

December 17, 2019

The Honorable Jim Wood, DDS  
Assemblymember, 2<sup>nd</sup> District  
State Capitol  
P.O. Box 942849  
Sacramento, CA 94249-0002

Dear Assemblymember Wood,

Innovation is the driver of the California economy. From high-tech to bio-tech, our state is making the investments in technological and medical advancements that will define the 21<sup>st</sup> Century. At the same time, healthcare is the fastest-growing sector of the California economy. A strong economic future is increasingly dependent on the healthcare sector and it is critical that the state and federal government continue to invest in policies that will help business grow jobs and fairly compete in this sector.

Unfortunately, there is a practice currently in place affecting the pharmaceutical market that is stifling innovation and potentially denying patients new and more effective drugs. Certain pharmaceutical companies are gaining an unfair advantage in the healthcare market through contracts often referred to as rebate walls or a rebate trap.

Rebate walls work like this: A drug manufacturer that has established a dominant position in the market, say with a blockbuster drug, provides to payers (pharmacy benefit managers, health insurers and providers) conditional rebates and discounts off the list price for a multi-product bundle of drugs or indications. The drug manufacturer uses the bundled rebate to protect its already established position with the payers.

While the word “rebate” is often synonymous with a benefit, research suggests that these rebate walls could actually be increasing the cost of prescription drugs and dissuading other manufacturers from making investments into new branded and biosimilar drugs since they will not be able to bring them to market.

Rebate walls also take the doctor out of the decision-making process; a patient may not have access to the best, newest and most effective drug because of one company’s monopoly.

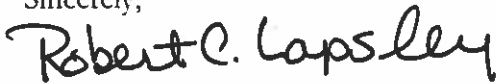
Competition is critical in the innovation market. All pharmaceutical manufacturers should have the right to compete in a free and fair market. This not only helps push the innovation envelope, driving new and better treatments, but it also helps bring down costs as all companies compete equally in the marketplace.

Rebate wall contracts have not been widely discussed at either the state or federal level. We strongly encourage you and other leaders in the state pushing for lower drugs costs and better access to care, including those listed on this letter, to take a closer look at this issue in 2020. Additionally, since pharmacy benefit managers (PBMs) play a critical role in the rebate wall discussion, we are hoping the taskforce you helped establish can look into this issue as part of its ongoing research and discussions.

California could one again be a national leader in the healthcare debate should you or other state regulators choose to engage on this important issue. No other state has taken a closer look at the rebate wall practice and the federal government, including Senator Kamala Harris, are just beginning the investigative process.

Thank you in advance for your consideration of this important matter. I am happy to discuss the issue with you or your staff at your earliest convenience.

Sincerely,



ROBERT C. LAPSLEY  
President

cc: The Honorable Gavin Newsom, Governor  
The Honorable Xavier Becerra, Attorney General  
The Honorable Ricardo Lara, Insurance Commissioner  
Members, Assembly Health Committee  
Ms. Elaine Howle, California State Auditor

Enclosure

# STAT

## **Drug ‘rebate walls’ should be dismantled by the FTC’s antitrust arm**

By DAVID BALTO

<https://www.statnews.com/2018/12/04/ftc-dismantle-drug-rebate-walls/>

DECEMBER 4, 2018

While policymakers are giving considerable attention to escalating drug prices and ways to rein them in, the Federal Trade Commission needs to use its muscle by opening antitrust investigations and bringing enforcement actions against pharmaceutical manufacturers where necessary.

It can start by addressing a questionable contracting practice in the pharmaceutical industry known as a rebate wall or rebate trap. Although “rebate” sounds like something that should benefit consumers and result in lower prices, there is increasing evidence that rebates from pharmaceutical manufacturers to pharmacy benefit managers and others have actually inflated the price of drugs and stifled the ability to compete by rival manufacturers of less expensive drugs to compete.

As Robin Feldman wrote in the Washington Post last week, “the system contains odd and perverse incentives, with the result that higher-priced drugs can receive more favorable health-plan coverage, channeling patients toward more expensive drugs.”

Rebate walls work like this: A drug manufacturer that has established a dominant position in the market, say with a blockbuster drug, provides to payers (pharmacy benefit managers, health insurers, and providers) conditional rebates and discounts off the list price for a multi-product bundle of drugs or indications. The drug manufacturer uses the bundled rebate to protect its already established position with the payers. As Feldman put it, “the name of the game is volume. The more volume a drug company has with a particular PBM or hospital, the better deal it can offer as a temptation to exclude rival drugs.”

Naturally, the payers pocket the rebates in an effort to maximize revenue streams without passing all of the discounts they receive on to consumers. As Nicholas Florko and Ed Silverman noted in their recent STAT article on biosimilars, conditional discounts to a payer on a portfolio of drugs creates a rebate trap because if the payer was to purchase a competing drug, it would lose its discounts on the entire portfolio of drugs.

Both the Trump administration and the industry recognize this practice as anticompetitive. Earlier this year, Department of Health and Human Services Secretary Alex Azar told the Senate Health, Education, Labor, and Pensions Committee, “I am very much aware that these rebate walls can prevent competition and new entrants into the system. ... I do not like that practice. I think it’s using their market power in ways that are not appropriate. I want to make sure we are looking at that. I think Congress could look at that question as part of this whole initiative.”

Vas Narasimhan, chief executive officer of Novartis, has called for action, stating that “we need to tear down the rebate wall and create better contracting models that help patients access” cost-saving treatments. Several major drug manufacturers, including Pfizer and Shire, have filed antitrust suits challenging rebate walls as antitrust violations.

The rebate wall practice relates to how branded drug manufacturers get on payers’ preferred drug formularies. In theory, these rebates could have a positive impact if they benefited consumers through lower prices. But in practice this is simply isn’t the case. These deals are often structured in ways that handcuff payers so they can’t choose a lower-cost drug or a better one.

This is illustrated by the Pfizer and Shire cases. Because of rebate walls, Pfizer was unsuccessful in marketing Inflectra, a lower-cost immunosuppressive biosimilar used to treat Crohn’s disease, rheumatoid arthritis, and other conditions. It was in competition with Johnson & Johnson’s Remicade. The rebates for Remicade were allegedly bundled with other Johnson & Johnson products, which disincentivized insurers from reimbursing for Inflectra and providers from purchasing Inflectra or other biosimilars. Shire was unsuccessful in penetrating the Medicare Part D market with Xiidra, used to treat dry-eye disease, which by all accounts is a better alternative than Allergan’s Restasis. Allergan’s rebates on Restasis were bundled with a broader portfolio of drugs so Medicare Part D plans lacked the financial incentives to purchase Xiidra instead of Restasis.

Related: Rush to end drug rebates may be bad for patients, payers, and pharma  
Rebate walls distort the workings of the free market, result in higher drug prices, and reduce patients’ access to affordable branded drugs.

Rebate walls are particularly insidious because incumbent drug manufacturers — those that have dominant positions with a drug that has been in the market for years — enter into exclusionary contracts and structure rebates among a wide set of their products or indications to limit competition from new rival branded drug manufacturers that cannot provide the same range of products or indications in a bundled rebate.

By extending rebates to several products or indications, a firm is effectively penalizing a payer that chooses an alternative innovative branded drug. In other words, when a rebate wall is erected, payers simply do not have the economic incentive or ability to switch to a new and improved rival drug that provides a more cost-effective treatment. Why not? Because the monetary penalty for doing so — losing their rebates not only on the incumbent branded drug but on all the products or indications with which the rebates are bundled — is too high.

Some payers have claimed that the rival branded drug could be provided for free and the numbers still would not justify switching. Ultimately, rebate walls tie payers’ hands so they cannot choose a less expensive or more effective product. In addition to hurting patients directly, rebate walls raise the cost of health care.

We need tangible action to avert such mischief designed to protect monopoly positions by drug companies that provide no benefit to patients but serve only to increase profits for drug companies and payers alike.

The FTC is uniquely equipped to investigate, demand answers, and push for change to stop contracting practices that increase the cost of care and reduce access to more affordable and

effective treatments. Given the competitive risks posed by rebate walls, the FTC should immediately address this suspect contracting practice by opening investigations into exclusionary rebates, multi-product and indication rebates, and conditional pricing discounts. Doing so can help tear down the rebate wall and allow new drugs open and fair access to the market and consumer access to cost saving treatments. If the FTC discovers that the alleged pricing practices are having an anticompetitive, exclusionary effect, it should bring its own enforcement actions.

Appropriately targeted investigations by the FTC are essential to protecting competition in prescription drug markets.

David Balto is a public interest and antitrust lawyer who served as the policy director of the Federal Trade Commission's Bureau of Competition in the late 1990s, where he helped design and implement the commission's pharmaceutical enforcement program. He now advocates for consumer groups on health care competition issues.