

Congress of the United States
Washington, DC 20515

Secretary Sylvia Mathews Burwell
The U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Director Francis S. Collins
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Secretary Burwell and Director Collins,

We respectfully urge you to utilize your existing statutory authority to respond to the soaring cost of pharmaceuticals. Under certain circumstances, when taxpayer-funded federal research results in a new drug patent, NIH may require the patent holder to license the federally-funded intellectual property to third parties.

In 1980, the Bayh-Dole Act authorized federal agencies that fund private research to retain certain rights in patented inventions, including to assert “march-in rights,” under 35 U.S.C. § 203(a)(2), when “action is necessary to alleviate health and safety needs which are not being reasonably satisfied” or, as noted in 35 U.S.C. § 201(f), when the benefits of the patented product are not “available to the public on reasonable terms.”

Since NIH has not previously offered official guidance regarding the situations in which march-in rights would apply, we believe that reasonable guidelines can discourage drug price gouging. We urge NIH to issue guidelines to accomplish this goal.

While NIH has appropriately referred to march-in rights as an “extraordinary remedy,” too many families and providers are facing an extraordinary challenge from unreasonably priced pharmaceuticals. In short, too many drugs are not “available to the public on reasonable terms.”

High prescription drug prices are not limited to one type of treatment or one type of disease. For example, the rapidly rising costs of specialty drugs, like those to treat cancer, which are frequently developed with taxpayer funds, are keeping those in need from being able to access care. A recent report found that in 2013, the average annual price of specialty prescription drugs was 18 times higher than the average annual price for brand name prescription drugs, and 189 times higher than the average annual price of generic prescription drugs. By 2020, specialty drugs will account for only about 2% of prescriptions, but an estimated 30% of drug spending. Over time, these rising prices could result in higher taxes and/or cuts to public programs like Medicare and Medicaid, which are already spending \$140 billion on prescription drugs annually.

We are confident reasonable guidance can be put in place to address price gouging while ensuring that march-in rights are exercised with transparency and fairness. We want pharmaceutical manufacturers to have the certainty of clear guidelines that indicate when march-in rights apply. Because these rights would only be used when wrongdoing occurs, innovation should not be threatened. Establishing strong guidelines protects consumers while reducing the need for having to actually exercise “march-in” rights. With adequate guidance, pharmaceutical companies should be able to make better-informed pricing decisions.

When declining to exercise these march-in rights in response to previous petitions, NIH has suggested that controlling drug costs is a legislative duty. While that is accurate, Congress legislated long ago on a bipartisan basis in delegating authority to federal agencies such as NIH the responsibility to address one aspect of this problem. We call upon you to do that job. The failure to act in the past has undoubtedly sent an unfortunate signal that prices for federally-funded inventions can be set as high as a sick or dying consumer will pay. In 2013, for example, NIH rejected a request to issue rules related to pricing disparities between the United States and other high-income countries. While this may not be the sole standard considered, it exemplifies the type of standard which could be set.

While some experts estimate that about one-quarter of priority-reviewed drugs—drugs deemed especially important by the FDA—could be impacted by NIH fully exercising its march-in rights, we believe that just the announcement of reasonable guidelines in response to price gouging would positively influence pricing across the pharmaceutical industry. The decision how to best use that conduit is appropriately addressed through your prompt action. Just beginning that process will have at least a modest salutary impact on this troubling healthcare problem.

We look forward to prompt response in bringing relief for struggling patients and families.

Sincerely,

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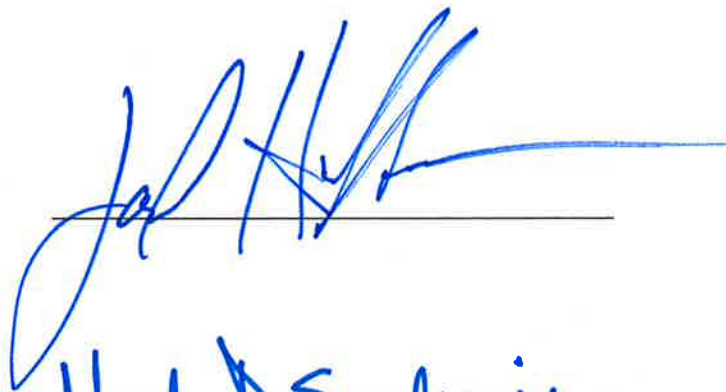
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Mark Sh

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Mark DeSaulnier

A cursive handwritten signature in blue ink, appearing to read 'Michelle Lujan Grisham', written above a horizontal line.

Michelle Lujan Grisham

A cursive handwritten signature in black ink, appearing to read 'Stephanie Waters', written above a horizontal line.

Stephanie Waters