

Pharma data play larger role in anti-doping effort

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Some of the world's biggest drugmakers are playing a larger role in antidoping efforts at this year's Winter Olympics: They're providing information on drugs that once would have been considered proprietary trade secrets.

GlaxoSmithKline, Amgen and Roche are among the drugmakers that have begun sharing "confidential research and data" with anti-doping officials about experimental drugs they are developing, as part of an effort to stay one step ahead of <u>drug</u> cheats.

The increasing cooperation comes as doping athletes move away from easy-to-spot drugs like anabolic steroids to more sophisticated, obscure performance-boosting substances—many which were first formulated in pharmaceutical research labs.

"If you want to predict the future of doping it's essential that you have collaborations with the pharmas," says Olivier Rabin, science director of the World Anti-Doping Authority, which oversees the testing standards for the Olympics and other international competitions.

Building on its agreements with individual companies, in 2011 WADA signed a "declaration on cooperation" with the Biotech Industry Organization, which represents most of the world's biotech drugmakers. Under the agreement, companies voluntarily pass along early information about drugs in their pipelines that could be used to boost endurance, build muscle or aid recovery.



Some of the drugs WADA is looking for never even made it out of the laboratory. Drugs like GW501516, an experimental compound from GlaxoSmithKline, which was briefly hailed as "exercise in a pill" after studies in mice showed it lowered fat, boosted muscle and improved exercise endurance by nearly 80 percent.

Glaxo initially hoped to develop the drug to boost "good cholesterol," but the company pulled the plug in 2009 after animal studies showed links to tumors in the liver, bladder, stomach and other organs.

Yet last year WADA-affiliated laboratories caught five professional cyclists using the substance, despite a rare warning from the agency in March about its toxic side effects. The drug continues to be promoted on online forums and websites that traffic in doping products, many which are mixed by overseas laboratories in places like Thailand and Mexico.

"A lot of what dopers are looking for is under the radar. They're looking for drugs that were terminated and that enforcement agencies don't know about yet," says Mark Luttman, who coordinates Glaxo's anti-doping program with WADA.

Dr. Don Catlin, a pioneer of drug testing, says anti-doping organizations are often financially outgunned by the very athletes they are supposed to oversee.

He points out that WADA's annual budget of roughly \$28 million is less than the \$29 million-a-year salary of baseball superstar Alex Rodriguez, who was suspended in January for reportedly using a cocktail of banned substances, including testosterone, peptides and growth hormone. The U.S. Anti-Doping Agency reported that Rodriguez's regimen also included dozens of blood tests to make sure the drugs were metabolizing at undetectable levels.



"We need the help and assistance of the legitimate pharmaceutical industry," says Catlin, former head of the UCLA Olympic Analytical Laboratory. "We have to have access to their clinical trials and drug standards before we can develop at a test."

Catlin says he learned the importance of such cooperation at the 2002 Winter Olympics in Salt Lake City, when he discovered a new oxygen-boosting drug in urine samples from three skiers.

The drug, known as Aranesp, had been launched just a few months earlier by biotech giant Amgen to treat anemia, a blood disorder that affects patients with kidney disease and cancer. By increasing levels of oxygen-carrying red blood cells, Aranesp can help sickly patients perform simple tasks, like walk up a flight of stairs or lift themselves out of bed. But in athletes it can provide a super boost in energy and endurance, especially in long-distance events.

"It was the farthest thing from my mind that this might be an agent with doping potential, we were thinking about treating seriously ill patients" says Steve Elliott, the retired Amgen scientist who developed Aranesp. "But obviously that changes when you find out that your drug was doped with."

Aranesp was a follow-up to Amgen's first blockbuster, Epogen, another blood booster that was at the center of a doping scandal at the 1998 Tour de France. But athletes apparently did not expect officials to be testing for Amgen's next-generation drug at the 2002 games.

With the cooperation Elliott, WADA officials secretly developed a urine test for Aranesp in the weeks leading up to the games. Ultimately one skier from Spain and two skiers from Russia were disqualified from the competition based on their test results.



In 2008, Swiss drugmaker Roche introduced its own oxygen-boosting drug called Mircera. Again, WADA officials worked with the company to develop a test for the drug, catching four athletes at the Summer Olympics in Beijing.

The industry's involvement with anti-doping efforts reached a new level in 2012 as GlaxoSmithKline provided a \$30-million laboratory for testing officials at the London Summer Olympics. It was the first time any private sponsor had funded such a project at the Olympics.

Testing experts suggest the assistance is overdue.

"Fifteen years ago the drug companies would never think about helping a lab—today they do," says Catlin.

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