Industry Is Slow to Post Info Onto Online Trial Registries

BY CARL SHERMAN
Contributing Writer

NEW YORK — When questions were raised about possible concealment of clinical trial data, two pharmaceutical companies agreed last year to set up Web sites where such data would be posted.

It appeared at that time that others in the industry would follow suit, "but as it turns out, very little has happened," Norman Sussman, M.D., said at a meeting on psychopharmacology sponsored by New York University.

An Internet search performed at the beginning of March, followed by inquiries to the companies themselves, found that information was for the most part incomplete, difficult to use, or entirely absent.

"This says something about the goodwill of the companies," said Dr. Sussman, professor of psychiatry at the university.

In June 2004, New York State Attorney General Eliot Spitzer filed suit against GlaxoSmithKline Inc., charging that the company's selective release of trial data on the use of paroxetine (Paxil) in children constituted consumer fraud. As part of a settlement of the lawsuit at the end of August, the company agreed to post clinical trial results for all GSK drugs on its Web site.

An inquiry by the attorney general's office into data relating to off-label use of drugs manufactured by Forest Laboratories Inc. led to a similar agreement with that company.

Dr. Sussman's Internet investigation found that one pharmaceutical company has done what was promised, and it was neither of those originally involved: Eli Lilly. Its Web site (www.lillytrials.com) supplies clinical trial data on all its psychotropic drugs, broken down into "completed" and "initiated" trials.

For completed trials, the site supplies PDF files of basic information—"not everything you want to know, but a sense of how the study was designed, the method, and outcomes," he said. For the most part, it is raw data: "If you were expecting something simple, it's not here. You have to have an understanding of research methodology to evaluate these," he said.

The "initiated trials" section lists phase II, III, and IV studies that were begun since July 2004, most of which are still recruiting patients. "The idea is that once you do this, you can no longer hide the results of the study," Dr. Sussman said.

The speed with which Lilly put such complete data on its Web site "tells you that any company that wanted to could do it tomorrow. They all have internal documents that summarize studies," he said.

The GlaxoSmithKline registry (http://ctr.gsk.co.uk/welcome.asp) is "a little more restricted," he said. The site only posts results of studies done after Glaxo and SmithKline merged—which excludes most of those involving Paxil and children, Dr. Sussman said.

The GSK presentation includes less narrative discussion of study findings than the Lilly site. "It's mostly numbers. … You have to look into the statistics and form your own conclusion. It's not intended for the average practitioner," he said.

The other company that agreed to post data, Forest Laboratories, has set up a registry (www.forestclinicaltrials.com), but while completed trials are listed, there are as yet no data from ongoing studies. "If you call Forest, they send you from one department to another," Dr. Sussman said.

An industry association, the Pharmaceutical Research and Manufacturers of America, maintains a Web site of its own (www.clinicalstudyresults.org), but clinical trial data, supplied by pharmaceutical companies, are fragmentary.

A government site (www.clinicaltrials.gov) lists some ongoing trials but no results, he said. ■

COX-2 Uproar Will Alter Drug Trial Landscape

BY PATRICE WENDLING
Chicago Bureau

CHICAGO — Recent events surrounding selective cyclooxygenase-2 inhibitors will have far-reaching implications for future drug trials, Gary S. Hoffman, M.D., said at a symposium sponsored by the American College of Rheumatology.

Drugs that are under investigation for chronic diseases such as arthritis will require longer trials and follow-up than they required in the past, in part because of their likely long-term use among the patients who need them.

"We can no longer endorse or not endorse these drugs based upon short-term studies, some of which have been as short as 6 weeks or 12 weeks and usually, certainly, less than a year," said Dr. Hoffman, a member of the Food and Drug Administration's arthritis advisory committee.

NSAID trials now will include cardiovascular and thrombotic events among the adverse events they monitor.

But this raises a number of questions, including whether there are other adverse events such as cancer, autoimmune effects, or neurocognitive dysfunction that are beyond our current knowledge, said Dr. Hoffman, professor of medicine and chair of rheumatic and immunologic diseases at the Cleveland Clinic Foundation.

"Are we looking at this with blinders on because of recent events, or are there other important AEs that we should also be casting a broader net for?" Dr. Hoffman asked.

"Perhaps there are increases in malignancies if you follow patients who take drug x, y, or z long enough," he continued. "How long should those patients be studied in the context of randomized trials?"

Although answers to these questions are lacking, it's obvious that closer premarket drug scrutiny will come at a greater cost, he said.

A number of forces, such as the market, consumers, and the medical community, will need to determine how cost-effectiveness will be measured, and they also will need to determine who will ultimately pay.

New strategies must be developed to make new drug studies cost effective, he said.

Ironically, it was adverse events associated with nonselective NSAIDs that drove the COX-2 market in the first place, he noted. Research suggests that as much as one-third of every dollar spent on NSAIDs goes to managing adverse events.

Aging Baby Boomers May Overwhelm Health Care System

BY TIMOTHY F. KIRN
Sacramento Bureau

SAN FRANCISCO — The baby boomers might do more than bankrupt Medicare—they could break the entire medical system, members of a panel said at the annual meeting of the American College of Physicians.

With 76 million baby boomers starting to approach age 65, the elderly population will double by 2040, potentially bankrupting the Medicare trust fund by 2020 and Social Security by 2042.

But they may also overwhelm the health care system with chronic conditions. The medical system is set up to assume that patients with a chronic condition have only one, but most of the elderly have more than one chronic condition, said Robert A. Berenson, M.D., a senior fellow in health policy at the Urban Institute in Washington.

Of persons older than 65 years, 84% have at least one chronic condition, 62% have two or more, and 20% have four or more. People with chronic conditions see more physicians more often, which greatly increases the potential for inefficiency and confusion in their care, Dr. Berenson said.

The average person with no chronic conditions sees 1.3 physicians a year and has two medical visits. In contrast, the average person with five chronic conditions sees almost 14 physicians (including radiologists and anesthesiologists) per year and has a total of 37 visits, Dr. Berenson said.

The growth of the elderly population is a problem compounded by the obesity epidemic and the sedentary lifestyle of many Americans.

A Harris survey asking persons with a chronic condition about their care in the preceding 12 months found 54% had been told they were at risk for a harmful drug interaction because of what they were taking, 54% had duplicate tests or procedures, 52% had received different diagnoses from different physicians, and 45% had received contradictory medical information.

Fundamental problems in the medical system must be addressed to manage the influx of baby boomers with multiple needs. These problems include the shortage of geriatricians; training oriented toward hospital care, rather than prevention and management of chronic conditions; and even the reliance on guidelines for care. Guidelines are generally written for one condition and tend to ignore comorbidities, Dr. Berenson said.

The growth of the elderly population is a problem compounded by the obesity epidemic and the sedentary lifestyle of many Americans, said David K. McCulloch, M.D., of GroupHealth Cooperative, Seattle.

To respond to this "triple whammy" crisis in health care, the medical system will have to reinvent itself to embrace more prevention and coordinated care, including adopting pay-for-performance strategies that offer providers incentives for keeping patients well, Dr. McCulloch said.

There is evidence that a chronic-illness model of care delivery that coordinates care and provides wellness services can reduce costs and hospitalizations and benefit patients. Many of the patients who can benefit from this approach are diabetic patients, he said.

At Dr. McCulloch's HMO, a 3-year pilot program for 18,000 diabetic patients decreased hospitalizations by 25% and overall costs by 11%, although pharmacy costs increased 16%. The program was credited with improving the patient group's average hemoglobin A_{1c} levels significantly.

An unpublished Rand study found evidence that this type of program can be implemented in private physicians' practices, and that when one practice in an area adopts such an approach, other practices in the area begin to copy it, he said.

Dr. Berenson commented that the relative value resource-based system of payment might have to be overhauled so that there is more incentive for good chronic-disease management. ■