Rep. Fred Upton brings 21st Century Cures talks on fostering medical innovation to Kalamazoo

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KALAMAZOO, MI — Pharmaceutical companies, medical device makers and other medical innovators need the intervention of the federal government to invest in research, promote new pathways to development, provide stable funding and lead the way to new collaborations.

That's what a group of 10 medical leaders told **U.S. Rep. Fred Upton** at a roundtable discussion at Western Michigan University Homer Stryker M.D. School of Medicine on Tuesday. The discussion was one of about two dozen that Upton has held across the country as part of his 21st Century Cures initiative to promote conversation about how to accelerate the pace at which medical treatments and devices are discovered, developed and delivered to the American public.

"If you think research is expensive, you should try disease," said Dr. Francis Collins, director of the National Institutes of Health. "We could actually not have a lot of disease if we could unleash the research enterprises that are so ready" to tackle key issues.

Other members of the roundtable were: Kirsten Axelsen, vice president, worldwide policy, Pfizer Inc.; Stephen Benoit, CEO, **Metabolic Solutions Development Company**; Douglas Boothe, executive vice president and general manager **Perrigo Pharmaceuticals**; U.S. Rep. Dr. Michael Burgess,of Texas, vice chairman of the Energy and Commerce Health Subcommittee; Dr. Hal Jenson, founding dean of the **WMU School of Medicine**; Dr. Peter Jones, director and chief scientific officer of the Van Andel Institute; **Kevin Lobo**, chairman and CEO of Stryker Corporation; Tony Mandarino, director of the Alex Mandarino Foundation, Dr. Joseph Mirro, president, CEO, chief medical officer of the **West Michigan Cancer Center**; and Dr. Jeffrey Shuren, director, Center for Devices and Radiological Health, Food and Drug Administration.

Upton said he hopes to have draft legislation based on the 21st Century discussions ready by January 2015.

Not surprisingly, one of the main complaints for those at the roundtable was the need for more funding and more stable funding for medical research.

Collins said because of reductions in funding the number of grants the NIH can fund has been reduced from 1 in 3 proposals to 1 in 6.

"We are leaving some really good science on the table because we can't support it," Collins said.

He said he participates in discussions with the leaders of medical research at countries around the world. He'll hear how China is increasing funding by 22 percent and India is hoping to invest 11 percent more. He, however, tells them that they're hoping they won't lose more than 5 percent of funding.

Jones of the Van Andel Institute said he is working with one of the best graduate students he's ever met, but this student had applied for jobs at six major laboratories and received no job offers. The reason? The unpredictable nature of NIH funding, Jones said.

"No one will offer her a job, because no one knows when they'll get the next grant," Jones said. "How do you expect young people to go into scientific research, when there's no funding?"

Collins and Shuren urged Upton to investigate the possibility of multi-year budgeting for their agencies, which would allow them more flexibility and to better plan their spending.

In the meantime, Shuren and Mirro, with the West Michigan Cancer Center, said there is a tremendous amount of data about patients, medicines and devices that cannot be accessed and analyzed. When medical electronic records first came online, Mirro said, there was much talk about how data would be shared. That hasn't happened, because multiple systems are being used and the systems cannot communicate with each other.

Medical communities and the government need to find a way to protect patient privacy but convince the public of the value of being able to share and analyze their data for research purposes. For example, electronic medical records could somehow be tied into a database of medical trials and alert patients to trials they may qualify for — or genomic sequencing information in records could be shared to help identify gene variants that impact certain diseases.

Other points from the discussion:

• "Fast tracking" devices is not enough, Lobo said. The government needs to ensure that patients are covered to try new technologies and therapies.

•Boothe, from Perrigo, argued there needs to be more flexibility in terms of generics. Taking the cost out of "mature" therapies would leave more funds to develop innovative therapies.

• Lobo agreed with Upton that the tax on medical devices discouraged innovation because it was a tax on sales, which was especially difficult for small startups that lack capital.

• Medical research needs to be better explained to patients, and enrollment in studies should be made easier, Jenson said.

• More needs to be done to educate the public on the role and value of medical research, Jenson said. He suggested that perhaps participation in medical research should be an "opt out" system rather than an "opt in" system.

• Mirro and Collins said more must be done to develop the country's stable of physician-scientists, doctors who spend at least half of their time doing research. Collins suggested combined M.D.-Ph.D programs help address that issue but those doctors should have some of their educational costs forgiven, so they won't be tempted to abandon their research to pursue more lucrative clinical practices.

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