Merck Reaches Fraud Settlements
Pharmaceutical company Merck & Co. has agreed to pay about $690 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 processes 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 disguise 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 included those discounts in its report to Medicaid. Under the terms of the two settlements, Merck has agreed to pay more than $160 million to the federal government and more than $290 million to 49 states and the District of Columbia. The company also has entered into a 3-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 2001 and an article by another author that was published a year earlier. An internal ad hoc committee at Harvard is conducting a preliminary investigation, according to a source familiar with the matter. The committee is expected to report to the Harvard dean. Dr. Simon’s article in the Journal of Rheumatology was originally published in 2001 and was reprinted in 2002, according to an article published in the Journal of Rheumatology. Dr. Simon’s article in January, saying that it "inherited 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 concludes. 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?”

Port D Costs Drop
The projected costs 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 its fiscal year 2009 estimates 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 $127 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 and maintain free policy and social norms, to help tobacco users to quit, and to prevent people from starting to smoke. The study was published in the Journal of the American Journal of Public Health.

Polio & Practice
Dr. Wells and Dr. Fleischmann made their remarks at a symposium sponsored by the Rheumatology and Immunotherapy Center in Oak Mountain, and “the storage fee is actually a new program without universal coverage,” according to the report, “Do Individual Mandates Matter?”

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—Mary Ellen Schneider

Clinical Trials in Your Office: Payoffs and Pitfalls
BY CAROLYN SACHS Contributing Writer

MAUI, HAWAII — Clinical trial participa- tion can be a moneymaker for a rheuma- tology practice with some realistic planning and sound decision making, according to Dr. Roy Fleischmann and Dr. Alvin Well. “If you’re looking to make a profit, you’ve got to get paid,” said Dr. Fleischmann. “If you’re getting paid what I’d get 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, and 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. Don’t count your real costs; rec- ommends 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 amend- ments to the protocol and deadline exten- sions, which associated increased costs. 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. Or 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 making much money. If you’re not making money, there are trials where you 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 compa- nies 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 a new program without universal coverage.” He referred to a case from his own practice, in which the FDA performed an audit on a study 18 years after its comple- tion. Since he still had the data, Dr. Fleischmann felt secure in asking what would happen 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, Agen Inc., Centocor Inc., Genentech Inc., and Wyeth: consultant/adviser, and research grants. He also is on the speakers bureau for Hoffmann-La Roche Inc. Dr. Wells disclosed that he is a consul- tant/adviser for Abbott, Agen, Bristol- Myers Squibb Co., Centocor, Genentech, and TAP Pharmaceutical Products Inc.