17 JANUARY 2018

Height Commentary

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Drug Pricing / Pharmaceuticals & PBMs

2018 Brings Opportunities, Minimal Risks for Branded Pharma

THE TAKEAWAY

In 2018, policymakers at the federal and state levels will continue to focus on drug costs. In Washington, we expect the focus to remain on increasing drug affordability for patients by addressing costs added by the drug supply chain. PhRMA will take advantage of this attention—and a presumed next HHS Secretary who was recently a drug company executive—by advancing some of their longstanding policy goals, specifically around reducing the volume of drugs they are required to sell at a discount. We also expect policies and efforts to encourage biosimilar uptake, allow for innovative drug payment models, and reduce the influence of PBMs. However, this will not come without a cost; we think 2018 could be the year for some wrist-slapping. Specifically, federal policymakers will reduce the ability of brand manufacturers to delay generic and biosimilar competition, and state policymakers will continue to implement price transparency requirements that could ultimately lead to federal transparency measures. This report outlines key opportunities and risks for pharma in 2018.

We predicted in 2017 that President Trump's verbal attacks on the pharmaceutical industry would not lead to significant changes for the industry because Congressional Republicans and the pharmaceutical lobby, represented by the Pharmaceutical Research and Manufacturers of America (PhRMA), would be able to maintain a defensive "wall" between the President's populist rhetoric and substantive policy changes.

This proved true, and Congress did not include drug pricing policies as part of Affordable Care Act (ACA) repeal or the FDA User Fee Reauthorization (UFA) legislation. In fact, the pharmaceutical industry and Congressional Republicans have effectively *capitalized* on the drug debate by deflecting its focus from the industry's pricing practices instead to costs added by the drug distribution chain that undermine affordability for patients.

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In 2018, we predict deflection tactics will result in additional scrutiny around drug industry intermediaries with an emphasis on patients' costs, which PhRMA will leverage to advance some of their longstanding policy goals, specifically around the 340B program. Additionally, they will take advantage of presumed next HHS Secretary Alex Azar's understanding of the pharmaceutical industry and his proficiency in the rulemaking process to advance their regulatory agenda.

But this will not come without a (small) cost; we think 2018 could be the year for some wrist-slapping. Specifically, FDA and/or Congress could scale back brand manufacturer's ability to delay access to REMS-protected drug samples needed by generics and biosimilar manufacturers. We also predict additional scrutiny at the state level but not as dramatic as excluding high-cost drugs from Medicaid formularies.

Opportunity #1: Limiting the Scope of a Growing Mandatory Drug Discount Program

Projected Outcome: Congress will develop--and possibly pass--bipartisan legislation to limit the discounts manufacturers are required to give certain hospitals under the 340B drug discount program. The outcome would benefit pharmaceutical manufacturers at the expense of certain nonprofit hospitals.

PhRMA has pursued legislative 340B reform since 2014. This year, we predict Congress will begin to negotiate —and possibly pass—revisions to the program. Because the legislation would need to be bipartisan, we think the most likely outcome would benefit pharmaceutical manufacturers by limiting *growth* of the volume of discounts they are required to provide 340B hospitals. Currently, the 340B statute requires manufacturers to sell outpatient drugs at deep discounts (on average, 22.5% lower than average sales price) to "covered entities" including approximately 45 percent of U.S. hospitals.

The 340B program accounts for 2.6% of the overall prescription drug market, but the number of qualifying hospitals is expected to grow as states expand Medicaid, and future Democratic Congresses could further expand the program as they did under the ACA. Therefore, stemming growth of the number of hospitals that qualify for the 340B program—and/or limiting the types of outpatient drugs subject to 340B discounts—would mitigate a growing threat to pharmaceutical margins. By extension, the outcome would limit a significant revenue stream for 340B hospitals, which received nearly $6 billion in discounts in 2015.

In our view, Congress is likely to act this year because the Administration gave PhRMA leverage to get hospitals to the negotiating table by dramatically cutting hospital reimbursements for 340B drugs by $1.6 billion in 2018. Because the cut reduces what Medicare reimburses hospitals for drugs purchased with a 340B discount, the policy does not directly impact pharma's bottom line—pharma must still sell those drugs at a discount. Rather, the $1.6 billion in reduced reimbursements will be added back to the Medicare reimbursement pool for outpatient services, boosting revenue for for-profit hospitals and other non-340B hospitals.

We think the prospect of legislatively reversing cuts of this scale is enough to bring 340B hospitals and their supporters in Congress to the negotiating table to reform 340B. If that proves incorrect, the Administration has another arrow in its quiver: we anticipate that HHS's expected revisions to the *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*will also be favorable to the drug industry and could further pressure hospitals to the negotiating table. These Administrative actions coincide with the timing of recommendations by the House Energy & Commerce Committee, which include providing statutory changes

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to the program. We expect the changes Congress ultimately agrees to will limit future growth of the program, alleviate a growing threat to pharmaceutical margins.

For more on the 340B Drug Discount Program, see our January 2 report.

Opportunity #2: Reducing Barriers to Uptake of Biosimilars

Projected Outcome: Biosimilars manufacturers will benefit from incremental regulatory improvements to the biosimilars market, but more impactful legislative action is unlikely this year.

Policymakers in Washington will continue to focus on reducing barriers to competition among complex biologic drugs, both through FDA approvals and CMS reimbursement policy. FDA will focus on increasing the number of biosimilars approved for marketing in the U.S. CMS will implement its shift to unique reimbursement codes for each biosimilar. While Congress could help by adjusting Medicare Part D policy, we consider statutory changes unlikely this year and more likely in 2019 and beyond.

- **FDA Action (underway and additional steps are highly likely)** – In 2017, FDA approved five new biosimilars, bringing the total number of biosimilars approved in the U.S. to nine. With 68 biosimilars under development, FDA will have an opportunity to speed the number of approved biosimilars in an effort to improve price competition. As part of its Drug Competition Action Plan, FDA will continue to provide clarity to biosimilars manufacturers around navigating the FDA approval process. FDA will also continue its educational outreach efforts to promote patient and physician understanding of biosimilars to improve uptake.
- **CMS Action (underway)** – In 2018, CMS is implementing a major change to reimbursements for biosimilars under Part B. CMS will now establish a unique billing code with distinct payment rates for each biosimilar instead of calculating a blended rate and grouping all biosimilars with the same reference product under the same Healthcare Common Procedural System ("HCPCS") code. This should allow manufacturers to command a higher price for biosimilars in the short term—providing a stronger incentive to market biosimilars—but as other competitors gain market approval they need to differentiate themselves by competing on price. The interaction of the unique billing code policy with the reimbursement cut for drugs purchased with a 340B discount could incentivize biosimilar uptake. Under the final 2018 OPPS rule, biosimilar drugs are exempt from the ASP - 22.5% policy, and they remain reimbursed at ASP + 6%. Innovator biologics, however, are subject to the reduced ASP - 22.5% rate.
- **Congressional Action (unlikely this year)** – Congress could encourage biosimilar uptake by authorizing changes to the Medicare Part D drug benefit urged by MedPAC. Currently, Part D enrollees and plans must pay higher cost sharing for biosimilar drugs than innovator biologics because biosimilars are exempt from the 50% discount that manufacturers are required to provide on brand-name products. Statutory changes to create greater parity could encourage patient demand for prescription biosimilars. We expect pressure to mount (and the cost savings of the proposal to grow more attractive) as FDA approves more biosimilars.

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Opportunity #3: Reducing barriers to outcomes-based contracting between drug manufacturers and payers

Projected Outcome: Pharmaceutical companies will gain greater regulatory certainty regarding outcomes-based contracting--which will alleviate pressure on them to reduce list prices--due to rulemaking by the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA). We do not expect Congress to provide further certainty through statutory changes this year.

While drug manufacturers are beginning to enter into outcomes-based pricing arrangements (sometimes referred to as "value-based pricing," but the terms have distinct meanings), some companies are avoiding these contracts, citing regulatory barriers. Some drug companies are starting to use outcomes-based contracting to mitigate pressures to reduce list prices or base a drug's price on its actual clinical value (a true "value-based" price), which tends to be lower. Therefore, gaining legal certainty around outcomes-based contracting is a priority for PhRMA.

We think this idea is ripe for movement in 2018. Alex Azar has a background well suited to the task of rewriting CMS and FDA rules to provide regulatory certainty to drug makers around outcomes-based contracting, and we think it is likely HHS will take this up under his leadership (he voiced support for it at his confirmation hearing). The Administration first signaled its support for "clarifying the treatment of value-based purchasing arrangements" in the 2018 Budget, and it was also mentioned in the widely reported leaked Executive Order on Drug Costs in June. Regulatory changes would likely include:

1. Altering pricing policies--including Medicaid "best price" rules, 340B ceiling prices, and Medicare's calculation of average sales price (ASP) for Part B drugs--to carve out outcomes-based contract prices;
2. Off-label promotion regulation and allowing drug makers to communicate with insurers about the efficacy and safety of drugs going through the FDA approval process; and
3. Clarifying that anti-kickback statutes do not apply to outcomes-based contracts

Drug makers are also seeking statutory changes to these policies in order to gain additional certainty. However, we have not yet seen this issue gain traction in Congress, so we do not expect regulatory changes will be paired with statutory changes this year.

One issue we have our eye on is whether—if CMS carves out outcomes-based contracts from "best price," ASP, or 340B calculations—drug makers will be able to "game" the change to reduce the volume of drugs they sell at a discount (or the amount of those discounts) by increasing the number of outcomes-based contracts.

Opportunity #4: Reducing the negotiating power of pharmacy benefit managers (PBMs)

Projected Outcome: Pharma will benefit from the reduced market power of PBMs as they respond to political and market pressures

PhRMA's campaign against the "rent-seeking" behavior of drug intermediaries put PBMs in their cross hairs in 2017. While we do not expect scrutiny of PBMs to disappear in 2018, we do expect it will subside as PhRMA shifts focus to the hospital industry's role in marking up drug prices.

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But on PBMs, the majority of the damage has been done: Congress questioned their business model in several hearings, and CMS proposed a rule that may eventually require PBM rebates to benefit patients more directly. However, in our view, these efforts will not result in actual policy changes. For one, Congress has not coalesced around a legislative solution. Second, the proposal on which CMS is seeking comment would raise Medicare Advantage premiums, increase Medicare expenditure, and go into effect in 2020 at the earliest—hardly an attractive or immediate solution.

In our view, this scrutiny, combined with managed care organizations' (MCOs) increasing skepticism of PBMs' value, has standalone PBMs looking to diversify. **CVS**, of course, is attempting to acquire insurer Aetna (**AET**), and Express Scripts (**ESRX**) is positioning itself as open to collaboration with Amazon (**AMZN**) or others. We also have our eye on another potential acquisition target: Diplomat Pharmacy (**DPLO**), a specialty pharmacy that recently acquired a PBM.

As Anthem (**ANTM**) prepares to become the fifth of the eight publicly traded MCOs to operate its own PBM, shifting covered lives away from current PBM ESRX, we see PBM market power eroding. As a result, PBMs' market power to negotiate large rebates should be reduced, which should lessen the need for pharmaceutical companies to increase list prices. In his confirmation hearing, Azar said he would like to reverse pharma's incentives to increase list prices; collapsing PBM rebates is a step toward that goal.

One longer-term policy opportunity we are tracking is the introduction of a PBM-like negotiating structure to Medicare Part B drugs. Currently, Part B drugs are reimbursed at ASP + 6%, but MedPAC recommended developing a drug value program whereby a small number of private vendors would contract with Medicare to negotiate prices for Part B products. Alex Azar hinted at support for considering this idea at his confirmation hearings. It could wind up being the Trump Administration's alternative to the Obama Administration's jettisoned Part B drug demonstration.

Risk #1: Fostering Generic Competition to Innovator Drugs

Projected Outcome: The FDA will continue to approve generic drugs at a record pace, and branded pharma's ability to "game" market exclusivity will be scaled back.

As an alternative to government price controls, Republicans favor "market-based" competition from generic drugs to bring down drug costs. FDA Commissioner, Scott Gottlieb cites promoting drug competition as a continuing priority for 2018, and Alex Azar said that, in his role as HHS Secretary, he would focus on a "robust generic market." Additionally, Congress incorporated modest policies to increase the generic drug approval pipeline into User Fee Amendments legislation enacted in August 2017. In 2017, the FDA recorded the highest ever number of generic approvals (1,027), and they expect to break this record in 2018 if current generic application trends continue.

Gottlieb, Azar, and bipartisan members of Congress have also targeted "gaming" of exclusivity and patents by branded drug companies as a priority, specifically REMS-protected drugs. We believe regulatory changes, which would be less impactful than statutory changes, are more likely to be implemented this year than robust legislative changes.

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- **Administrative Action on REMS (highly likely; lower impact)** - We expect the FDA to issue additional guidance in 1Q2018 about circumstances under which the FDA will waive shared REMS requirements, incrementally benefiting generics manufacturers because it would likely speed the marketing of an approved generic or biosimilar drug.
- **Legislative Action on REMS (possible; high impact)** - A more impactful policy change would be to help generic manufacturers access innovator drug samples in order to test bioequivalence required for FDA approval; drug manufacturers often block access to samples, citing safety reasons. The bipartisan CREATES Act would allow the FDA to authorize generic companies to purchase product samples, and allow generic companies to sue branded manufactures for blocking access. We place moderate odds of Congress passing the CREATES Act this year—it saves $3.3 billion and could be modified into something PhRMA could live with—and are looking to other healthcare legislation or "must-pass" funding bills as vehicles. *For more on REMS-restricteddrugs, see our June 2017 report.*

Risk #2: State-Level Efforts to Limit Drug Spending

Projected Outcome: Additional states will pass drug price transparency measures, laying the groundwork for a federal drug transparency law. CMS will not grant waivers to state Medicaid agencies to exclude drugs from their formularies.

Following successful passage of bipartisan drug price transparency legislation in California in 2017, we expect additional states to take up and pass similar bills. California's new law requires drug makers to notify purchasers and provide an explanation of drug price increases of 16 percent or more over a two-year period. The legislation also requires health insurers to report a list of the 25 drugs with the highest annual spending and the highest year-over-year increase in total spending. In response, PhRMA filed a lawsuit challenging the constitutionality of the new law; however, we expect legislatures to consider similar legislation as they seek to put downward pressure on state drug spending. In 2017, at least 63 transparency bills were filed in state legislatures, and drug price transparency legislation was more likely to pass in 2017 than previous years. We believe this momentum will continue in 2018. Investors should note that this could pave the way for federal-level transparency legislation on a three-to-five year timeframe. As pharma is required to comply with different state requirements, they will prefer a federal law that preempts the patchwork of state legislation.

Additionally, states including Massachusetts and Arizona, will not succeed in securing Medicaid waivers to exclude certain drugs from their formularies. PhRMA and Congressional Democrats oppose this fiercely. Additionally, CMS Administrator Seem Verma threw cold water on the idea.

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COMPANIES MENTIONED IN THIS REPORT

Aetna Inc (AET), Amazon.com Inc (AMZN), CMS Energy Corp (CMS), CVS Health Corp (CVS), Anthem Inc (ANTM), Express Scripts Holding Co (ESRX), Diplomat Pharmacy (DPLO)

RISKS

The legislative and regulatory agendas are subject to change at the discretion of leadership. Unprecedented economic conditions could instigate unanticipated and/or sweeping shifts in policy. Predicting the future is a hazardous endeavor and economic / market forecasting is an imprecise science. Actual outcomes may differ substantially from our forecasts. The predictions and opinions expressed herein are subject to change at any time.

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