Tucson non-profit seeks to get cures to patients faster

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A little-noticed 2004 report from the Food and Drug Administration contained a bombshell. Although spending on research and development had been rising for the previous decade, applications for new drugs and medical products had been falling.

In other words, the United States was facing a severe productivity crisis, if not outright stagnation, in the pharmaceutical and biotech industries. The success rate in getting new drugs to market was 11 percent, and only 5 percent for cancer drugs. It meant delays for potentially lifesaving drugs and impossibly high prices.

Developing one drug had taken $231 million and seven years in 1991, but that had become $802 million and 12 years by 2003. By 2010, the report warned, the cost would rise to $2 billion.

In calling for a new "critical path" to develop drugs and medical devices, the FDA opened the door to an idea that Dr. Raymond Woosley had been nursing. Then vice president of health sciences at the University of Arizona, Woosley led a community effort in Tucson to establish a research laboratory that would speed drugs and devices to market.

Now 2 years old, the Critical Path Institute, or C-Path, is emerging as another Arizona biomedical asset, along with the Translational Genomics Research Institute, the Biodesign Institute at ASU and UA's Bio5.

Led by Woosley and funded with $10 million from foundations, private donors in Tucson and a state grant, C-Path is an independent, non-profit agency. It takes no money from drug companies.

That independence is essential, Woosley said, in establishing C-Path as "a trusted third party" where regulators, companies and academic researchers can work together to set standards and find more efficient ways to get cures to patients.

Woosley praised the "blank slate" of Arizona's biomedical efforts as a place where the organization could flourish.

"Arizona has a plan that few other states have. There's nothing like C-Path in the country. I had wanted to do this when I was at Georgetown (University), but it wouldn't have flown."

C-Path received attention for its part in speeding the development of a drug to treat valley fever. In September, it won a $675,000 grant from the FDA to focus on drugs to treat cardiovascular disease. The grant could grow to $2 million.

Big pharmaceutical companies have slowly welcomed C-Path and are even beginning to sit down with competitors to find better paths for development. One spur, no doubt, was the fatal experience with Vioxx.

Another is that the drug industry's innovation has declined, especially relative to other sectors.

A study this year by the Congressional Budget Office showed that drug research and development productivity was poorer than that in the computer or communications industries.

One collaboration is a consortium to predict drug toxicity. In the past, individual companies' methods haven't been independently validated, so the FDA refused to accept them. Now the competitors will share practices, and C-Path will analyze the data and submit them to the FDA. The result could be a faster path to drug safety.

Woosley said the plummeting productivity of the biomedical sector is not the inevitable consequence of more complex science.

He points to the development of AIDS drugs in little more than three years, in response to political pressure.

"It shows we can develop drugs quickly and without shortcuts."