Opening Statement of Republican Leader Michael C. Burgess, M.D.
Subcommittee on Health
"Improving Safety and Transparency in America's Food and Drugs"
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As Prepared for Delivery

Thank you, Madame Chair. The Food and Drug Administration is the oldest comprehensive consumer protection agency in the federal government. Dating back to the 1906 Pure Food and Drugs Act, the FDA has been the administrative body tasked with protecting Americans from adulterated and misbranded drugs and food. Since 1906, the FDA's authority and responsibilities have grown to include cosmetics, tobacco, and other public health programs.

Today we are considering a number of drug and device policies. Representative Guthrie's bill H.R. 5663, the Safeguarding Therapeutics Act, allows the Secretary of HHS to destroy certain counterfeit medical devices. Counterfeit devices pose a risk to Americans. I saw this firsthand when I visited the JFK International Mail Facility with Former FDA Commissioner Scott Gottlieb and was taken aback. Many counterfeit devices come in through facilities like the one I saw, and this

bill would allow for such devices to be destroyed at the point of entry. Granting authority to the Secretary to ensure that these counterfeit devices will be destroyed will help protect patients from bad actors who distribute counterfeit devices into the marketplace.

H.R. 4712, the Fairness in Orphan Drug Exclusivity Act seeks to clarify conditions for exclusive approval and licensure of drugs that receive orphan drug designation under the non-profitability provision of the Orphan Drug Act. The government has an important role with respect to orphan drugs. Without government assistance, the manufacturers and innovators of drugs for rare diseases may never be able to bring these products to market. This legislation appropriately balances the support necessary to promote orphan drug development without allowing for orphan drug manufacturers to inhibit competition. We must make sure to walk that fine line of competition and encouraging new cures.

Another bill aimed at innovation is H.R. 4866. This bill would designate certain qualifying higher education institutions as National Centers of Excellence in Continuous Pharmaceutical Manufacturing to support the advancement and development of continuous manufacturing. Continuous manufacturing has many benefits, including allowing for more flexible tracking and tracing in the event of product failure and eliminated hold times between steps of production. This is important technology because the ability to track and trace during a product failure could minimize the risk of a drug shortage. Additionally, a fast and efficient production of pharmaceuticals is beneficial to patients.

Less often has the Health Subcommittee held hearings on the food jurisdiction of the FDA. The FDA is the authoritative agency on labeling and nutrition, ingredients and packaging, and food defense. It is important for Americans to be aware of what's in their food - from the nutritional value, to what additives and allergens may be present.

Some bills before us today are aimed at these issues. H.R. 2117, the Food Allergy Safety, Treatment, Education, and Research Act of 2019 would require sesame to be a major allergen for the purposes of labeling. H.R. 2269, the Infant Formula Protection Act of 2019 would require infant formula to be considered adulterated by the FDA if it is passed the use by date.

Some of the other bills before us today dealing with food requirements overstep into the authority of the FDA. The FDA is the expert body on food regulation and safety. Well-intentioned legislation may result in unforeseen negative consequences, particularly where the FDA has not found a need for regulation.

Unfortunately, the FDA is not a witness today; however, I look forward to hearing from our witnesses on these pieces of legislation. I yield back.

Yield to Mr. Guthrie