Policy & Practice

Merck Reaches Fraud Settlements

Pharmaceutical company Merck & Co. has agreed to pay more than $650 million to federal and state governments to resolve claims that the company provided kickbacks to physicians to purchase Merck products and failed to pay proper rebates to Medicaid. The company did not admit wrongdoing as part of the settlement. "Merck believes its pricing and sales and marketing policies and practices were consistent with all applicable regulations and contracts during the relevant time," the company said in a statement. In a lawsuit filed in Philadelphia, a former Merck employee alleged that from 1997 to 2001 Merck sales representatives made illegal payments to physicians to purchase its drugs and disguised those payments as fees for training or funding for market research. In addition, the suit against Merck alleged that the company offered hospitals substantial discounts for purchasing Zocor (simvastatin) and Vioxx (rofecoxib) if they used those drugs primarily over other competing brands. Merck is alleged to have excluded those discounts when reporting price information to Medicaid, which is entitled to receive the "best price" under the law. In a separate lawsuit against Merck, a physician in New Orleans alleged a similar scheme in which the company would offer substantially lower prices on its Pepcid (famotidine) products once a hospital agreed to use the drug primarily over a competitor's product. Once again, Merck is alleged to have excluded those discounts in its reporting to Medicaid. Under the terms of the two settlements, Merck has agreed to pay more than $360 million to the federal government and more than $290 million to 49 states and the District of Columbia. The company also has also entered into a 5-year Corporate Integrity Agreement with the Health and Human Services Department Office of Inspector General.

M.D. Faces Plagiarism Charges

Dr. Lee S. Simon, a rheumatologist and associate clinical professor of medicine at Harvard Medical School, Boston, is under a cloud of suspicion after a computer program found significant similarities between an article he authored that was published in 2004 and an article by another author that was published a year earlier. An internal ad hoc committee at Harvard is conducting a preliminary review of the situation, according to a spokesman for the university. A computer program called eTBLAST, which was developed by researchers at the University of Texas Southwestern Medical Center at Dallas, identified duplications between Dr. Simon's article on the treatment of rheumatoid arthritis in Best Practice & Research Clinical Rheumatology in 2004 and a 2003 article published in the journal Expert Opinion on Drug Safety. Elsevier, which publishes Best Practice & Research Clinical Rheumatology and this publication, retracted Dr. Simon's article in January, saying that it "included the reproduction of several sections of text and much of the reference list" from the other paper. Dr. Simon had no comment on the accusation as of press time.

Individual Mandates Necessary

Unless the United States adopts a single-payer health system, it will not be possible to achieve universal coverage without a mandate that requires individuals to purchase health insurance, a new report from the Urban Institute concluded. A system that encouraged but did not require people to get health insurance would tend to enroll disproportionate numbers of individuals with higher-cost health problems, the report said. This could create high premiums and instability in the insurance pools that enroll those individuals, the report said. In addition, the government would have difficulty redirecting current spending on the uninsured to offset some of the cost associated with a new program without universal coverage, according to the report, "Do Individual Mandates Matter?"

Part D Costs Drop

The projected cost of providing Medicare beneficiaries with a prescription drug benefit through private health plans has dropped again, according to the Centers for Medicare and Medicaid Services. The CMS said in its fiscal year 2009 budget documents that the overall projected cost of the Part D drug benefit will be $117 billion lower over the next 10 years than it had estimated last summer. The difference between the two projected costs results from the slowing of drug cost trends, lower estimates of plan spending, and higher expected rebates from drug manufacturers, the CMS said. Compared with original projections, the anticipated net Medicare cost of the drug benefit will be $243.7 billion lower over the 10 years ending in 2013.

Programs Cut Smoking Rates

State tobacco control programs are effective at cutting adult smoking rates, according to a study by researchers at the Centers for Disease Control and Prevention and RTI International. The researchers were able to quantify the link between comprehensive tobacco control programs and a decrease in adult smoking, observing a decline in prevalence from more than 29% in 1985 to less than 19% in 2003. Among individual states, declines in adult smoking prevalence were directly related to increases in state per-person investments in tobacco control programs, the researchers wrote. Such programs use educational, clinical, regulatory, economic, and social strategies to establish smoke-free policies and social norms, to help tobacco users to quit, and to prevent people from starting to smoke. The study was published in the February issue of American Journal of Public Health.

—Mary Ellen Schneider

Clinical Trials in Your Office: Payoffs and Pitfalls

BY CAROLYN SACHS
Contributing Writer

MAUI, HAWAII — Clinical trial participation can be a moneymaker for a rheumatology practice with some realistic planning and savvy negotiations, according to Dr. Roy Fleischmann and Dr. Alvin Well.

"If you're looking to make a profit, you've got to get a profit," said Dr. Fleischmann. "If I'm getting paid double what I'd get paid for seeing the patient, I have a feeling I'm OK." That provides a cushion to cover the unexpected, said Dr. Fleischmann of the University of Texas Southwestern Medical Center at Dallas.

Dr. Fleischmann explained, "You've got to figure out what your real charges are," and that includes allocating a portion of overhead to cover the phone and utility costs incurred because of the project. He said he calculates the average amount of overhead attributable to a patient visit and incorporates that in his cost estimate.

"You do have to think about your time," as well, in determining the costs of doing a trial, Dr. Fleischmann added. "You have to go to the investigative meeting—it costs you a day. You have to do the site opening—that costs you an hour. You have to fill out the case report form. You have to sign all those lab reports when they come in."

Once you know your real costs, he recommends negotiating a minimum of 30% profit, which can act as a cushion to protect against unforeseen expenses. "I can guess, in looking at the protocol, what's going to happen if it goes perfectly well," Dr. Fleischmann said. But things do not usually go perfectly well with resulting amendments to the protocol and deadline extensions, which associated increased expenses.

The key is to have someone other than the rheumatologist negotiate the contract with the company running the research. Dr. Fleischmann has an accountant do it. He or she must be someone you trust "to have the wherewithal to say 'This is what we really need.'" He added, "You're not getting rich on this, but it's a fair value, and they need to understand that."

Dr. Wells noted that costs and the bottom line cannot be ignored in the decision of whether to participate in a clinical trial. In estimating what he needs to be paid for a study, Dr. Wells, director of the Rheumatology and Immunotherapy Center in Oak Creek, Wisc., explained that he works with his billing staff to see what he is being paid for various patient visits, and then adjusts those numbers upward by 20%.

Dr. Wells, who is not part of a large practice, uses his coordinator to negotiate.

Dr. Wells and Dr. Fleischmann made their remarks at a symposium sponsored by Excellence in Rheumatology Education.

Beyond planning for a profit, physicians should pick their research projects carefully. Dr. Fleischmann noted that it's important to pick studies for which you have the patients. Be realistic about how many patients you can deliver, he added. His own large group practice is participating in two studies involving patients who have not responded to anti–tumor necrosis factor agents. He has committed to providing "1 or 2 patients; we're not going to do 12 of them," Dr. Fleischmann said.

Although physicians always have the option of advertising for patients to meet recruitment goals, Dr. Fleischman advised against this. Work with patients from your own practice, he urged.

Dr. Wells noted that convincing your patients to be in a trial can be tough. He found it difficult to enroll patients in the current trial of celecoxib (Celebrex). Bad publicity about COX-2 inhibitors and an increased risk for heart attacks and strokes gave patients pause. "Many times the patient will do it because of [their loyalty to] you," Dr. Wells noted.

Dr. Fleischmann urged audience members to "be your own center" when doing a study. Or join up with a group of physicians with whom you are an equal partner. Avoid going through contract research organizations when doing trials, he urged.

Contracts should include clauses to provide for renegotiation if the company makes a change during a trial. "Sometimes, companies will listen to it, and sometimes companies won't," he said. "But if you've got the study," and "you have patients in the study, you actually have a hook." For instance, your patients can be withdrawn.

Dr. Wells observed that there are bound to be differences in perspective between physicians working in large group practices and those working in solo practices; between someone who has done "tons of clinical trials in a huge research group and somebody who is just essentially starting."

Dr. Wells said he "might be willing to break even to get my foot in the door on a trial, or even make maybe just a little less of a profit." And, he said, "If you take the Celebrex trial as an example, you get to answer some interesting questions."

Dr. Fleischmann agreed that sometimes there are reasons to do a trial other than for money. "There are trials where we don't make money," he said, "because there's an answer that we want to get."

There's no right answer on how long to keep records after a trial. "A lot of companies will say 15 years," Dr. Fleischmann said. But the Food and Drug Administration can ask to see the data at any point. He stores his records from clinical trials at Iron Mountain, and "the storage fee is actually part of the budget."

He referred to a case from his own practice, in which the FDA performed an audit on a study 18 years after its completion. Since he still had the data, Dr. Fleischmann felt secure in asking what would have happened if he had not had the data. "We could send you to jail," he was told.

Dr. Fleischmann disclosed the following relationships with Abbott Laboratories, Amgen Inc., Centocor Inc., Genentech Inc., and Wyeth: speakers bureau, consultant/adviser, and research grants. He also is on the speakers bureau for Hoffmann-La Roche Inc.

Dr. Wells disclosed that he is a consultant/adviser for Abbott, Amgen, Bristol-Myers Squibb Co., Centocor, Genentech, and TAP Pharmaceutical Products Inc. ■