Statement on Lowering Drug Prices Senator Susan M. Collins July 30, 2019

Mr. President, I rise today to highlight the bipartisan work underway in the Senate to help Americans struggling with the high cost of prescription drugs. This problem particularly affects our seniors, 90 percent of whom take at least one prescription drug. It is critical that we continue to build momentum on this important pocketbook issue that I believe bridges the partisan divide.

Since 2015, I have chaired eight hearings on drug pricing as Chairman of the Aging Committee. Mr. President, we have heard so many heartbreaking stories from people who are struggling to afford the medication that they need.

I will never forget standing in line at the pharmacy counter in Bangor, Maine, where I live, and the couple ahead of me received their prescription drug and the unwelcome news that their copay was going to be \$111. The husband turned to his wife and said "honey, we simply cannot afford this" and they walked away, leaving that needed prescription on the drug store counter. I asked the pharmacist and told him I didn't mean to overhear, I just happened to be next in line. But I asked him, "how often does this happen?" and he gave me the terrible news that it happens every single day.

At a hearing on the skyrocketing price of insulin, we heard compelling testimony from Paul Grant, a father of four who lives in New Gloucester, Maine, who discovered one day that the cost of a 90-day supply of insulin for his 13-year old son who has Type I diabetes had tripled overnight to more than \$900. He had to resort to paying out-of-pocket for much lower-cost insulin from Canada, without any credit towards his insurance deductible.

At our hearing on rheumatoid arthritis, Patty Bernard from Falmouth, Maine, testified that her out-of-pocket costs soared from \$10 to \$3,800 per month for Enbrel when she transitioned from employer-sponsored insurance to Medicare. She simply could not afford this expense and had to switch to a different drug, which was not self-administered. This switch required her to go to a doctor's office once a month for a two-and-a-half-hour infusion and it did not work nearly as well for her.

At another hearing, we heard from Pam Holt, who was diagnosed with multiple melanoma. Ms. Holt is among the one million Medicare beneficiaries with annual out-of-pocket prescription drug costs exceeding \$5,100, placing her in the catastrophic part of Medicare Part D. Seniors still pay five percent of a drug's cost above that threshold, and Ms. Holt had to refinance her home to afford her treatment. The price of her medication is staggering at more than \$250,000 per year.

This is not an optional cost, Mr. President. These are costs that are necessary to preserve the life and wellbeing of our seniors, in particular.

These stories of Americans like Paul, Patty, Pam, and millions of others, who are finding it extremely difficult to afford the exorbitant cost of the medication they need to maintain their

health or the health of their loved ones is motivating Congress to act on a bipartisan, bicameral basis.

The Senate HELP Committee (Health Education Labor and Pensions), for example, recently reported out the *Lower Health Care Costs Act*, which incorporates more than 14 measures to increase drug price competition, using market forces to do so. It includes major provisions from the *Biologic Patent Transparency Act*, a bipartisan bill that I authored with Senator Kaine, which is cosponsored by Senators Braun, Hawley, Portman, Shaheen, Stabenow, Paul, and Murkowski. It is intended to prevent drug manufacturers from gaming our patent system. Now patents play a key role in encouraging what can be billions of dollars in investment to bring new drugs from the lab table to the bedside of a patient. But the patent system should not be misused to prevent lower-priced generic drugs from coming to market once the initial patent has expired. Our bill requires earlier and greater disclosure of the web of patents held by biologic manufacturers, thus making it easier for their competitors, which are known as biosimilar companies, to develop more affordable alternatives without being stymied by the filing of last-minute new patents that are intended simply to keep competition out of the marketplace.

And it's particularly important that we look at biologics, they have been miracle drugs for many Americans, but they are also the most expensive category of drugs, accounting for approximately 40 percent of total drug costs. According to former FDA Commissioner Scott Gottlieb, if all of the biosimilars that have been approved by the FDA were successfully marketed in the U.S. in a timely fashion, Americans would have saved more than \$4.5 billion in 2017. This is an expert calculation from the former FDA commissioner. Instead what happens, in too many cases, is the biosimilar competitor is available now in Europe, in Canada, but not in the United States.

The HELP Committee package also includes the *CREATES Act*, which addresses anticompetitive practices of companies that delay or even block access to a sufficient quantity of the brand name drug needed to conduct the bio-equivalency test required by the FDA as part of the generic drug approval process. This addresses one of the problems identified by a major investigation the Aging Committee undertook in 2016 examining the explosion in prices of off-patent prescription drugs for which there still is no generic equivalent. What we found, in some cases, is that the brand-name manufacturer was making it extremely difficult for the generic competitor to buy up a sufficient quantity of the drug to do these bio-equivalency tests that are required as part of the generic approval process—that's just plain wrong. Due to the provisions in the bill to spur competition, the CBO estimates that "the entry of certain generic or biosimilar products could be accelerated by one or two years, on average." This would make a tremendous difference, and would reduce consumer, as well as federal and private insurance, spending for prescription drugs.

And Mr. President, the point I want to make is this is just allowing the market to operate as it should, with competition and transparency and an end to the obstacles and gaming of the system that prevents lower price pharmaceuticals. In addition the *Lower Health Care Costs Act* contains several important provisions to shed light on what is currently a complex and opaque system. In fact, Mr. President, I cannot think of any other product that we buy where the price is so opaque and lacking in transparency and in which there are such variations in what the costs

may be, from plan to plan, from pharmacy to pharmacy, from manufacturer to manufacturer, and that is due to a very complex system that I am going to refer to.

At the Aging Committee's hearing on the high cost of insulin, the American Diabetes Association spoke about a lack of transparency when you trace insulin from the manufacturer to the pharmacy counter. And keep in mind that insulin was first isolated nearly a century ago, in 1921 in Canada. And the discoverers provided it for only a dollar, because they wanted to make it widely available. The ADA chart illustrated the complexity and the perverse incentives in the supply chain for prescription drugs. And what was clear was that rebates are a key problem in driving up the cost of insulin.

There is a system here that is rife with conflicts of interests. If the manufacturer has a high list price, then the pharmacy benefit manager, who is negotiating on behalf of the insurer, has an incentive to choose that manufacturer's version of insulin rather than another manufacturer's because the pharmacy benefit manager is usually compensated by getting a percentage of the list price. Well obviously the manufacturer wants to have its version of insulin chosen to be offered by the insurer to its customers. So here we have this system which is rife with conflicts of interest and incentives that encourage higher prices, because then the middle man is going to make more money. And that discount that the middleman, the pharmacy benefit manager is negotiating, almost never makes it to the pharmacy counter, to the patient who is purchasing the prescription drug.

Now sometimes part of that does indeed go to the insurer who can use it to lower overall premiums slightly, but we're talking about trying to help the person who desperately needs the drug, and who is buying it at the pharmacy counter.

As Co-Chairs of the Senate Diabetes Caucus, Senator Jeanne Shaheen and I, as well as Senators Cramer and Carper, have introduced legislation to address the flaws in the system and to hold PBM's and manufacturers accountable.

We have come up with a bill that would help to reduce the price of insulin. What a benefit that would be for the parents of children who have Type 1 diabetes, for whom insulin is literally a matter of survival. It would also help those older Americans with Type 2 diabetes, some of whom are insulin dependent. Another significant change included in *The Lower Healthcare Costs Act*, requires significantly more disclosure on the costs, the fees, and the rebate information associated with PBM contracts. It also includes an amendment that was offered by Senator Baldwin, which I supported, to require more reporting of drug prices to the Department of Health and Human Services and a justification for why prices have increased.

These provisions all build on a law that I authored last year to block pharmacy gag clauses. I told the story about the pharmacist who was so frustrated because so many people, day after day, were unable to afford the copays or the deductibles on their needed prescription drugs. Well I met with a group of community pharmacists who told be how the system worked. And

they told me that there were actually gag clauses in their contracts where they were prohibited from sharing with the consumers whether it was cheaper to pay out-of-pocket rather than through insurance. Well I'm pleased to say that working with former Senator Claire McCaskill and Debbie Stabenow and others, that we were able to get gag clause prohibitions enacted into law last year. And according to one study, banning these gag clauses could help Americans save money in nearly one out of four prescription transactions. So this is significant legislation. And I talked recently to a pharmacist in Maine who said what a relief it was to her to now be able to volunteer to her patients that there may be a less expensive way for the patient to purchase needed prescription drugs. One out of four, nearly one out of four prescription transactions should benefit from the laws that we wrote last year.

Another bill that I authored in 2017, will promote more competition from lower priced but equally effective generic drugs and it is already showing promise. To date, the FDA has granted nearly 200 application requests under the new expedited pathway that my law provides and 10 have been approved. That is a much faster pace than in the past.

As Co-Chair of both the Senate Diabetes Caucus and the Congressional Task Force on Alzheimer's Disease, I know all too well from listening to families in Maine and across the country that the path toward finding new discoveries and treatments is often long and difficult and that success can be elusive, but we must continue our efforts. And when pharmaceutical companies start twisting around the incentives that were designed to encourage innovation and instead distorting them into obstacles to competition, Congress simply must act. And that is exactly what we are doing. I want to applaud the work of the HELP Committee. All of us contributed to the bill, and we were ably led by Chairman Lamar Alexander and Ranking Member Murray. And I also want to recognize the hard work of Senator Graham and Senator Feinstein on the Judiciary Committee, for the bipartisan package of reforms that they produced last month.

And finally, Mr. President, I want to salute the Finance Committee Chairman Chuck Grassley and the Ranking Member Wyden for taking bipartisan action, just last week, in passing the significant *Prescription Drug Pricing Reduction Act*. That has many important provisions in it that will require more disclosure. It includes a bill that Senator Casey and I have authored, as well as many other important provisions, including putting a medical inflation cap on certain pharmaceuticals.

Mr. President, I know how much you personally care about this issue and have contributed greatly to this work as well. My hope is that we can build upon this momentum. That we can seize the moment where three different committees of the Senate have all been successful in reporting to the full Senate three bipartisan bills. Our HELP Committee bill was reported by a vote of 20 to 3. That is remarkable consensus. Let us bring all of these bills to the Senate floor this fall, or certainly by the end of the year, so that we can deliver real results to the American people, by lowering the price of prescription drugs. We could then be very proud of listening to our constituents and addressing a problem that affects millions of Americans.