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Drug Testing Doesn't Always Tell the Whole Story

By **BARRY MEIER**

Last December, medical school researchers came to a professional meeting in Puerto Rico with a sense of urgency. Federal drug regulators were reviewing unpublished data from their studies on the use of antidepressants in children and adolescents to see if the drugs increased suicide risks.

The group included many of the researchers whose published positive findings had helped persuade doctors to prescribe antidepressants like Paxil, Zoloft and Prozac to young patients. Now, faced with growing safety questions, the researchers had been trying for months to gather all the test data about those and similar drugs to see if they had missed a pattern not apparent in any single trial.

But they could get only pieces of that information.

Some drug companies refused to turn over data to the group, even though these researchers had helped come up with it, the researchers recalled. In other cases, they could not freely share their own data with colleagues who had not worked on a test. The reason, they said, was that medical schools, in agreeing to run the tests, had signed agreements with the drug makers that kept the data confidential.

Academic institutions and researchers are widely viewed as the impartial, independent heart of the system this country uses to test drugs and medical devices. But that independence often comes with strings attached, sometimes making academic institutions and their researchers obstacles to the exchange and discussion of test results.

The upshot is that doctors may not get all the information they need. In the wake of revelations about unpublished test data showing the potential risks of pediatric antidepressants, some doctors have stopped prescribing them. And even doctors who continue to prescribe the drugs question why they were kept in the dark.

"I think it would have been more helpful for everyone to have known what was going on at the time that it was happening," Dr. Robert Feder, a psychiatrist in Manchester, N.H., said.

In recent months, the outrage over the withheld antidepressant data has led calls for change and promises of some. Drug companies, faced with widespread criticism about their handling of test information, have promised to release more of it. Legislation has been introduced in Congress that would require all makers of drugs and medical devices to list clinical trials and their results in a public database.

Critics say, however, that academic institutions and their researchers need to examine their own practices because they share part of the blame.

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