odds are that every American will know a family who will directly benefit from the programs and research made possible by this legislation," Jon Shestack, cofounder of Cure Autism Now, said in a statement.

Conviction in ALS Fraud Case

A federal jury recently convicted a New Jersey physician and her coconspirator of defrauding patients with amyotrophic lateral sclerosis. Dr. Charlene C. DeMarco was convicted of one count of conspiracy to commit mail and wire fraud, three counts of mail fraud, six counts of wire fraud, and one count of money laundering. Over the course of the trial, the prosecutors presented evidence that Dr. DeMarco, who specialized in the treatment of Lyme disease, offered treatment to ALS patients that used stem cell therapy, and that she charged families up to \$35,000 for treatments that were never performed. Dr. DeMarco told four patients and their families, all of whom lived in Louisiana, that she was running an ongoing study of stem cell treat-

ment of ALS and required an up-front fee. Dr. DeMarco is scheduled to be sentenced in April.

Alzheimer's Research Funding

Alzheimer's disease research got a boost recently when Weill Cornell Medical College in New York announced that it will establish the Appel Institute for Alzheimer's Research. The institute is funded by a donation of \$15 million from Helen and Robert Appel. The new institute will focus on novel and cross-disciplinary approaches to research into Alzheimer's disease and other neurodegenerative conditions. "By employing an interdisciplinary approach to the study of this condition, researchers at the Appel Institute will be able to obtain groundbreaking insights into the physiology of the disease," Dr. David Hajjar, vice provost and dean of the Weill Cornell Graduate School of Medical Sciences, said in a statement. "Instead of simply following existing clinical protocols, these diverse research collaborations will offer a 360-degree view of Alzheimer's—hopefully exposing its cause and eventually its cure."

New Approaches to Epilepsy

The Epilepsy Research Foundation, a collaboration of nonprofit organizations, recently announced a total of \$400,000 in grants to fund translational research for three potential epilepsy treatment approaches. One grantee will work on developing adenosine-releasing brain implants to treat temporal lobe epilepsy in rat models. Another will evaluate the benefit of huperzine A, which is derived from a Chinese herb, as an add-on therapy for patients with refractory epilepsy. The phase IIA dose-escalation study will consider the safety and tolerability of the compound and provide initial information on its effectiveness in treating seizures. The final grant will be used to fund research into the development of a galanin-based therapy for the treatment of refractory epilepsy.

Easing Use of Experimental Drugs

The Food and Drug Administration is proposing to widen access to experimental drugs. The agency has been accused by patient advocates and some drug makers of obfuscating the criteria physicians need to seek to use investigational drugs in their patients. In 2003, an Arlington, Va.-based advocacy group, the Abigail Alliance, sued the FDA to get unfettered access to unapproved therapies. The plaintiffs were backed by a federal appeals court in May 2006, and a rehearing of the case is expected to begin in March. In the meantime, the FDA's proposed rule, published last month, said the agency was going to make it easier for physicians to access experimental therapies, and for manufacturers to make them available. In a statement, the Abigail Alliance said the FDA proposals "merely clarify their existing policies."

—Mary Ellen Schneider

UC Davis Medical School Bans Drug Company Gifts

BY TIMOTHY F. KIRN
Sacramento Bureau

SACRAMENTO — Another medical school has joined what could be a growing movement to ban faculty and residents from accepting any gifts whatsoever from drug company representatives.

The University of California, Davis, Health System decided in late November to forbid its medical staff to accept any gifts from drug salesmen, including drug samples, pens, mugs, and meals, however small they might be. Earlier, the school had banned drug company representatives from walking into the clinical areas on a preceptorship.

By taking this action, the school joins a cadre of institutions that includes Yale University, which implemented its policy in 2005, the University of Pennsylvania, which did so in July 2006, and Stanford University, which implemented its policy in October 2006. At UC Davis, the policy goes into effect in July 2007.

The new prohibition "picks off the low-lying fruit" in an attempt by the institution to create a greater distance between its clinical practice and the pharmaceutical industry, said Dr. Timothy E. Albertson, the university system's executive director of clinical care.

The school has plans to look at the issue of conflict of interest in further detail, particularly in regard to relationships with and practices of other vendors, he said. "We're certainly not trying to change capitalism, but we are trying to redefine the ethics of this type of involvement."

The efforts at UC Davis and the other academic medical centers were spurred in part by an article in the *Journal of the American Medical Association* (2006;295:429-33).

The article noted that many authoritative bodies, including the Pharmaceutical Research and Manufacturers of America and government agencies, have made attempts to curtail practices that constitute a conflict of interest for physicians. But the article also said those actions have largely failed to change the current climate. Thus, the 11 authors of the paper urged academic medical centers to take the lead by, among other things, banning the acceptance of gifts, samples, and payment for time spent at meetings.

Academic medical centers need to adopt such policies because the medical profession looks to them for leadership, and because academic medical centers shape the ethics of the profession, the proposal said.

The article notes that 90% of the marketing dollars spent by the pharmaceutical industry were directed at doctors, despite the increase in money spent on direct-to-consumer marketing in recent years.

According to IMS Health, a pharmaceutical information and consulting company, drug companies spent \$27 billion on product promotion in 2004, of which \$16 billion was for free drug samples and \$7.3 billion, including gifts and meals, went to sales representative contacts.

The pharmaceutical industry, which

adopted strict guidelines on gift giving in 2002, says that limiting the practices and access of their sales representatives will deprive physicians of the best expertise on their medicines.

But gifts, however insignificant, establish an unspoken quid pro quo between physicians and pharmaceutical companies. If gifts did not serve this purpose, companies would not give them, the JAMA authors say. They note that the research bears this out.

According to a 2003 survey of more than 1,000 third-year medical students, an average third-year student receives one gift or attends one company-sponsored activity a week (*JAMA* 2005;294:1034-42). That is precisely the point of the no-gift policies proposed by the JAMA article, said one of its authors, Dr. Jerome P. Kassirer, former editor-in-chief of the *New England Journal of Medicine*.

"These meals and gifts give residents and trainees the idea that pharmaceutical largesse is all right and the way things work, but it taints the profession," Dr. Kassirer said in an interview. "They wouldn't pass out these gifts if it didn't matter."

"I think the academic medical centers needed a little nudge," he added, noting the impact the article appears to be having. "It's a beginning."

At the academic medical centers, free meals appear to be the biggest issue impeding acceptance of the policies among staff. The free meals allow physicians to attend midday meetings they otherwise would not have time to attend, and they are a big ticket item.

At the UC Davis Cancer Center alone, it is estimated that companies spend about \$70,000 on free lunches a year. The center will now pick up those costs, and other departments may have to do the same.

At the University of Pennsylvania Health System, the adoption of its policy caused some grumbling at first, along with the loss of some legitimate educational programs that were sponsored. For the most part, however, physicians and other staff members have adjusted, said Dr. Patrick J. Brennan, the chief medical officer of the university health system.

He said there is "much less evidence" of sales representatives around the clinics and school. At one suburban clinic run by the university, sales reps turned in their identification badges in protest; but, he believes, the sales force may have adjusted. He has lately seen an increasing number of medical education programs offered to faculty and staff sponsored by a third party hired by a drug company.

At UC Davis and some of the other institutions, efforts are being made to help patients who previously might have benefited from receiving free drug samples or devices; these items have been very helpful, especially for lower-income patients, Dr. Albertson noted. The university is going to try to purchase some of the equipment that has been donated in the past, such as training inhalers for asthma patients and supplies for those with diabetes. ■