Statement on FDA Reauthorization Act
Senator Susan M. Collins
August 3, 2017

Mr. President, I rise today in support of the Food and Drug Administration (FDA) Reauthorization Act that we are now considering. Let me begin by commending Chairman Alexander and Ranking Member Murray of the Senate Health, Education, Labor, and Pensions (HELP) Committee for their leadership in bringing this important legislation to the Senate floor.

This bill is the product of bipartisan, bicameral work and is proof that we can make progress when we work together on areas where we can find agreement.

FDA user fees, which are reauthorized under this bill, are critical to moving the most advanced research from a promise to a cure and ensuring that new treatments reach patients in need.

User fees, where companies fund a portion of the pre-market review of their products, account for more than a quarter of all FDA funding, yet the FDA's authority to collect these fees will expire at the end of next month unless Congress acts, and thus the urgency of getting this bill across the finish line. That is why it is imperative that we advance this bill now and ensure that work on these promising new pharmaceuticals continues uninterrupted.

In May, the HELP Committee, on which I am pleased to serve, overwhelmingly approved bipartisan legislation to extend and reauthorize the FDA fees in order to support the public health of our nation. The bill before us also incorporates many provisions that were advanced by individual Committee members. It's a great example of how a committee process should work. It was collaborative, we each brought ideas to the table, and during our markup those ideas were offered as amendments, and in many cases incorporated into the legislation.

I want to thank the Chairman and the Ranking Member for including in this important legislation provisions that I authored with Senator Claire McCaskill, those provisions seek to accelerate the review process for prescription drugs in cases where there is limited or no competition. Our purpose is to lower, or at least moderate, the escalating prescription drug prices that are one of the key cost drivers in our health care system today.

During the last Congress, our Senate Aging Committee, which I chair, and at that time Senator McCaskill was the ranking member, had a bipartisan investigation into the causes, impacts, and potential solutions to the egregious price spikes for certain off-patent drugs for which there were no generic competitors. Now let me explain this situation a little more, Mr. President. What we found was happening is that in cases where the patent on the original brand name pharmaceutical had expired, there were these companies that were not traditional pharmaceutical companies, they were not firms that invested hundreds of millions or even a billion dollars in R&D in order to develop a new prescription drug. That's not what we're talking about. We're talking about these pharma companies, I call them hedge fund pharma's, that wait until the patent has expired, and then buy the pharmaceutical drug and virtually overnight impose

egregious price increases. As one of the executives of these companies said when asked why he did so, he answered simply, "because I can." Well, obviously that has a very detrimental impact on patients, on health care providers, on insurers, on federal programs, such as Medicaid and Medicare.

So, building on our investigation, Senator McCaskill and I sponsored legislation, the Making Pharmaceutical Markets More Competitive Act, to foster a more competitive generic marketplace and to improve access for affordable medicines. That's key Mr. President, if we can have more competition in the prescription drug marketplace, that's what drives down costs, that's what drives down prices. And we know that from our experience when generic drugs come on the market.

The bill that we are considering today includes key provisions based on our legislation that were adopted unanimously as an amendment that I sponsored during the Committee mark-up.

First, our provisions would require the FDA to prioritize the review of certain generic applications. It would set a clear timeframe of no more than eight months for the FDA to act on such applications where there is inadequate generic competition.

This would help to resolve situations where there are drug shortages as well as circumstances where there are not more than three approved competitors on the market. The Aging Committee's investigation into sudden price spikes found that older drugs with only one manufacturer and no generic competitor are particularly vulnerable to dramatic and sudden price increases.

One company we investigated, Turing Pharmaceuticals, increased the price of a drug called Daraprim, a lifesaving drug for serious parasitic infections, from $13.50 a pill to $750 a pill—an increase of more than 5,000 percent, and they did so literally overnight. Now keep in mind that this company, Turing Pharmaceuticals, had nothing to do with the costly research and development that brought about this lifesaving drug known as Daraprim, but after they bought the drug, after the patent had expired and saw there was no generic competitor, they increased the price by 5,000 percent overnight. This price hike for a drug that has remained unchanged since 1953 is unacceptable, and underscores the urgent need for legislation to prevent bad actors from taking advantage of a non-competitive marketplace.

Second, the bill would improve communications between FDA and eligible sponsors prior to the submission of an application for the approval of a generic drug. That would improve the quality of applications from the beginning, increasing the chances of successful approval by the FDA.

Third, new reporting requirements would provide increased transparency into the backlog of applications for drug approvals and pending generic and priority review applications.

Fourth, this bill would provide the public with accurate information about drugs with limited competition. Drug manufacturers would be required to notify and provide rationale when

removing a drug from the market, and the FDA would publish a list of the off-patent brand name drugs that lack generic competitors so that if you're a generic drug company you would know that this is an opportunity to develop a competitor drug. I want to give the new FDA commissioner a great deal of credit for incorporating some of our suggestions. He cares deeply about this issue

Finally, this bill would streamline the regulatory process to address incidents in which delayed re-inspection of manufacturing facilities becomes a barrier to generics entering the marketplace.

By taking these steps, we will enhance regulatory certainty for generic drug companies, help prevent shortages, increase competition to lower prices and prevent monopolies, and deter practices that can lead to unjustifiable, exorbitant price hikes.

I am pleased that the legislation also includes another bill that resulted from our Aging Committee investigation. This provision will help prevent bad actors from receiving unwarranted vouchers under the tropical disease voucher program.

This program was intended to incentivize the development of medicines for neglected diseases, yet was exploited by the notorious Martin Shkreli, the founder of Turing. After spiking the price of Daraprim, he purchased another decades-old drug – one once again without a competitor that is used to treat a life-threatening infection that is rare in the United States. Mr. Shkreli sought to use the tropical disease voucher program to gain exclusivity and hike the price for a drug that is not in fact a new drug. Our legislation revises the program to better ensure that it achieves its intent, which is spurring the development of therapies that are truly new to treat and cure neglected diseases.

Mr. President, drug companies should not be able to increase their prices dramatically by thousands of percent overnight without any justification, without the development of modifications in the drug that improve its effectiveness, for example. Our legislation will help to foster a much healthier and more competitive marketplace as the best defense against such exploitation. I am pleased that our bipartisan plan will increase generic competition, which is so important to American families and particularly our seniors, who take a disproportionate number of the prescription drugs that are prescribed in this country.

Before closing, let me just briefly mention another important provision in the bill before us, the Over the Counter Hearing Aid Act of 2017. Approximately 30 million Americans experience age-related hearing loss, yet only about 14 percent of those with hearing loss use assistive hearing technology, often because they simply cannot afford the price of costly hearing aids. We know from a hearing that we recently held in the Aging Committee that social isolation among our seniors can be exacerbated by hearing loss that is left untreated. That in turn increases that social isolation and increases the risk of serious mental and physical health outcomes. By making some types of hearing aids available over the counter, just as people buy cheaters – eyeglasses – over the counter to help see better, this legislation will help increase access to and lower the cost of these products for the consumers who need them.

Mr. President, the legislation we are considering today will help bring lifesaving drugs to the marketplace. It will ensure that the FDA continues to operate smoothly, and most important, that promising therapies make it to the American people. Again, I want to commend Chairman Alexander and Ranking Member Murray for their leadership, and I encourage all of our colleagues to join me in supporting this important legislation.

Thank you, Mr. President. I yield the floor.