

# The White House's Drug Pricing "Blueprint"

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On May 11, 2018, the White House released the President's "Blueprint to Lower Drug Prices" (the "Blueprint"). Because President Trump and members of the administration have made strong statements about the need to reduce prescription drug prices, many in the pharmaceutical industry were worried about the types of drug pricing proposals the administration would release. At least for now, however, the Trump administration has eschewed a more heavy-handed approach to drug pricing, such as price controls or allowing the Centers for Medicare & Medicaid Services ("CMS") to negotiate the purchase of all drugs for the Medicare program. Instead, the Blueprint focuses in large part on promoting competition and altering misaligned incentives. In the aftermath of the announcement, the stock price of many drug companies and other healthcare companies such as pharmacy benefit managers ("PBM"s) rose. It remains to be seen, of course, whether or not the proposals will be implemented, whether through new regulations or other authorized agency action, or through the enactment of new legislation.

We address key elements of the Blueprint below, focusing on significant proposals affecting the Food and Drug Administration (the "FDA") and CMS.

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## FDA-RELATED PROPOSALS

The Federal Food, Drug, and Cosmetic Act (the "FFDCA") does not grant the FDA direct regulatory authority over drug pricing. The Blueprint, however, includes several initiatives that the FDA is already implementing with the aim of promoting competition and thereby indirectly reducing drug prices. These measures include:

- **Facilitating development of biosimilars.** Scientific advances have resulted in the increased development and marketing prominence of biologics. Biologics are chemically complex, long-chain molecules, and are therefore more challenging to produce than most small-chain synthetic drugs. After the applicable patent and exclusivity periods expire, pursuant to the Biologics Price Competition and Innovation Act of 2009, biologics may be subject to competition from lower-cost

“generic” versions (known as “biosimilars”). The FDA is working on facilitating the development of biosimilars and educating providers, consumers and payors regarding applicable regulatory pathways and their overall availability.

- **Facilitating approval of Abbreviated New Drug Applications (“ANDA”s).** The FDA has expressed concern about innovators allegedly misusing the Risk Evaluation and Management Strategies (“REMS”) process to prevent generic drug companies from obtaining necessary drug samples for testing purposes. Pursuant to the REMS process, safety and mitigation strategies are implemented for drugs that potentially present serious risks. The REMS process sometimes will involve limitations on how a drug can be prescribed or distributed. As a result of such restrictions, generic manufacturers may be unable to obtain drug samples in certain situations. Without such samples, generics cannot conduct the bioequivalence testing that is required to file ANDAs. The Blueprint does not specify how the FDA plans to address this issue. On May 17, 2018, the FDA publicly released a list of approximately fifty innovator drugs for which the agency received complaints that the manufacturer was allegedly prohibiting access to drug samples (thereby purportedly impeding competition from generic drug companies). FDA stated that this unprecedented step was taken “because we believe greater transparency will help reduce unnecessary hurdles to generic drug development and approval.” Critics contend that public shaming in the guise of “transparency” may not have the effect FDA is intending.

Some members of Congress introduced the Creating and Restoring Equal Access to Equivalent Samples (“CREATES”) Act to address this issue. In sum, this statute would allow generic companies to file suit against innovators in certain circumstances if innovators did not provide generics with the drug samples they needed for testing purposes. Innovators could face large fines if they were found to have violated the statute. The CREATES Act has been strongly opposed by the innovator pharmaceutical industry and is not mentioned in the Blueprint.

- **Accelerating development of Over-the-Counter (“OTC”) drugs.** Many drugs that do not require a prescription are sold pursuant to OTC drug monographs developed as part of the OTC Drug Review. OTC drug monographs specify the ingredients, claims, warnings, and other aspects of an OTC drug that, if implemented, authorize the drug for marketing in the absence of a new drug application. In other words, an OTC drug monograph is the equivalent of a “recipe book” for specific OTC drugs.

The OTC monograph process, however, has not been appreciably updated since the 1970s, and the FDA believes many aspects of the process are antiquated. The FDA and industry players are working with Congress on new monograph legislation. In one of its most recent iterations, this proposed legislation would, among other things, (i) impose user fees on manufacturers of OTC drugs; these fees would fund the FDA’s

review of applications to approve new monographs or change existing ones; (ii) accelerate the process for changing OTC drug labeling; and (iii) provide a period of exclusivity to companies that, among other things, receive FDA approval to add a new active ingredient to an OTC monograph.

***Communications between drug companies and payors.*** As a general rule, federal law prohibits drug manufacturers from promoting drugs for uses other than those on FDA-approved labeling. The Blueprint alludes to a proposal by Commissioner Gottlieb indicating that it may be appropriate for pharmaceutical manufacturers to provide information to payors about potential off-label uses for their drugs if those off-label uses can result in cost savings. The FDA has not yet issued a guidance document addressing this subject.

The Blueprint also includes a new proposal: an FDA review of the potential mandatory inclusion of drug prices in direct-to-consumer (“DTC”) drug advertising. Alex Azar, Secretary of the Department of Health and Human Services, recently argued that, from a perspective of “fair balance” in DTC advertising, consumers should be told how much drugs will cost them. The Blueprint, however, does not provide any further details regarding this proposal. In particular, it does not address the challenging question of determining what is meant by a drug’s price. Consumers typically do not pay the drug’s list price. Unlike OTC drugs, the price paid by consumers for prescription drugs is dependent on a variety of factors, including (i) whether the consumer has a high-deductible insurance policy and/or a prescription drug deductible, (ii) which tier of the formulary the drug is placed on, and (iii) the size of the co-pay for the applicable drug. Price may also vary because of other factors including geographic region and pharmacy. Thus, there is no standard price that is paid by consumers.

The Blueprint’s proposal to include prescription drug prices in DTC advertising also fails to address the impact of such a policy on price flexibility and the potential unintended consequences that may result if drug companies were precluded from lowering prices during the course of an advertising campaign. In addition, the Blueprint does not address contentious legal issues that may emerge, including issues implicating the First Amendment and the FDA’s authority to require price disclosures under the FFDCA. Finally, this proposal would have no relevance to many of the highest-priced orphan drugs, which are aimed at a very small population and therefore are often not widely advertised.

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## CMS-RELATED PROPOSALS

- **Medicare Part D.** Medicare Part D provides coverage for outpatient prescription drugs. Part D plans are administered by private insurers, who employ PBMs to develop a formulary of drugs that are covered under the plan. The Blueprint includes several proposals that would facilitate the ability of Part D plans to manage prescription drug costs. For example, the Blueprint raises the concern that Part D plans are not currently able to negotiate prices for drugs in the six “protected classes.” Part D formularies must cover all drugs in these classes because they are vital to treating certain conditions. The Blueprint proposes giving Part D plans “full flexibility” to manage the cost for such drugs, but it does not state how the administration plans to accomplish that objective.
- **Medicare Part B.** Part B covers drugs that are administered in outpatient clinical settings. Part B covers many high-cost specialty drugs that treat conditions such as cancer, blood disease and ophthalmological disorders. Part B drugs are reimbursed based on a formula dictated by law. That is different than Part D, where PBMs generally can decide which drugs are included on formularies (outside of the protected classes) and drug manufacturers may have to offer rebates to be included on the formularies. The Blueprint suggests that some unspecified prescription drugs might be shifted from the Part B to the Part D program.
- **Value-based pricing.** The last decade has seen increased interest in tying the level of healthcare reimbursement to the value of the healthcare services or drugs provided.

The Blueprint proposes that CMS develop value-based pricing models for prescription drugs—but it does not identify the types of criteria that could be used as the basis for value-based pricing. There are multiple value-based pricing models that could be implemented, and it remains to be seen whether it becomes commonplace, for example, for drug and healthcare companies to make reimbursement contingent on satisfying a performance metric in individual patients (or cohorts of patients).

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## PHARMACY BENEFIT MANAGERS

The Blueprint reflects the view that PBMs have contributed to rising drug prices. PBMs often condition the placement of a drug on their formularies on the manufacturer’s willingness to offer a sizeable rebate off the drug’s list price. PBMs often keep a portion of the rebate as compensation. This practice could be seen as encouraging high list prices and large rebates, although PBMs cite procompetitive benefits associated with their services.

The Blueprint raises the prospect of imposing a fiduciary obligation on PBMs to act in the interest of patients. Separately, Commissioner Gottlieb raised the possibility that the government could consider eliminating the “safe harbor” under the Anti-Kickback Statute for drug rebates. Were that to happen, it might become impossible for drug companies to continue offering rebates for drugs whose purchase was subsidized by the federal government.

The healthcare marketplace, however, is in flux and may already be in the process of addressing the market impact of PBMs. In recent years, private insurers have been merging with PBMs, including (i) UnitedHealth’s purchase of Catamaran in 2015; (ii) the 2017 agreement by CVS (which owns Caremark PBM) to purchase Aetna; and (iii) the 2018 agreement by Cigna to purchase Express Scripts. Moreover, UnitedHealth recently announced that, starting in 2019, it would have rebates passed on to consumers enrolled in fully insured commercial group plans. To the extent there is increased integration between PBMs and health insurance companies, the combined entities may have a greater interest in controlling drug prices.

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## WHAT’S NOT IN THE BLUEPRINT

The Blueprint, like previous pronouncements from the administration on drug pricing, does not contain two of Mr. Trump’s campaign proposals: (i) allowing unregulated importation of prescription drugs from Canada and (ii) allowing CMS to leverage its purchasing power to negotiate drug prices for the Medicare program. It is worth noting that Secretary Azar recently delivered a speech outlining why he believes these proposals are ineffective. According to Secretary Azar, there is no effective way to ensure that the drugs imported from Canada by consumers are safe and not counterfeit. He added that both the Congressional Budget Office and President Obama’s Office of Management and Budget considered the proposal for CMS to negotiate the purchase of all drugs for the Medicare program and determined that it would not generate any savings.

Secretary Azar added that the only way that direct negotiations with drug companies could achieve savings would be for the government to deny certain medications to Medicare beneficiaries or to impose price controls by government fiat. The administration opposes rationing or price controls because it would harm quality and access. However, he warned that the best way for the pharmaceutical industry to keep price controls off the table in the long term was to engage in meaningful negotiations over the price of Part D drugs and to limit increases on drug prices.

Please do not hesitate to contact us with any questions.

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