Opening Statement
Senator Susan M. Collins

"From Joint Pain to Pocket Pain: Cost and Competition Among Rheumatoid Arthritis Therapies"

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Good morning. 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. For many Americans, access to affordable prescription drugs is not only critical for health, but also can be literally a matter of life or death.

Developing these medicines is a lengthy, expensive, and uncertain process. It often takes more than a decade to bring a new drug from the laboratory to the market; the process is often very costly, and most drugs fail during testing.

If we want new medicines to reach consumers who need them, the companies that invest in the research and take the risks necessary to develop these drugs must see a fair return on their investment.

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. Americans are expected to spend more than $387 billion on prescription drugs this year alone. Of this amount, individuals will pay about $48 billion out-of-pocket. The federal government is a major payer and will pick up another $172 billion in payments through Medicare, Medicaid, Veterans Affairs, and other programs. And of course, the cost of prescription drugs affects what we pay for private health insurance as well.

While we understand that research and development are expensive, consumers are also familiar with reports of prescription drugs that have undergone significant and unwarranted price increases. Last Congress, this Committee conducted a bipartisan investigation into the sudden, dramatic price increases of certain decades-old prescription drugs.

At the end of our investigation, we published a report documenting cases in which companies that had not invested a single dollar in the research and development of a drug, nevertheless bought it, hiked its price to unconscionable levels.

Today, the Committee will examine why prices have soared for drugs used to treat a disease affecting 1.3 million Americans – rheumatoid arthritis, a chronic autoimmune and inflammatory condition that attacks the lining of joints. Untreated, RA can lead to permanent joint damage and is associated with significant morbidity. While it can begin at any age, the likelihood of onset increases with age and is highest among women in their sixties.

Biologic medicines have proven life-changing for many patients, halting the progression of symptoms and allowing them to remain actively engaged at work, at home, and in life. Derived from living organisms, biologics are much more complex than their chemical counterparts. They may require special handling and are often administered by injection or infusion. Sometimes referred to as "specialty drugs," these medicines can have astonishingly high price tags that are continuing to increase every year.

For example, the price of Humira, a self-administered biologic approved at the end of 2002 to treat RA, has risen from about $19,000 per year in 2012 to more than $38,000 per year today. Enbrel, another biologic that was first approved for treatment of RA in 1998, costs about the same. Sales of Humira reached $16.1 billion in 2016. It is the world's best-selling pharmaceutical drug, and Enbrel is number three.

The FDA approved biosimilars for both Humira and Enbrel in 2016, but neither has come to market. That's disturbing since we know that competition tends to drive down prices or at least curb increases. In the case of Remicade, a less expensive biologic approved for treatment of RA, two biosimilars did come to market at discounts of 15 and 35 percent. That raises the important question: Why haven't the biosimilar competitors of Humira and Enbrel become available to consumers? According to reports, Humira is covered by more than 100 patents, many of which were added as the expiration date of the drug's main patent approached in 2016.

Similarly, Enbrel's main patent has expired, yet the drug remains protected by at least two other so-called "submarine" patents nearly 20 years after it was first approved by the FDA. According to a CRS report from 2017, five of the seven biosimilars that had been approved by the FDA "have been delayed, or alleged to be adversely impacted, by actions of the brand-name manufacturers."

Treating rheumatoid arthritis costs the U.S. health care system an estimated $19 billion a year. As a result of the increasing costs of these drugs, we hear of the struggles of older Americans who face not only the pain of the disease, but also the financial pain associated with maintaining treatments.

One of these patients is my constituent, Patty Bernard. She is among the more than 8,000 people in Maine who live with rheumatoid arthritis. Mrs. Bernard is 80 years old, hope you don't mind that we told your age at this hearing, and she was diagnosed with rheumatoid arthritis at age 55. In the early years of her diagnosis, she tried many different drugs, but her symptoms continued to get worse.

In 1998, when Enbrel came to market, she was one of the first in Maine to try the drug. She calls the medicine "God-given." Joint by joint, she felt her life come back. When Mrs. Bernard retired last year, she learned that on Medicare she would have to pay $3,800 per month for the medication, an unaffordable cost.

We look forward to hearing from all of our witnesses today and to better understanding what can be done to moderate the price of prescription drugs without discouraging the innovation that helps us live healthier lives.