Opening Statement of Chairman Greg Walden
Subcommittee on Health
Markup of H.R. 1876, H.R. 2026, and H.R. __, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018
January 17, 2018

Today we will be marking up three bills that improve public health. The first will help improve the supply and response of trained health professionals that can offer aid in a federally declared disaster. The other two initiatives will help improve access to innovative, safe, and effective medications and treatments.

Among the bills we will consider is H.R. 1876, the Good Samaritan Health Professionals Act, sponsored by Chairman Marsha Blackburn (R-TN). This bill provides limited liability protections for health practitioners providing care to those in a federally declared disaster.

We recently experienced an extremely destructive and deadly hurricane season as well as devastating wildfires in Oregon and throughout much of the West. Natural disasters and other large-scale emergencies require an all-hands-on-deck effort when rescue crews are overloaded treating victims. The willingness of qualified volunteers to offer their expertise to those in need should not be deterred by the fear of liability actions against them.

When we reviewed this bill back in May of last year, Dr. Martin Levine, who treated the injured at the Boston Marathon bombing stated that, "providing uniform federal standards for professional liability will help ensure that a sufficient health care workforce can be mobilized without unnecessary delays or confusion."

By filling in some gaps in our current liability protections, we can help speed getting medical personnel on the ground.

I want to thank my colleague Marsha Blackburn for championing this important issue. She, with the assistance of Morgan Griffith, worked with stakeholders to ensure that the text strikes the right balance in protecting both patients and health providers.

We'll also be considering legislation led by Vice Chairman Guthrie to facilitate communication between medical product developers and payors prior to FDA approval.

As many of us will recall, the landmark approval of Sovaldi as a cure for Hepatitis C came as an unforeseen challenge to state Medicaid directors across the country. While the discovery of a cure to a devastating disease is something to be celebrated, private insurers and public programs alike were not prepared for the impact it had on their budgets.

The amendment in the nature of a substitute we are considering today will codify practices currently permitted by FDA through draft guidance. It will allow developers of medical products to share economic and scientific information with payors prior to final FDA approval, based on clinical data those developers will rely on for FDA approval.

Last year we saw groundbreaking advances in the field of cancer immunotherapy through the approval of two CAR-T therapies. These products offer hope to patients with specific kinds of blood cancers, and more products are

showing promise for other devastating conditions. If payors are not prepared to cover these therapies the moment they come to market, it could mean the difference between life and death for patients.

Finally, we'll be considering legislation to modernize the arcane process by which over-the-counter (OTC) health products are made available to consumers.

The OTC Monograph was established more than 40 years ago, yet it remains incomplete today. This burdensome, inflexible framework has proven unworkable for the Food and Drug Administration (FDA), and developers of consumer health products alike, resulting in little to no innovation in the OTC market.

I would like to recognize the efforts of representatives Latta, Green, Guthrie, DeGette, and Dingell, who have worked with FDA and participants in the consumer health products marketplace over the course of several congresses. The resulting legislation we are considering today would create a balanced regulatory framework that will allow for innovative new products to reach consumers. This bill is supported by a wide range of organizations including the manufacturers of national OTC brands and store brands, the Pew Foundation, and the National Association of County and City Health Officials among others.

I urge my colleagues on both sides of the aisle to support these critical bills, and look forward to continuing our work at the full committee level soon.