

REMS Abuse and the CREATES Act



Health Policy Brief

The CREATES Act would address REMS abuse by creating a legal pathway for generic manufacturers to sue brand sponsors for not providing product samples.

THE ISSUE

Risk Evaluation and Mitigation Strategies (REMS) are drug safety programs required by the Food and Drug Administration (FDA) to ensure the safe use and distribution of certain drugs and biologics that have a high risk of serious side effects. REMS programs can require a manufacturer to communicate directly with patients or providers about a drug's risk and its appropriate use, or incorporate elements to assure safe use (ETASU), which are more extensive and can require limited distribution chains.¹

Brand manufacturers may use REMS programs, particularly ETASU, to deny generic manufacturers access to product samples needed for equivalence testing.² This effectively blocks lower-cost generics from entering the market, which drives up costs for patients, employers, and taxpayers.

THE EVIDENCE

Currently, 76 products have a REMS program and about two-thirds use ETASU.³ Given the revenues generated by some of these products, the incentives for abuse are high. For example, Celgene accounts for 31 (nearly 20 percent) of total inquiries from companies wanting samples of its multiple myeloma drugs Revlimid, Pomalyst, and Thalomid.⁴ By blocking access to product, Celgene has been able to earn more than \$200 million annually for Thalomid and \$4 billion annually for Revlimid.⁵

In an effort to shine more light on the potential for abuse, the FDA recently published a list of 54 brand products for which it says manufacturers refused to give generic drug developers product samples.⁶ Across all of these products, the agency received 173 inquiries from generic drug developers that seek FDA assistance in obtaining drug samples.⁷ Overall, it is estimated that REMS abuses cost the US health care system \$13.4 billion annually by delaying generic entry.⁸

\$4B

Annual revenues for Celgene's multiple myeloma drug Revlimid, one of the most cited drugs for blocking access to samples

54

The number of brand-name drugs that, according to the FDA, refuse to give generic drug developers product samples

\$13.4B

What REMS abuse cost the US health care system annually by delaying generic entry

THE SOLUTION

The CREATES Act (H.R. 965) would create a legal pathway for generic manufacturers to sue brand sponsors for damages lost by not providing product samples.⁹ While generic sponsors can sue brand manufacturers currently, as Mylan did in 2014, the process is cumbersome and requires a high burden of proof to establish that anticompetitive behavior took place. H.R.965 also would allow generic sponsors to create a separate REMS program, eliminating the often slow and complicated negotiation process when generic and branded products have to share the same REMS systems. The bill would establish a narrow pathway and would provide an efficient means of litigating this issue which is likely to deter brands from withholding product.¹⁰ CBO found that H.R. 965 would decrease the deficit by \$3.9 billion over the next 10 years.¹¹

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¹ <https://www.fda.gov/Drugs/DrugSafety/REMS/ucm592636.htm>

² https://accessiblemeds.org/sites/default/files/2018-09/REMS_WhitePaper_September2018%5B2%5D.pdf

³ <https://www.accessdata.fda.gov/Scripts/Cder/Rems/index.cfm>

⁴ <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/reference-listed-drug-rld-access-inquiries>

⁵ <https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away>

⁶ *Supra* note 4.

⁷ *Ibid.*

⁸ https://accessiblemeds.org/sites/default/files/2018-09/REMS_WhitePaper_September2018%5B2%5D.pdf

⁹ <https://www.congress.gov/bill/115th-congress/senate-bill/974/text>

¹⁰ <https://www.heritage.org/testimony/the-creates-act-ending-regulatory-abuse-protecting-consumers-and-ensuring-drug-price>

¹¹ <https://www.cbo.gov/publication/55226>