

Opening Statement of the Honorable Joseph R. Pitts
Subcommittee on Health
Markup of 21st Century Cures and the Microbead-Free Waters Act
May 14, 2015

(As Prepared for Delivery)

Today, we are considering two bills: an Amendment in the Nature of a Substitute to the Committee Print for the 21st Century Cures Act – offered by Chairman Upton, and myself, along with Rep. DeGette, Ranking Members Pallone and Gene Green. And H.R. 1321, Microbead-Free Waters Act of 2015, sponsored by Chairman Upton and Ranking Member Pallone.

The 21st Century Cures Act represents the culmination of a concerted effort and hard work from a number of important individuals – perhaps the most critical and often least recognized is the Office of Legislative Counsel. Without their tireless efforts and commitment to answering our calls, and responding to our requests, this legislation would not be ready for today's proceedings. In addition, I would also like to thank the Congressional Budget Office for their help. They, too, are often underappreciated but no less committed in their efforts. Thank you.

I want to point to specific provisions in the Cures Act for which I am particularly proud of: first and foremost is the section on patient-focused drug development. Title II, Section 2001 requires FDA to establish a structured framework for the meaningful incorporation of patient experience data into the regulatory decision-making process, putting patients more directly in the center of finding treatments.

Title II, Section 2201 provides for priority review for breakthrough devices, which is another big step in the right direction and will undoubtedly help bring safe, innovative technologies to patients with life-threatening diseases more quickly.

Going forward, we must also find ways to improve CMS evaluation and coverage for these breakthroughs. I continue to hear from device companies that these coverage delays are significantly hindering investment in new medical innovations. We will solve many but not all issues in this Cures legislation, and recognize that our work is not finished. We look forward to continue our work in solving these remaining issues even after Cures is signed by the President.

21st Century Cures is about growing good biotechnology jobs here in the United States. To that end, the bill also includes my provision to ensure American manufacturers do not face needless red tape in overseas markets like the European Economic Area. Section 2162 provides much needed reform to level the playing field for products manufactured here in the United States.

The bill also includes important new incentives to repurpose approved drugs for patients with rare diseases. This provision will help bring hope to the 30 million Americans suffering from a rare disease – often have no access to an approved therapy on the market today.

As I think about each of the three titles in this bill – each is necessary and none is greater than another. Without discovery, there is no development. If there is no development, there cannot be delivery. And so – to begin to accelerate the pace in which we bring cures to patients faster, we look at each of the elements of the entire cures cycle and look for ways to break down barriers and speed along each segment of the cycle.

There is much in this bill to be proud of and enthusiastic about and even optimistic for, but I also realize we still have more work to do and improvements to make. I thank our staff for the tremendous effort put forth to get us here today. And I look forward to continuing our work.

And now a quick word about the second bill before us today, H.R. 1321, "Microbead-Free Waters

Act of 2015". Our Health Subcommittee held a hearing on this bill on May 1 and heard from industry and environmental stakeholders alike that this legislation is needed to prohibit the distribution of cosmetic products that contain microbeads. A national standard for regulating products that contain synthetic plastic microbeads, with appropriate phase-out dates, appropriate definitions and inclusion of over-the-counter products will be important.

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