NCTR DRUG RESEARCH COULD SAVE CONSUMERS MILLIONS

By AMP Staff

Nestled discreetly in a densely wooded area of Jefferson County is the U.S. Food and Drug Administration's only research lab located outside of the Washington, D.C., metropolitan footprint.

The National Center for Toxicological Research (NCTR) was established in 1971 with a vision to "conduct scientific research to provide reliable data for FDA's decision-making and develop innovative tools and approaches that support FDA's public health mission." This makes NCTR part of an entity that regulates 25 cents of every $1 in consumer spending.

The FDA serves as an essential oversight. NCTR is here to protect consumers, providing an essential safeguard to assuring that products ranging from lifesaving drug treatments to farm-raised produce are safe for public use. Animal testing has long been a method that NCTR researchers have used to determine product efficacy and safety. However, promising new techniques are leading NCTR into an exciting alternative direction for testing.

Dr. Laura Schnackenberg is an Arkansas Research Alliance (ARA) Academy Member and NCTR's director of the Division of Systems Biology. She leads a multidisciplinary team exploring a wide range of innovative research. One area of research is focused on reducing the use of animal testing in nonclinical studies. After all, many drugs are withdrawn post market simply because animal physiology is not a perfect predictor of how a drug will affect humans.

This discrepancy between man and animal can lead to a significant cost. In the United States, about 45 percent of the population takes at least one prescription medication. On average, about 4,500 drugs and devices are pulled from U.S. shelves each year. Of course, animal testing is not to blame for all drug recalls, but the price tag of drug recalls can cost companies (and eventually customers) hundreds of millions of dollars. Any effort to mitigate testing discrepancies would lead to significant consumer savings.

"Traditionally in the development of a new drug, there has been a reliance on animal testing," Schnackenberg explained. "Animals currently serve as surrogates for humans, but no animal can completely mimic a human. What we're trying to do is develop in vitro models that can theoretically better mimic the human situation."

The answer may lie in two-dimensional models derived from humans, which can capture accurate genetic components. The 2D model works well as a quick screen, but a more complex version of this technology is called a tissue chip (or "organ on a chip") — engineered microsystems that represent units of human organs (such as the lung, liver and heart) modeling both structure and function. A tissue chip is more physiologically relevant, as it includes four major cell types that account for about 95 percent of the cell.

Dr. Laura Schnackenberg with ARA's Jerry Adams, NCTR Director Tucker Patterson and former Gov. Asa Hutchinson.

Tissue chip technology will likely make drug development, especially toxicology and efficacy screening, more reliable. It may also eliminate the need for animal testing — eventually.

"The technology is very promising, but for the time being cannot fully replace animal testing," Schnackenberg said. "For now, animal testing must still be used to validate the results garnered from in vitro models."

Schnackenberg says that the NCTR Division of Systems Biology is also working on computational models, which will also help in speeding up the drug development process. Currently in NAMS research, it that would take almost 80 different organs on a chip to recapitulate the holistic system of what can be done in one mouse model.

In the meantime, Schnackenberg is hoping that the work conducted by the NCTR Division of Systems Biology, currently staffed by 15 research investigators, receives its well-deserved notice.

"The Systems Biology Division is something I'm very passionate about," she said. "We have some incredible investigators who are doing some amazing work. I'd love to see them receive the recognition they deserve."

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