



## FDA commissioner to drug middlemen: You're part of the problem

- The Food and Drug Administration has approved nine biosimilars, generic versions of biologic medicines, but only three are available in the U.S.
- Drug manufacturers are using several schemes to "hamstring biosimilar competition," FDA Commissioner Scott Gottlieb said. He added he worries pharmacy benefit managers have been "complacent participants" in them.
- Gottlieb delivered his remarks at the Pharmaceutical Care Management Association's PBM Policy Forum.

[Angelica LaVito](#) | [@angelicalavito](#)

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Dr. Scott Gottlieb, commissioner of the Food and Drug Administration

Drugmakers may not be the only ones keeping less-expensive drugs off the market.

[The Food and Drug Administration](#) has approved nine biosimilars, generic versions of biologic medicines, but only three are available in the U.S.

Manufacturers are using several schemes to "hamstring biosimilar competition," FDA Commissioner [Scott Gottlieb](#) said at the Pharmaceutical Care Management Association's PBM Policy Forum, according to [a copy of his prepared remarks](#).

He added that he worries pharmacy benefit managers have been "complacent participants" in the schemes.

Pharmacy benefit managers are companies that control which drugs are covered and negotiate discounts on branded drugs with manufacturers. In some cases, restrictive contracting, rebating and distribution agreements deter biosimilars from being covered and reimbursed, Gottlieb said Thursday in a speech to an audience of PBMs.

"While such schemes may have the immediate impact of reducing the costs of these therapies, the net result is a lopsided playing field that disincentives biosimilar developers from making the sizable investment in bringing such products to market. I am concerned this will lead to reduced competition in the long-run and unsustainable costs for these treatments," Gottlieb said in his prepared remarks.

PBMs and insurers may stick with branded biologics because they receive discounts from manufacturers on these treatments. That can leave consumers paying for costly treatments when less-expensive ones are available while PBMs make more money on these discounts, known as rebates.

"Many of these practices persist because high list prices enable lucrative returns across the drug supply chain as the spread between list and net price is carved up and shared among participants," Gottlieb said in his prepared remarks.

"It's easier to log profits this quarter than to think about what the market will look like in two years' time or five," he said.

PBMs have become an increasingly popular target for their role in rising drug costs. Manufacturers say these middlemen pocket rebates they give them instead of sharing them with customers and reducing patients' out-of-pocket costs. Critics blame the opaque system for preventing people from knowing much about how PBMs operate.

A PCMA spokesman responded to Gottlieb's prepared remarks in a statement to CNBC:

Pharmacy benefit managers (PBMs) have long been strong supporters of bipartisan legislation that would prevent brand drug manufacturer abuses of risk evaluation and mitigation strategies (REMS) that block generic competition. Allowing generic and biosimilar drugs to get to market more quickly will reduce overall drug costs.

A broad group of other stakeholders support this legislation, including the Association for Accessible Medicines, the Academy of Managed Care Pharmacy, Public Citizen, and Blue Cross Blue Shield Association.

Gottlieb has not been shy about his thoughts on how different players in the health-care system are contributing to rising drug prices. [His message](#) last month to health insurers: You're doing it wrong.

Thursday, he applauded insurers who have recently pledged to pass manufacturer's drug rebates directly on to some of their members. Both [Aetna](#) and [UnitedHealth Group](#) said last month they would do so for fully insured members.

"This is a bold action that will help create a fairer, more transparent market," Gottlieb said in his prepared remarks. "I hope that other insurers, employers, and manufacturers follow their lead. I also hope that your industry will continue to innovate to make it more transparent to pass along these rebates."