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Opinion | Angry at high drug prices? A letter in The Post is to blame (sort of).

The drug industry has used a 2002 letter to the editor published in the newspaper to beat back government attempts to lower prices.

By Peter S. Arno and Kathryn Ardizzone

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A letter to the editor published in this newspaper 22 years ago is part of the reason Americans pay such high prices for prescription drugs today.

Here's the story. In 2002, Peter and a co-author <u>published an op-ed in The Post</u> arguing that the federal government should step in to lower high prescription drug prices. It was authorized to do so, they wrote, <u>based on the Bayh-Dole Act</u>, a 1980 law that created a mechanism known as "march-in rights" that allows the government to re-license drug patents to a generic manufacturer if the drug is not publicly available at a reasonable price.

Not long after, The Post published <u>a letter responding to that op-ed</u>. It was written by the sponsors of the Bayh-Dole Act — then-former senators Birch Bayh of Indiana and Robert Dole of Kansas — and maintained that the law was not intended to be used in response to high drug prices.

And ever since, the drug industry and its allies have used that letter as a cudgel to beat back any government attempts to rein in skyrocketing drug prices for Americans.

Now the Biden administration <u>has proposed a new framework</u>, based on march-in rights, that could lower drug costs for millions. Opponents, predictably, are pulling out all the stops to undermine the initiative — and they are relying, again, on the Bayh-Dole letter.

It's worth noting that in 1997, Bayh had actually asked the federal government to use march-in rights to deal with drug prices. But even apart from that, giving weight to the letter is not only misguided, it's wrong. The law's language is clear: When our tax dollars go toward researching and developing a drug, and the manufacturer offers that drug at a sky-high price, the government has a right to step in.

Moreover, the <u>Supreme Court has ruled</u> that legislators' statements about a law they sponsored have little to no value in determining the meaning of that law.

The Bayh-Dole Act and its legislative history make clear that the claims in the letter are incorrect. According to the act, the government can exercise its march-in rights if a drug company has not taken steps to "achieve practical application" of the government-funded product. The <u>statute defines "practical application"</u> as requiring that the product's benefits be "available to the public on reasonable terms." Practically and legally, making drugs available to the public on reasonable terms clearly means making them available at a reasonable price.

The legislative history also supports the government's right to respond to high drug prices. Around the time the legislation passed, Congress's concern with march-in rights focused on maintaining competitive conditions, controlling profits and eliminating manufacturers' ability to overcharge for drugs. The march-in provisions became the linchpin of the congressional negotiations over the bill, because Congress wanted to balance the desires of private industry with the "public equity" that resulted from taxpayer dollars going toward producing these patented products.

The Senate committee overseeing the Bayh-Dole Act indicated that march-in rights were designed to "reassure the public" and prevent windfall profits. As U.S. Navy Deputy Commander Hyman Rickover <u>testified before the House</u>: "Imagine the public furor that would ensue if, under the terms of this bill, a contractor … developed at public expense a major breakthrough. … Is it proper for that company to be able to exercise monopoly rights over the distribution, use, and pricing of the results for 17 years — mind you, where the Government has paid for it? I think not." Sen. Russell Long of Louisiana testified that there is "absolutely no reason why the taxpayer should be forced to subsidize a private monopoly and have to pay twice: first for the research and development and then through monopoly prices." March-in rights were a compromise that helped get the bill passed.

Just as today, there was strong resistance from the pharmaceutical industry — which benefits from unfettered price-setting — during Congress's deliberations. Drug companies perceived march-in rights as a powerful tool that could allow the government to cut into their profits. Despite their objections, Congress passed the bill with the march-in provisions intact. Industry's fierce opposition is a testament to what they stood to lose and what the government and taxpayers stand to gain.

Today, Americans are being crushed by health-care expenses. About 1 in 5 adults (21 percent) say they have not filled a prescription because of the cost. More than 40 years after Congress created march-in rights, the Biden administration is finally in a position to exercise them. The act's plain language and legislative history confirm that the White House is well within its rights to do so — a two-decade-old letter to the editor notwithstanding.