

**Chairman Burgess
Opening Statement
Energy and Commerce Subcommittee on Health Hearing
“Examining Patient Access to Investigational Drugs”
October 3, 2017**

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

We are here today to explore an issue that is very personal to many patients, and their families, across the United States who are suffering from serious, life-threatening conditions or terminal illnesses — the availability to access investigational drugs and devices. Currently, the U.S. Food and Drug Administration conducts an expanded access program aimed at helping these patients who do not qualify for clinical trials gain access to therapies unapproved by the agency. I understand the feelings and passions of individuals who believe these therapies have the potential to save their life or to offer them a chance to alter the course of their illness. I also recognize that the Food and Drug Administration must strike the right balance between ensuring public safety and granting access to new treatments.

Today we will convene four panels of witnesses. First, I want to welcome Representatives Brian Fitzpatrick and Andy Biggs to our Subcommittee. We look forward to hearing your statement this morning on actions you both have taken. Next, I want to welcome Dr. Scott Gottlieb. Dr. Gottlieb, I believe today’s hearing is your first opportunity to come before our Subcommittee — it is nice to have you here. Afterwards, we welcome Mr. John Dicken, Director of Health Care at the

U.S. Government Accountability Office. Later, we will hear from other stakeholders who are deeply engaged on this issue.

Our nation has experienced an unprecedented amount of innovation and scientific breakthroughs over the last decade from researchers in our finest academic institutions and those working in the pharmaceutical and medical device companies. However, I hear from patients with serious, life-threatening conditions – my constituents from North Texas – being frustrated with what they see as regulatory barrier from trying and experimenting with new therapies when all others have failed. It seems we are at a crossroad when life-saving treatments, while not yet approved, exist but patients cannot access. Since 2014, 37 states, including my state of Texas, have passed a version of Right to Try laws, through a strong grassroots movement. With that in mind, it is my hope this hearing will start a constructive discussion on this important issue.

The Subcommittee will also examine several pieces of federal legislation: S. 207, the Trickett Wendler Right to Try Act of 2017, authored by Senator Ron Johnson of Wisconsin, Representatives Biggs and Fitzpatrick's House companion bills, and H.R. 1020, the Compassionate Freedom of Choice Act of 2017, introduced by our fellow Health Subcommittee member, Representative Griffith.

Members of this Subcommittee have many questions and are looking forward to hearing from all of our witnesses. We want to learn the Food and Drug Administration's steps to streamline the expanded access program. We want to dive into what the Government Accountability Office found recently regarding the expanded access program. We will hear from patient-advocates and thought leaders on this topic. There are strong views but I am confident what comes out of

this hearing will lead to a productive discussions and all of us getting closer to meeting the needs of all of our citizens.

I again want to welcome all of our witnesses and thank you for being here today. I look forward to your testimony.

I would like to yield the balance of my time to Ms. Blackburn of Tennessee for a statement.