Opening Statement Senator Susan Collins "Insulin Access and Affordability: The Rising Cost of Treatment" May 8, 2018

Good morning. When a team of three scientists at the University of Toronto discovered insulin in 1921, they revolutionized the treatment for diabetes, transforming it from a debilitating and ultimately fatal disease, to a manageable, chronic condition. The scientists sold the patent for one dollar each to the University; a move intended to ensure that those in need would always have affordable access. They explicitly stated that profit was not their goal.

Yet, the cost of insulin has soared in recent years. In 2013, more was spent on insulin than on all other diabetes medications combined. In a new report to be released today, the American Diabetes Association notes that between 2002 and 2013, the average price of insulin nearly tripled.

More than 30 million Americans live with diabetes, including one out of four seniors. In Maine, there are more than 137,000 people living with this condition – roughly 11 percent of our population.

Untreated, diabetes can lead to vision problems, nerve damage, kidney failure, heart disease, stroke, and ultimately death. Since 2015, diabetes has remained the 7th leading cause of death in the United States, claiming nearly 80,000 lives last year.

Fortunately, diabetes is treatable. Improving diabetes treatment has long been one of my top priorities since I founded the Senate Diabetes Caucus in 1997, and I have invited my co-chair, Senator Jeanne Shaheen, to join us here today. She'll be here shortly.

For those living with Type 1 diabetes, in which the body loses its ability to produce insulin, treatment requires life-long insulin administration. Five percent of adults diagnosed with diabetes have Type 1, and in children and youth with diabetes, this type accounts for the majority of cases. Those with Type 1 diabetes depend on insulin to survive and manage their disease. Insulin is also critical for many older Americans with Type 2 diabetes.

For some people with Type 2, lifestyle changes and non-insulin medications can allow them to manage their diabetes; however, approximately a third of those with Type 2 require insulin.

Medical costs for Americans with diabetes are more than double those incurred by individuals without diabetes. The disease costs our nation a total of \$327 billion per year; one out of three Medicare dollars go to treating people with diabetes.

Insulin is one of the most expensive categories of drugs purchased by private payers and government health care payers. People with diabetes who use insulin, particularly those with Type 1, need this medication every day in order to live – it is a matter of life or death.

The rising cost of insulin presents a barrier to care for a growing number of Americans with diabetes. We have heard stories from people across the country who have had to ration or skip doses altogether to make their insulin supply last longer. Some have sought medication from other countries, while others have turned to the black market. Still others have raised funds for their insulin using the internet. These measures can result in major risks that can compromise health and even life.

While the prescription drug market, and the insulin market specifically, is opaque to virtually everyone involved, one fact is clear: the patients are not getting the best deal. The price for a vial of Humalog increased from \$21 in 1996, to \$35 in 2001, to \$234 in 2015, to \$275 in 2017. Today, we will hear testimony from one of my constituents who paid more than \$320, out-of-pocket, for the same product last year – and that was even after using a coupon. This chart, which my staff compiled using publicly available price data, illustrates this disturbing trend.

As list prices have increased, so too have out-of-pocket costs. For Medicare Part D beneficiaries, out-of-pocket costs increased by ten percent per year between 2006 and 2013, outpacing overall inflation, medical care service costs, and spending on prescription drugs in general. For those without insurance, the costs are untenable. The cost of a single vial can be more than \$300, and some patients need more than one vial per month to effectively manage their disease.

Insulin products have changed since 1921. Early versions of insulin were produced from purified animal extracts, and scientists worked to improve duration and purity. In the late 1970's, the discovery of recombinant technology led to the approval of the first synthetic human insulin in 1982, which better mimicked human insulin and reduced allergic reactions. Continued improvements through the use of recombinant technology resulted in the development of insulin analogs with modified chemical structures and improved physiological effects.

Insulin analogs have provided greater flexibility in administration and have allowed many patients to better manage their conditions, especially those with Type 1 diabetes and those prone to having low blood sugar. However, as more products entered the market, prices began to increase significantly, even for the older versions of the insulin. The use of higher priced analogs has grown, while the use of lower-priced human insulins has declined, even though for many patients, clinical efficacy among the various products is not markedly different.

I have previously expressed my concern with a practice called, "evergreening." This means when pharmaceutical companies obtain patents based on small innovations to extend the exclusivity of a product after its initial patent expires. For insulin, a careful look is warranted to determine if minor modifications were used to just extend the patent protections and discourage competitors.

In the face of skyrocketing costs of newer versions of a time-tested therapy, too many consumers find themselves without affordable alternatives, and find that they are paying more each year.

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 dollar in the research and development of a drug nevertheless hiked its price to unconscionable levels.

In February, this Committee examined why prices have soared for drugs used to treat rheumatoid arthritis. Today, we continue our study of drug pricing as we examine why the price continues to climb for insulin, a life-saving drug for so many Americans.

Far too many individuals and families are familiar with the devastating toll diabetes has taken on people of every age, race, and nationality. The cost of a drug that is approaching its 100th birthday should not add to that burden.

I now would like to turn to our Ranking Member, Senator Casey, for his opening statement and express my appreciation to the members who have joined us today.