POLICY & PRACTICE

Outlook 2006

Wide access to imaging, increasing Medicare physician payment, and reforming the medical liability system still top this year's agenda for the American College of Cardiology. "They are all battles that have not yet been won," said Dr. Pamela S. Douglas, ACC president.

Imaging

Officials at the ACC have partnered with the Coalition for Patient-Centered Imaging, which also includes the American Society of Nuclear Cardiology and the Heart Rhythm Society, to ensure that imaging services are not restricted. Dr. Douglas said officials at the ACC want to ensure that all properly trained physicians continue to be able to perform and be paid for imaging services. The college has urged Congress to oppose efforts to impose physician certification policies benefiting one specialty over another. ACC officials also have opposed efforts to expand accreditation requirements for independent diagnostic testing facilities to physician offices. But the growth in imaging should be done with quality in mind, Dr. Douglas said.

Physician Payment

Without a fix to the Medicare physician payment system, this year's planned 4.4% cut will be the first of many years of cuts to physician fees for seeing Medicare patients. As a result, Dr. Douglas said ACC supports the elimination of the current Sustainable Growth Rate formula used in calculating physician reimbursement levels. The SGR is tied to changes in the gross domestic products, which does not accurately reflect the cost of providing care to Medicare patients, according to the ACC. Instead, the SGR should be replaced with a medical growth formula, Dr. Douglas said. As cardiovascular care is increasingly successful, patients are living longer but require more care to stay well. But the current payment system fails to recognize the complexity of care delivered by cardiologists, she said.

Medical Liability Reform

ACC officials have partnered with Doctors for Medical Liability Reform in a multiyear effort to win federal legislation to help curb rising professional liability insurance premiums. Last year, the House moved forward on medical liability reform by passing the Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act (H.R. 5), which would have imposed a $250,000 cap on noneconomic damages. But the issue failed in the Senate.

Pay for Performance

On the regulatory side, Dr. Douglas said ACC favors efforts to develop pay-for-performance programs as long as they are properly designed. But it's key that the programs include incentives for physicians and are not used solely as a way for payers to contain costs. There is a cost to physicians for tracking and reporting quality, Dr. Douglas said, and those costs need to be covered.

Redding Doctors Settle

Four physicians accused of performing unnecessary heart surgeries at Redding (Calif.) Medical Center have agreed to pay a total of approximately $27 million to settle lawsuits. The money will go to compensate patients and the Medicare and Medi-Cal programs. In addition, the Tenet Healthcare Corporation, which used to own Redding Medical Center, will pay $5.5 million. Tenet has already paid $54 million to settle claims that it defrauded the government by billing Medicare for unnecessary cardiac catheterizations and bypass surgeries. Two of the physicians from Redding Medical Center have also agreed to never again perform cardiology procedures or surgeries on Medicare, Medi-Cal, or TRICARE patients. Under the terms of the settlement, the physicians have received a commitment that the U.S. Attorney's Office will not initiate criminal charges against them.

New Head for FDA Women's Health

Dr. Kathleen Uhl has been named director of the Office of Women's Health at the Food and Drug Administration. Dr. Uhl, a family physician and a captain in the U.S. Public Health Service, was most recently a supervisory medical officer in the FDA's Center for Drug Evaluation and Research. "Kathleen brings a breadth of professional experience, as well as a strong science background and passion for women's health, to her new position," said Dr. Andrew von Eschenbach, FDA acting commissioner. Dr. Uhl's experience includes clinical practice, basic science and clinical research, drug application review, drug safety oversight, and women's health issues. She also has dual faculty appointments at the Uniformed Services University of the Health Sciences in family medicine and internal medicine.

Groups Sue Over Part D

Countless numbers of poor men and women "will fall through the cracks" during transition to the new Part D drug benefit, medical groups stated in a lawsuit against the federal government. More than 6 million "dual-eligible" patients—those who are enrolled in both Medicare and Medicaid—will lose their Medicaid drug coverage on Jan. 1. The groups said they're seeking protections for patients who are not seamlessly and immediately transitioned to the new drug program. "The poorest, sickest, and oldest Americans face grave risk of losing their life-saving medications once the clock strikes twelve on New Year's," said Robert M. Hayes, president of the Medicare Rights Center, a national consumer service group and one of the plaintiffs. In particular, those beneficiaries who are cognitively impaired or only have a high school diploma will have problems mastering the complexity of the new drug benefit, the lawsuit indicated. A spokesman with the Centers for Medicare and Medicaid Services said the agency was not commenting on the pending lawsuit.

—Mary Ellen Schneider

GUEST EDITORIAL

Truth Decay at the FDA

In March last year, a college student with known congenital heart disease died while he was mountain biking in Utah. The tragedy was compounded by the fact that an implanted defibrillator, which should have prevented his death, was found by the manufacturer to have short-circuited.

In fact, the same model had short-circuited earlier in more than two dozen other patients. When the boy's doctors asked the company (Guidant) about issuing a warning, the official response was that it saw no need.

BY LAZAR J. GREENFIELD, M.D.

But the company suddenly discovered a need when the New York Times published a story revealing that Guidant had known about the problem for 3 years. In fact, the company had corrected the problem in 2002, but had continued to sell flawed devices out of inventory. Guidant also reported the correction only as part of its annual report to the Food and Drug Administration in 2003.

In July 2005, with increased publicity about the problem, the company issued alerts or recalls on 20 models of defibrillators and pacemakers.

The FDA finally joined in and announced that the problem was a voluntary pacemaker recall and placed it in class I, which is life-threatening. But when the New York Times, under the Freedom of Information Act, requested performance information from the FDA on the company's defibrillators, the FDA declined to release the information, which it considers "confidential."

Is this an isolated incident of the FDA favoring corporate over public welfare? Unfortunately not. Instead, it reflects the growing influence that industry has in Washington, particularly in political appointments to administrative positions in the FDA.

During a sabbatical in 2004, some colleagues and I submitted a manuscript to the Journal of Vascular Surgery.

The paper, in which we analyzed the risk of abdominal aortic aneurysm rupture after insertion of the AneuRx endovascular graft in comparison with the mortality of similar patients undergoing open repair, had been cleared by reviewers at the FDA.

The study was prompted by reports of patients continuing to die from aneurysm rupture in spite of the endovascular graft. We found that the risk of rupture after the endovascular graft appeared to increase with the passage of time, and that after 3 years, it surpassed the mortality from the open operation.

After the paper had been peer reviewed, it was accepted for publication and an abstract was placed on the journal's Web site. It was then that the manufacturer, Medtronic, responded with legal threats to the journal and to the FDA if the article was published, based on a claim of data confidentiality.

However, the issue of confidentiality was actually moot because the FDA had issued a public health notice on the AneuRx graft in December 2003 based on the same data.

At this point, with no valid objection in evidence, FDA administrators could have stood by the findings of their own staff or dodged the problem with the customary disclaimer that the paper represented the views of the authors and not the official view of the FDA.

Instead, over the objections of the authors, they demanded that the article be withdrawn, thereby prompting a rebuke from the editors of the journal. There was also a front-page article in the Wall Street Journal deploring Medtronic's successful lobbying effort.

To add to the irony of the situation, Medtronic had been obligated to provide follow-up information as a condition of approval of the graft in 1999. And since the study was based on data provided to mid-2002, additional outcome data held by the company could have been used to refute or support the study's conclusions.

Instead, there are no additional data available, and FDA staff members continue to be frustrated by their administration's refusal to obtain the data and settle the issue.

These problems are not unique to the FDA's Center for Devices and Radiological Health.

The agency's ability to ensure drug safety also has been questioned because the warnings were late on suicide risk in teens on antidepressants, and on Vioxx because of its cardiovascular risk. In the Vioxx hearings, FDA epidemiologist David Graham revealed that he too had been forced to withdraw an article accepted by Lancet that would have exposed the risk of the drug.

Such censorship has a chilling effect on investigative work by FDA staff, and shows administrative willingness to let industry self-regulate. But we don't ask airplane manufacturers to investigate airplane accidents.

The advantage of more independent review of drug safety issues was finally acknowledged earlier this year by the FDA's establishment of the independent Drug Safety Oversight Board.

Such an approach is also needed for medical devices.

In the Senate, a bill has been introduced (S. 470) to expand the clinical trials drug data bank to include medical devices.

But unfortunately, more legislation is not likely to alter the pervasive Washington food chain that leaves the FDA vulnerable to political pressures. The only cure is sunshine and the court of public opinion. ■

DR. GREENFIELD *is professor of surgery and chair emeritus at the University of Michigan, Ann Arbor.*