



COMMITTEE ON ENERGY AND COMMERCE

Chairman Fred Upton
114th Congress

The 21st Century Cures Act (HR 6) Passed on the House floor 344-77

Help and Hope for Patients Through Biomedical Innovation

The pace of scientific advancement over the past two decades, including the mapping of the human genome, has been impressive, giving us a myriad of genetic clues about the underpinnings of disease. Translating these discoveries into new treatments for patients, however, has proven to be difficult. HR 6 accelerates the discovery, development and delivery of life saving and life improving therapies, and transforms the quest for faster cures by:

- **Removing barriers to increased research collaboration.**

Experts agree that more collaboration and access to data will produce faster cures and therapies. While protecting patient privacy, HR 6 breaks down existing barriers to sharing and analyzing the growing amount of health data generated in research and clinical settings.

- **Incorporating the patient perspective into the drug development and regulatory review process.**

HR 6 strengthens the FDA's ability to take the direct experience of patients with particular diseases and conditions, and the effect of their current therapies and use that data to modify and improve potential treatments.

- **Measuring success and identifying diseases earlier through personalized medicine.**

HR 6 provides guidance for the broader, more collaborative development, understanding, and utilization of drug development tools such as biomarkers, which can be used for earlier assessment of how a particular therapy is working and on whom. HR 6 would advance personalized medicine, making sure patients can be treated based on their unique characteristics at the appropriate time.

- **Modernizing clinical trials.**

Personalized medicine allows researchers to design more targeted clinical trials that can produce results faster and cheaper. HR 6 will allow greater use of patient generated registries that speed the recruitment of participants. It will also allow researchers to screen patients in advance to determine if their genetic predisposition makes them better candidates for targeted therapies. The legislation also clears the way to use new and creative adaptive trial designs and deploy the most modern statistical and data tools, while significantly reducing existing, duplicative or unnecessary paperwork requirements.

- **Removing regulatory uncertainty for the development of new medical apps.**

Regulatory uncertainty has slowed the development of medical apps that generate real time patient data. These apps hold tremendous promise for improving healthcare—saving time, money, and lives. HR 6 provides more certainty for app developers, clarifying their regulatory path moving forward and will speed the creation and deployment of these innovative health tools.

- **Providing new incentives for the development of drugs for rare diseases.**

Small populations and a lengthy development process often make the discovery of treatments for rare diseases and conditions challenging. HR 6 creates new economic incentives for the development of therapies for serious and life threatening conditions, including rare diseases. New incentives will translate to more, faster cures.

- **Helping the entire biomedical ecosystem coordinate more efficiently to find faster cures.**

Finding new cures and therapies requires more than a discovery in a laboratory. HR 6 creates a new coordinating mechanism to remove the choke points that slow the connections between scientific discovery, drug and device development, and how these therapies are approved and made available to patients. HR 6 improves the entire biomedical ecosystem ensuring the innovation infrastructure works as quickly and efficiently as possible.

- **Investing in 21st Century science and next generation investigators.**

HR 6 creates the “Innovation Fund,” a dedicated and offset funding stream of \$2 billion per year for 5 years that will allow congressional appropriators to invest additional resources without impacting current budget caps. Since experts believe investments in younger scientists will speed the discovery of new cures, HR 6 also includes provisions to invest more resources in the next generation of scientists for the next generation of drugs.

- **HR 6 helps keep and create jobs here at home.**

HR 6 is not only a patients bill; it is a jobs bill. The United States has led the global medical device and biopharmaceutical industries for decades, helping us become the medical innovation capital of the world and causing China and others to try to take our innovation and jobs. Because of our leadership, U.S. medical device-related employment totals over 2 million jobs, and the U.S. biopharmaceutical industry is responsible for over 4 million U.S. jobs. NIH funding currently supports over 400,000 jobs at research institutions across the country, including jobs for young scientists. The policies in HR 6 will help us fight off foreign competitors so we can keep these jobs, and add more, here at home.



The 21st Century Cures Initiative

*Health Innovation on the Fast Track: Accelerating
New Treatments for Patients Who Need Them Now*



WHAT THEY'RE SAYING

Francis Collins: “What Fred’s done here is to put together, in a bipartisan way, an effort to identify what are some of those roadblocks and what can we do about them. And this is a remarkable, encouraging kind of development for all of us who are trying to speed up the process of getting to cures”

Andrew von Eschenbach, former FDA commissioner and National Cancer Institute director: Cures “Has the potential of being one of the most transformational pieces of legislation...”

Dr. Siddhartha Mukherjee, physician, scientist, and author of The Emperor of All Maladies: Cures “Has an extraordinary impact on the lives of physicians, scientists, and really patients, most importantly.”

Dr. von Eschenbach and Paul Howard, Director of the Manhattan Institute’s Center for Medical Progress: Cures, “advances many of the precision medicine strategies and initiatives that the scientific, medical, and patient communities (including the FDA) have been advocating for over the last decade. It has been met with nearly universal acclaim from all quarters and both sides of the political aisle.”

John Feehery, political pundit: “This legislation is getting good stuff done for the American people. And that’s good news for everybody.”

Seventy-five research, life sciences, and patient advocacy organizations including Harvard, MIT, Stanford, UPenn, and Vanderbilt: “The scientific breakthroughs that take place across this nation with funding from NIH have raised life expectancy and improved the quality of life for countless Americans. ... The blueprint for funding included in this bill has the potential to provide NIH with the resources needed to improve how we prevent and treat many of society’s most vexing diseases, including the thousands for which we currently do not have effective treatments.”

Sixty-seven cancer centers across the country: “Your bipartisan work over the last year to accelerate research and discovery has made an impression on the cancer community and the academic health community at large....We ask members of the House of Representatives to cosponsor the bill, and we request that House leadership move H.R. 6 to floor consideration as quickly as possible. Thanks to you, your staff, and the Committee for your unwavering commitment to improving the discovery, development, and delivery of cures. We look forward to continuing to work with you toward a future without cancer.”

James Pinkerton: “Yet hope springs eternal, even in DC. On Tuesday in 2123 RHOB, the hearing room of E & C, Upton announced that he is working toward a ‘21st century cures initiative,’ which he defined as ‘a collaborative, bipartisan effort that aims to accelerate the pace of cures and medical breakthroughs in the US.’ In so announcing and defining, Upton made a significant departure from the familiar battle-as-usual pattern of Congress.”

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**Congresswoman Debbie Dingell
D-Michigan (Twelfth District)**



Congresswoman Debbie Dingell was elected to represent Michigan's 12th District in the U.S. House of Representatives in November 2014. Before being elected to Congress, Dingell was the Chair of the Wayne State University Board of Governors, and for 30 years, served one of Michigan's largest employers, the General Motors (GM) Corporation, where she was President of the GM Foundation and a senior executive responsible for public affairs.

An active civic and community leader, Dingell is a recognized national advocate for women and children. She successfully fought to have women included in federally-funded health research, and advocated for greater awareness of issues directly related to women's health, including breast cancer and women's heart health. She is a founder and past chair of the National Women's Health Resource Center and the Children's Inn at the National Institutes of Health (NIH).

Dingell has also led a number of efforts and initiatives related to young people and education stemming from her role as a WSU Governor and co-chair of the Children's Leadership Council, a business-led advocacy group that promotes investment in early childhood education. She chaired the Michigan Infant Mortality Task Force, the Baby Your Baby public education campaign that reduced infant mortality rates in Michigan, and has served on the board of Michigan's Children, the only statewide independent voice working to ensure that public policies are made in the best interest of children from cradle to career.

Congresswoman Dingell resides in Dearborn with her husband, retired Congressman John D. Dingell of Michigan. She holds both a B.S.F.S. in Foreign Services and an M.S. in Liberal Studies from Georgetown University.

**Congressman Fred Upton
R-Michigan (Sixth District)**



Fred Upton: Getting the job done for Southwest Michigan families.

Congressman Fred Upton is proud to represent the common-sense values of Southwest Michigan's Sixth Congressional District. A diverse section of the state that stretches from the shores of Lake Michigan, and includes key industries that range from agriculture to auto parts manufacturing, to high-tech biomedical innovation centers. It includes all of Berrien, Cass, Kalamazoo, St. Joseph and Van Buren counties, and most of Allegan County.

Prior to his election to Congress, Fred worked for President Ronald Reagan in the Office of Management and Budget (OMB). While at OMB, he learned from President Reagan's example that it does not matter who gets the credit, as long as the job gets done. That has been Fred's approach since he was first elected to Congress in 1986 and continues today.

In 2010, Fred was selected by his House colleagues to serve as Chairman of the Committee on Energy and Commerce, which has jurisdiction over matters concerning energy, healthcare, the environment, telecommunications, commerce, manufacturing, and trade, as well as oversight and investigations. Bipartisan success has been a staple during Fred's tenure as chairman of the committee. During the 112th Congress, 88 Energy and Commerce bills passed the House, and 40 of them were signed into law. That success continued in the 113th Congress, with 91 E&C bills passed by the House and 51 signed into law.

Fred's top priorities are job creation, economic growth, and working to help all residents of Southwest Michigan live longer, better lives.

Fred has long pushed for a greater emphasis on biomedical research to improve the public health. In 2014, along with Rep. Diana DeGette, D-Colorado, Fred launched the **21st Century Cures** initiative. This multi-year effort aims to bring researchers, industry, and patients together to speed up the discovery, development, and delivery of life-saving cures. The pursuit of these 21st century cures also supports Southwest Michigan employers and jobs by ensuring the United States remains the world leader in medical innovation.

Fred was born on April 23, 1953 and holds a bachelor's degree in journalism from the University of Michigan. He and his wife Amey have two children.