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C-Path forms drug-testing pact

Effort will speed development, FDA approval

By Joseph Barrios

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The Tucson-based Critical Path Institute on Thursday announced an unprecedented agreement with eight major pharmaceutical companies to share drug-testing methods in an effort to improve drug safety.

The agreement was announced in Washington, D.C., by the FDA along with a long-awaited list of research initiatives aimed at speeding drug development and approvals.

The agreement gives Tucson a chance to be seen as a place for innovation and medical product development, said Dr. Raymond Woosley, C-Path's president and CEO and former chief of health sciences at the University of Arizona.

"I've never seen the federal government and the industry come together like this. It's always been the regulators and the regulated," he said. "If you want to work in the drug-development industry, you should go to Philadelphia or San Francisco. If you want to see how drug development should be in the future, that discussion and that planning is taking place in Tucson."

Hear about C-Path
What: A town hall meeting with representatives of C-Path and Tucson Regional Economic Opportunities Inc. Representatives will talk about economic development in Tucson.

When: Wednesday, 7-8:30 p.m.

Where: Eastside City Hall, 7575 E. Speedway

For more information, call 791-4687.

C-Path was created in 2004 as a partnership of the UA, the U.S. Food and Drug Administration and the technology development firm SRI International Inc. The FDA is trying to modernize the drug development process by 2010 in an effort to get new medicines to patients in faster, safer and less expensive ways.

With more than nine out of 10 experimental drugs failing when tested in humans, the number of innovative drugs reaching the market hit a 20-year low in 2004 — even as pharmaceutical research and development spending has increased, according to the FDA.

C-Path will now work with the participating pharmaceutical companies to determine which of their proprietary lab tests should be recommended by the FDA to screen drugs and identify potential side effects before drugs are tested in humans.

Participating companies include Bristol-Myers Squibb Co., GlaxoSmithKline, Johnson & Johnson Pharmaceutical Research & Development, Merck and Co. Inc., Novartis Pharmaceutical Corp., Pfizer Inc., Roche Palo Alto and Schering Plough Research Institute.

Private and public partnerships like C-Path's work with the pharmaceutical companies is vital to getting drugs approved in a safer, more timely manner, said Mike Leavitt, secretary of health and human services.

Companies will share details about their testing methods and then agree to test each other's methods to determine if the results can be reproduced. Outside experts may also conduct some testing. Participants will conduct tests while looking for "biomarkers" — standard biological responses that can be used to determine how a patient would respond to a drug.

C-Path employees will compare test results and submit a summary to the FDA. The agency will then use reliable testing methods to form guidelines about which safety tests should be used in drug development.

The agreement between C-Path and the drug companies is just one on a list of 76 initial research priorities intended to modernize drug development. The list amounts to an invitation to private companies and

academics to pursue research that will further the FDA's push to reform.

"We really need to incorporate more modern science into the process," Janet Woodcock, deputy commissioner of operations for the FDA, said at a press conference in Washington. "We have this tremendous science in the lab discovering new innovations that would help people, but the process for development is actually what we did 100 years ago."

In January, the FDA issued suggestions on how researchers can more efficiently evaluate the promise of new laboratory discoveries and separate out those drug candidates most likely to succeed from those doomed to fail.

The Critical Path Institute stood to receive its first funding last month, when the FDA requested $6 million for fiscal 2007.

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● Includes information from The Associated Press and Bloomberg News. ● Contact reporter Joseph Barrios at 573-4237 or jbarrios@azstarnet.com.

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