Statement on the Pharmaceutical Patent Transparency Act
Senator Susan M. Collins
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I rise today to discuss Senate Bill 659, the *Biologic Patent Transparency Act*. This bill would help encourage competition in the prescription drug marketplace and begin to put an end to the harmful patent strategies that block new drugs from coming to market. I am pleased to be sponsoring this legislation with my friend and colleague from Virginia, Senator Tim Kaine, as well as with Senators Portman, Shaheen, Braun, and Stabenow, all of whom have joined us as original cosponsors.

Prescription drugs are vital to the health and well-being of Americans, especially our nation's seniors, 90 percent of whom take at least one prescription drug in any given month. Developing these medicines is a lengthy, expensive, and uncertain process. It often takes more than a decade, and can cost billions of dollars to bring a new drug from the laboratory to the patient. Most drugs fail during the clinical trials. If we want new medicines to reach consumers who need them, the companies that invest in this research and development and take the risks necessary must see a fair return on their investment.

To encourage such investments, Congress grants inventors limited periods of patent protection during which their products are legally shielded from competition. Rewarding these investments has proven to be beneficial to many Americans. The past century could be termed the Age of Miracle Drugs, with discoveries such as insulin and penicillin and treatments for cancer, heart disease, HIV, and other serious medical conditions. Today, however, we might well define a "miracle drug" as one that has not doubled in price since the last refill.

Although our country leads the world in prescription drug innovation, we also lead the world in drug spending. According to one estimate, U.S. spending on prescription drugs will reach between $580 and $610 billion by 2021. In 2017, Americans spent more than $330 billion on retail prescription drugs, and nearly a quarter of individuals surveyed reported difficulties paying for the cost of their prescription medications.

How well I remember standing in the pharmacy line several months ago behind a couple who were informed by the pharmacist that their copay would be $111. The husband turned to his wife and said, "Honey, we just can't afford that." They then turned around, left their prescription on the counter, and left the pharmacy. I asked the pharmacist how often that happens, and he told me, "Every day." That's the kind of onerous burden that too many Americans are facing, and it's causing them to forego fulfilling prescriptions, to stretch out doses, or simply choose to buy the medicine and short themselves on food or be late in paying their rent or mortgage.

Among the most expensive drugs on the market today are biologics. These are incredibly promising drugs for the health and well-being of many Americans. They have revolutionized treatment for many serious and life-threatening conditions, from diabetes and rheumatoid arthritis to cancer and multiple sclerosis.

Today, fewer than two percent of Americans use biologics, yet biologics account for nearly 40 percent of total spending on prescription drugs. Last year, the Senate Aging Committee, which I chair and which the presiding officer is a member of, held a hearing to examine the price increases for one of these ground-breaking treatments. Humira, the world's best-selling prescription drug, is a biologic that was first approved for the treatment of rheumatoid arthritis by the Food and Drug Administration in 2002. In 2017, U.S. sales of this product generated an astonishing $12.3 billion in revenue for the drug's manufacturer.

Humira is truly a miracle drug for many patients. It's used to treat a variety of conditions, ranging from rheumatoid arthritis to Crohn's disease to ulcerative colitis and plaque psoriasis. So a wide range of diseases and conditions are responsive to Humira. According to various reports, more than 200 patent applications have been filed for Humira, with nearly 90 percent of those filed after Humira was first approved by the FDA in 2002.

According to the manufacturer's CEO, more than 130 patents are included in Humira's patent portfolio today. Protections provided by these patents could block competition and extend the drug's market monopoly until 2034. Keep in mind that this is for a drug that was first approved in 2002. We're talking about extending the patents until 2034. Humira has increased in price yet again this year, and although biosimilars have been approved by the FDA, patent litigation is blamed for keeping these lower-cost alternatives from reaching the market. And Humira is not the only biologic to be protected by such an extensive portfolio of patents, what we call a "patent thicket."

Enabling the creation, approval, and marketing of competitive biologic products must be among our top priorities when we consider ways to reduce the health care costs of Americas. The *Biologic Patent Transparency Act* is an important step that Congress can take to shine light on the patent thickets that protect these biologics and stop some of the gaming that has prevented consumers from accessing lower cost, FDA-approved products.

So what would our bill do? It has three major components. First, our bill would require manufacturers to disclose to the FDA the web of patents that protect their approved biologics from competition by biosimilar manufacturers – a process that we already know works. It has worked remarkably well for the small molecule drugs that are governed by the Hatch-Waxman Act of 1984.

Although generics accounted for only 13 percent of U.S. prescriptions immediately before the Hatch-Waxman Act was passed, today they make up 90 percent. These generics often cost 70 to 90 percent less than the branded product. They have significantly reduced costs and expanded access to necessary treatments for Americans. According to one estimate, generics have saved consumers more than $1.6 trillion in drug costs over the last decade.

Second, our bill would tackle the patent strategies that are intentionally designed to block competition by limiting the enforceability of late-filed patents against biosimilar manufacturers that have already filed applications with the FDA. According to one estimate, over 70 of the patents covering Humira were applied for and granted within three years prior to the expiration of the initial patents.

So here's what happening: a manufacturer of a wildly successful drug sees that its patents are about to expire and that a competitor, a biosimilar manufacturer, is on the way to getting approval by the FDA for its product. So what the original brand manufacturer does is make small alterations, frequently, in the product. It doesn't change the product in a dramatic way, doesn't come up with a brand new medicine, but changes it ever so slightly or decides to patent an aspect of it that was not previously patented. And the whole purpose is to prevent that biosimilar manufacturer from bringing to market a more affordable product that consumers could access. That's just wrong. That's not what patents are intended for. And as I made clear earlier in my statement, I support a limited period of exclusivity for the innovator manufacturer. I think we should reward that investment in research and development and clinical trials, which is often very expensive. But it's not right for the patent system to be gamed this way, for it to be exploited and last-minute patents to be filed for the sole purpose of precluding a competitor from coming to market with a less expensive equivalent drug.

Restricting the enforcement of these late-filed patents that are filed after the application by the biosimilar manufacturer has been filed with the FDA will still protect the important investments made by the manufacturers while encouraging the biosimilar manufacturers to bring important innovations to consumers sooner and at a lower cost.

Finally, the third part of our bill would require the FDA to publish regularly specific information related to approved biologic products, making it easier for prospective competitors to evaluate and plan for the development and introduction of biosimilars. In addition to the name and patent information for all approved biological products, our bill would require the FDA to publish information, including the drug's marketing status, applicable reference products, periods of exclusivity, biosimilar or interchangeable products, and approved indications for usage. The FDA will be required to regularly update this information as well, so that it is readily available and up-to-date.

So what this will do is allow the biosimilar manufacturer to go to what is known as the "Purple Book" at the FDA, take a look at the drug that it wishes to compete with, and learn what existing patents are there, how long they are going to be in effect, and plan accordingly.

America's system of protecting innovation has provided our citizens with tremendous benefits, especially in the area of pharmaceuticals. Of that there can be no doubt. We must provide pharmaceutical manufacturers with the ability to recoup their investments, but at the same time, we cannot be blind to the costs of these drugs, nor to cases where patent laws are manipulated to preserve monopolies and prevent lower-cost equivalent drugs from coming to market. Passing the *Biologic Patent Transparency Act* is a major step we can take to put a stop to the patent gaming that blocks consumers from accessing lower-cost drugs. I encourage my colleagues to support this crucial legislation.