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Statement of Rep. Henry A. Waxman
Committee on Energy and Commerce
Subcommittee on Health
Hearing on "21st Century Cures: Examining Ways to Combat Antibiotic Resistance and Foster New Drug Development"
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As we learned in the series of hearings this Subcommittee held in 2010, the problem of antibiotic resistance is a growing and dangerous threat to the public health. It is an issue that deserves the full and complete attention of this Committee. Our overarching goal must be ensuring that people continue to benefit from these life-saving treatments, both here in the U.S. and around the globe.

This is an inherently difficult goal to achieve. After all, the very use of antibiotics leads to the development of pathogens that can no longer be treated by those antibiotics. Rather than "use it or lose it," with antibiotics it is "use it and lose it."

Unfortunately, we are at great risk of losing much of the progress that has been made in fighting infection and subsequent disease. Many Americans die or are infected each year from antibiotic resistant microbes. We pay a high price in other ways as well. Additional hospital stays, hospital re-admissions, and increased doctor visits all add -- unnecessarily -- to the nation's annual health care bill. It will take a multi-pronged approach to overcome this very serious problem. There is no question that our arsenal of effective antibiotics is dangerously low today as a result of antibiotic resistance. So we need to replace ineffective antibiotics with new ones.

In the 2012 FDA user fee legislation, we enacted a law designed to create incentives for companies to do just that. That legislation included provisions from the Generating Antibiotic Incentives Now Act, called the GAIN Act, which granted a five year term of exclusive marketing for new antibiotics for serious and life-threatening diseases. I look forward to hearing today from our witnesses about what impact that legislation is having on investment in these drugs.

Exclusivity rewards drug companies by allowing them to charge higher prices. As a result, it also imposes a significant burden on patients and on the healthcare system overall. So we need to approach this particular form of incentive with great caution. One bad idea is the concept of "transferable market exclusivity," which is also called "wild-card exclusivity." This form of exclusivity would give a company that developed a new antibiotic the ability to transfer a term of exclusivity to any other drug. This is a hugely costly idea that leads to unfair cross-subsidies. If Astra Zeneca were to develop a specified antibiotic, it could earn a term of

exclusivity that it could transfer to Nexium, a treatment for heartburn which was the second highest grossing drug last year, earning over $6 billion. Even if the term of exclusivity were just 6 months, that would result in a reward of almost $3 billion. That means Nexium patients pay higher prices for longer, even though they may never ever actually take the antibiotic itself.

As we tackle the problem of antibiotic resistance, we need to ensure that whatever form the incentive takes, it bears some reasonable relationship to the amount of the investment the company makes.

I hope we will discuss today another approach to getting new antibiotics on the market, the Antibiotic Development to Advance Patient Treatment or the "ADAPT" Act. That bill would establish a "limited population approval pathway" that would permit FDA to approve drugs based on smaller clinical trials. This is an idea worth examining.

If we do create such a pathway, any drugs approved as a result would need to be clearly marked with a prominent symbol to alert providers and patients that the safety and effectiveness of these drugs has only been assessed on a limited population. Requiring a designation is integral to the idea of a limited population approval pathway because providers have to know that these drugs are to be used only when absolutely necessary. Otherwise, they will not only put patients at risk, but will contribute to the more rapid development of antimicrobial resistance to the drug.

In addition to incentives for developing new antibiotics, we must find ways to cut back on the overuse and mis-use of these drugs. Patients cannot expect to get them every time they come down with a cold, and physicians should only prescribe them when they are truly necessary. Perhaps most important, the indiscriminate administration of these drugs in animal agriculture operations needs to stop. We should mandate an end to this practice. But if we ca not take that step, we should at least have better data about how and where antibiotics that are important for humans are being used in food animals. We know practically nothing about this situation.

As a recent Reuters article points out, the data exists in the hands of the major corporations producing these animals like Perdue and Tysons. I have a bill that would finally give the public access to this information—H.R. 820, the DATA Act. I hope this common-sense bill can be included in the 21st Century Cures legislation.

I thank the witnesses for their testimony and look forward to hearing from them.