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Other Views: Bill would eliminate loopholes that drug companies use to keep high prices

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Health care innovation is as Wisconsin as dairy farming. From the research labs in the UW System to GE Healthcare, the contributions made toward improving health care help define the state's economy. Wisconsin has played an important role in health care innovation; vitamins A and B were both discovered at the UW-Madison campus in 1914, as was Coumadin, the first safe medical anticoagulant.

Most innovation in the global drug market stems from the efforts of U.S. universities, research labs and drug companies, and this innovation has been remarkable: Diseases such as AIDS and hepatitis C that not long ago amounted to a virtual death sentence have been rendered manageable, and many other treatments have improved the quality of life for millions.

However, these extraordinary innovations have not come cheaply, and drug prices in the U.S. are often daunting. The profits earned by drug companies incentivize them to identify new drugs and endure the enormous expense of testing them for safety and efficacy.

When the Food and Drug Administration approves a new drug, it grants the manufacturer a patent, or the right to sell the drug exclusively for a period of time. Once it expires other companies may replicate and sell copies of the drug, known as generics. The FDA must ensure that each company's version of a generic drug is safe and chemically identical to the original.

And therein lies the rub. To produce a generic drug the company must obtain sufficient quantities of the original. However, it has become increasingly common for drug companies to try to prevent generic manufacturers from procuring their drug. As they delay, consumers in Wisconsin and elsewhere pay higher prices that result from reduced competition.

Specifically, the FDA can require manufacturers of drugs with known risks to develop risk evaluation and mitigation strategies, or REMS, programs, which often includes restricted distribution channels. For example, some drugs can only be dispensed in hospitals or infusion centers.

Some companies effectively use REMS programs to deny generic manufacturers access to samples of drug products, which blocks generic companies from producing lower-cost medicines. Some companies have set up REMS programs for drugs for which it is not required, solely to slow the entry of generics into the market.

These and other tactics can delay the introduction of a generic drug into a new market for a year or more, giving the developers of original drugs longer periods of exclusivity than the law intended while collectively costing consumers billions of dollars.

Scott Gottlieb, the FDA commissioner, recently decried these practices; a bill called the CREATES Act, supported by congressional Republicans, Democrats and the administration, would eliminate many of the impediments to competition.

The legislation would provide generic developers the authority to challenge continued delays after the FDA has certified that the generic manufacturer has the necessary protocols in place to ensure samples of original drugs are handled safely—removing the main excuse offered by drug companies for denying generic manufacturers access to their drugs. It's a bipartisan, pro-consumer piece of legislation that is too rare in Washington these days.

Wisconsinites fill more than 65 million prescriptions each year and save billions when lower-cost treatment options are available. Congress should address this lacuna in the current law and move to hasten the arrival of generic drugs to the market.

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