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Client Alert

Government Matters: FDA and Life Sciences

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Trump Administration Releases 'Blueprint' to Address Drug Prices

On Friday, May 11, the Trump Administration released a 39-page "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" ("Blueprint"). The Blueprint raises in very broad strokes potential Administration strategies to address what is perceived to be a national crisis in drug pricing. It is not, however, draft legislation, regulations, or guidance. At this point, it is nothing more than a series of aspirational proposals, ideas and questions. Inasmuch as the policy direction of the Administration can be gleaned from the questions it chooses to ask (and those it elects not to), however, this is an important document.

The Blueprint identifies four challenges that the Administration sees in the U.S. market for drugs: (1) high list prices; (2) seniors and government overpaying for drugs due to lack of tools with which to negotiate; (3) rising out-of-pocket costs for consumers; and (4) free-riding by foreign governments on American investment in innovation.

The Blueprint groups its potential strategies to address these challenges – rather, sets of questions that suggest potential strategies – into four categories: (1) improve competition; (2) better negotiation; (3) lower list prices; and (4) reduce patient out-of-pocket spending. Many ideas are floated in this document, any one of which could impact manufacturer business models in substantial ways. Taken together, they are an impressive list of (mostly) manufacturer-friendly areas for deeper consideration. We list them below for your reference.

The Administration has a number of vehicles that it could use to implement or foster its reforms. The Blueprint does not identify paths to implementation for any of the proposed strategies. Options include, from least difficult to implement to most onerous: further political rhetoric and pressure; enforcement under the current regime; issuance of executive orders; promulgation of executive agency guidance; notice and comment regulatory reform; and legislative change.

Many proposals remain unclear in both their scope and potential impact. One such suggestion is to modify the discount safe harbor to the Anti-Kickback Statute to challenge PBM and payor rebate arrangements. In

this case, as an example, it is already clear that the discount safe harbor does not protect such arrangements; OIG has indicated that the potentially applicable safe harbor would be the Group Purchasing Organization safe harbor. In the end, we expect that the Administration will use different tactics and approaches to take action on the various Blueprint initiatives, although not all the ideas may actually be implemented.

The Blueprint notes that "HHS is soliciting comments on these and other policies under active consideration." Blueprint at 23. Unlike a traditional proposed regulation published in the *Federal Register*, however, the Blueprint does not specify exactly how stakeholder input is to be provided, or any deadline by which comments must be submitted. This is of a piece with the informal nature of the Blueprint. We recommend that manufacturers with opinions to share consider drafting letters to Secretary Azar. We are, of course, ready to assist you in this exercise, including helping to identify particular proposals that may be more or less successful, as well as industry friendly approaches for implementation.

It is impossible to tell at this point how quickly any of these initiatives might move. We are skeptical that the President and Congress will be able to push a major piece of drug pricing legislation through in this election year. Given the political salience of this issue, however, we would not be surprised if the Administration pushed forward with at least one or two of the proposals before November, such that it could claim that it had taken action before the elections.

The Blueprint does *not* raise for discussion repeal of the noninterference clause in Part D, or reimportation from Canada and other countries, both strategies that candidate Trump appeared to support in 2016. Also importantly, the Blueprint does not float other strategies promoted by Democrats, such as the appointment of a "price gouging" enforcer, or a federal requirement that drugmakers provide written advance justifications for price increases.

Strategies about which questions are posed in the Blueprint include:

IMPROVE COMPETITION

- FDA action to prevent manufacturer "**gaming**" of the regulatory process, including through REMS and distribution restrictions.
- FDA policies to improve the availability, competitiveness, and adoption of **biosimilars**, including improvements to the Purple Book and education of physicians and patients.
- HHS programs to create **incentives to promote affordable pricing** (including a review of the impact of Medicaid Best Price).
- Review the **Affordable Care Act taxes and rebates**, particularly their impact on list and commercial prices.

BETTER NEGOTIATION

- CMS demonstration projects to encourage **value-based arrangements**, including addressing the drug pricing and anti-kickback impediments to adoption.
- Allow **Part D PDPs more flexibility** to (a) adjust benefit design mid-year in the event of price increases, (b) manage high cost drugs, including those in the protected classes, and (c) establish indication-based coverage/payment.
- Identify drugs or classes of Part B drugs for which **savings could be gained by moving them to Part D**.
- Resurrect the Part B **Competitive Acquisition Program** ("CAP").
- A cross-agency initiative to **address drug price disparity** in America and other developed countries ("global freeloading").

- Consider whether savings could be had in adopting **indication-based payment mechanisms**, **long-term financing models**, and **site neutrality strategies** in Medicare and Medicaid.
- Improvements to reports of **national drug spending data**.

LOWER LIST PRICES

- FDA to evaluate if drug manufacturers ought be required to **include "list prices" in direct-to-consumer drug advertising**.
- Increase **public transparency of Medicare and Medicaid pricing** and "hold drug makers accountable" for price increases.
- Review/reconsider/repeal the statutory **cap on Medicaid Unit Rebate Amount** (at 100% of AMP).
- Examine the **fiduciary duties of PBMs**, and PBMs' role in encouraging high list prices.
- Examine the role and impact of **rebates** as a pricing mechanism.
- Incentives or regulatory changes to **restrict the use of rebates**, including revisiting the safe harbor under the Anti-Kickback statute for drug rebates (*e.g.,* removing the discount safe harbor).
- Develop Part D and Part B **incentives** to lower or not increase list prices.
- Consider the inclusion of **PBM rebates in Best Price** (and AMP).
- Review the effect of **copay assistance** on consumer cost and list prices, study the effect of eliminating the copay exclusion from AMP and Best Price, and consider whether federal program beneficiaries ought to be permitted access to copay assistance.
- Seek comment on many aspects of the **340B drug discount program**, including on the rapid growth of the program; the impact of 340B on list and commercial prices; the unintended consequences of the program; the need for explicit general regulatory authority over the program; the effects of reforming the rules governing patient definition, contract pharmacies and child sites; and the effectiveness of current mechanisms for preventing duplicate discounts (both Medicaid and commercial).

REDUCE PATIENT OUT-OF-POCKET SPENDING

- Increase **price transparency** in Part D EOBs.
- Improve **Part D PDP end-of-year statements** on drug price changes and rebates collected.
- Federally preempt and prohibit contracted **pharmacy gag clauses**.
- Develop ways to better inform Part B and Part D beneficiaries about **cost-sharing and lower-cost alternatives**.

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It is clear from the Blueprint and the recent statements of the President, Secretary Azar and Commissioner Gottlieb that this Administration wants to be seen as taking action to reduce drug prices. Their interest appears to be in reducing prices in the abstract (*i.e.*, WAC), and in the actual amounts patients pay at the pharmacy counter. The Administration is willing to look at many strategies both within the immediate governmental sphere of influence (*e.g.*, drug price reporting and reimbursement, requirements for Part D PDPs, FDA policies) and without (*e.g.*, a trade approach to 'global freeloading,' market rules to define the roles of commercial PBMs), while not opening up for discussion some of the more aggressive solutions making the rounds in Washington (*e.g.*, Part D interference, reimportation).

Manufacturers should see the Blueprint as an invitation to engage with policymakers in the Administration and on Capitol Hill. It is clear that none of these strategies are in the least locked-down. King & Spalding would welcome the opportunity to bring our extensive life sciences expertise to bear on your behalf in this important pharma policy exercise.