Insight

How Congress Is Attempting to Lower Drug Costs

TARA O'NEILL HAYES | JULY 16, 2019

Executive Summary

- Multiple Senate and House committees have been working for months on legislation to bring down drug costs, almost exclusively by either directly or indirectly increasing competition.
- The bills take three broad tacks: Some seek to end tactics that prevent competitors from entering a market, some aim to increase transparency around pricing practices, and some look to reduce the costs of developing new drugs.
- While there is still some disagreement, these bills generally have bipartisan support.

Introduction

Multiple Senate and House committees have been working for months on legislation to bring down health care costs. The array of policies discussed here all relate to drug pricing and aim to do a variety of things: spur competition and stop anti-competitive behavior, increase transparency around drug prices and costs to various stakeholders, penalize drug makers whose prices are deemed to be too high or increasing too quickly, and reduce the cost of developing new drugs.

Below are explanations and analyses of the policies in several recent bills. The policies discussed here are included in: S. 1895, The Lower Health Care Costs Act, passed by the Senate Health, Education, Labor, and Pensions (HELP) Committee; H.R. 2296, the More Efficient Tools to Realize Information for Consumers (METRIC) Act, passed the House Energy and Commerce (E&C) Subcommittee on Health; and four bills (S. 1416, S. 440, S. 1227, and S. 1224) passed by the Senate Judiciary Committee. Most of the bills included in H.R. 2296 have also been considered and passed by the House Ways and Means Committee.

Attempts to Spur Competition

Perhaps the largest focus of these bills is on increasing competition among drugs, particularly by encouraging the development of generics. Higher competition typically puts downward pressure on prices while giving consumers greater choice.

CREATES Act: One long-awaited provision in the Senate HELP Committee's bill (S. 1895) is the CREATES Act, which is intended to bring generic drugs to market more quickly. An increasing number of drugs are being developed that require the use of safety protocols, known as Risk Evaluation and Mitigation Strategies (REMS), due to the potential or known serious health risks associated with exposure to the drugs. As explained here, REMS protocols may be used by brand-name drug manufacturers to block or delay the entry of a generic competitor by impeding the generic manufacturer's ability to obtain enough samples of the brand-name drug to prove their product's bioequivalence to the reference product. The CREATES Act will allow generic and biosimilar manufacturers to sue brand-name manufacturers if they fail to provide sufficient samples in a timely manner.

New FTC Authorities: A Senate Judiciary Committee bill (S. 1416) would also try to limit anti-competitive practices. First, the Federal Trade Commission (FTC) would be authorized to file suit against a manufacturer of an innovator product if: (1) the manufacturer, just before generic market entry, withdraws an existing drug's approval and markets a follow-on product; or (2) the manufacturer takes an action to "unfairly disadvantage" the original drug relative to the follow-on drug and impedes competition from a generic or biosimilar manufacturer. Second, drug manufacturers would only be able to assert 20 patents, and no more, in a suit against a competitor market entrant that the manufacturer alleges is infringing on its patent rights.

These provisions are intended to address behaviors that some have accused brand-name manufacturers of engaging in to block competition by continuously extending their patent protections. One example, known as "evergreening," refers to the practice of making a small tweak to a drug (and earning a new patent) shortly before a generic competitor may enter the market and subsequently voiding approval of the original drug. The manufacturer can then market the "new" drug and extend their exclusivity via the newly obtained patent. And because the original drug's approval was voided, a generic manufacturer can no longer rely on the original drug's clinical trial studies showing it's safe and effective for expedited approval through the generic pathway; the generic manufacturer would have to go through the full approval process for a new brand-name drug. Drug makers are also said to thwart competition by earning as many patents as possible, making it difficult for another manufacturer to bring a similar drug to market.

Clarifying Exclusivity Rights for New Chemical Entities: Another proposal intended to address the issue of evergreening is one included in the Senate HELP Committee's S. 1895, which would reverse a recent Food and Drug Administration (FDA) policy change and again limit five-year exclusivity only to drugs containing no previously approved chemical entity. Current law provides manufacturers five years of market exclusivity for new chemical entities. Originally, FDA interpreted this law to apply only to products which contained no previously approved active chemical entity. Then, in 2018, FDA issued new guidance allowing fixed-combination products to receive the full five years of exclusivity if the product contains a new chemical entity, even if it also contains a previously approved entity. While some worry this limitation could discourage innovation and product improvements, proponents of the provision argue that current policy has led to evergreening.

New requirements for the Orange Book and Purple Book published by the FDA: The Orange Book lists all drugs approved by FDA, including patent and exclusivity information, as well as all drugs that may serve as a therapeutic alternative for a given drug. The Purple Book is a compendium of all biological products, including biosimilars, approved by the FDA along with the date of approval, whether the product received market exclusivity rights, and if so, the date on which that exclusivity expires. Additionally, all reference products with a biosimilar will cross-reference each other and indicate whether the biosimilar has also been deemed interchangeable. S. 1895 would require drug manufacturers to provide a list of all of their products' patents for which they could reasonably assert a claim of patent infringement. All information must be made publicly available in a single, searchable format online, updated every 30 days.

S. 1895 would also add a new requirement to the rules governing the Orange Book: If a patent has been deemed inoperative or invalid or a patent claim has been cancelled, then that patent information must be removed from the Orange Book. This requirement is intended to encourage development of products in areas no longer patented. Such an invalidation will not, however, impact the exclusivity period of an existing generic for such a drug, so as not to discourage timely development of generic drugs. While some may view these provisions as transparency measures, they are primarily intended to spur competition by making it easier for potential generic and biosimilar makers to better understand the market, how much competition for a given product exists, and when a product's exclusivity period will end.

Citizen Petitions: Reforms to the FDA's Citizen Petition process are included in S. 1895 in an attempt to end the abuse of such petitions to delay the approval of a new drug. Citizen Petitions can be used to request that FDA take a certain action regarding the products it regulates, such as disapproving a drug product application, adding a warning label to a

drug's label, or changing a product from prescription to over-the-counter status. FTC and FDA officials have noted that numerous petitions have been filed with no scientific claim and seem to have the sole purpose of delaying approval of a generic drug. In response, S. 1895 (similar to S. 1224, the Stop STALLING Act, passed by the Senate Judiciary Committee) does three notable things: It provides FDA the authority to deny a petition if the agency determines its primary purpose is to delay approval of an application; it requires the petition to be submitted within 60 days after the petitioner knew (or should have known) the information upon which the petition is based; and it allows the Department of Health and Human Services (HHS) to refer petitioners to FTC for anti-competitive behaviors.

Biologic Competition: Biologic products that are currently technically classified as "drugs" but which will transition to being classified as biologic products in March 2020, such as insulin, will not be able to receive new, extended market exclusivities under S. 1895, although any existing, unexpired exclusivities will be preserved. This categorization change will allow new biosimilar versions of insulin to finally come to market; the current regulations governing insulin have thus far prohibited such competition. The bill also clarifies that manufacturers that submit a biosimilar application under the current approval pathway at least six months in advance of the transition will not have to resubmit their application under the new approval pathway if their application has not been approved by the time the transition takes effect.

Efforts to Increase Transparency

Several provisions seek to increase the amount of information available to patients, doctors, and the government. Disclosing such information is intended to boost competition and improve efficiency.

PBM Oversight: Much attention over the past few years has focused on the pricing and contracting practices of pharmacy benefit managers (PBMs). Little is known about the value of discounts and rebates obtained by PBMs from drug manufacturers, which makes it difficult to know the net cost of drugs and which parties are profiting most from rising drug prices. Section 306 of S. 1895 requires that health insurance plan sponsors (e.g. an employer) receive a report at least every six months from the health insurance issuer or entity providing pharmacy benefit management services detailing a broad array of prescription pricing and utilization data for the enrollees of their plan. PBMs would also be barred from engaging in spread pricing—a practice in which the PBM charges the plan sponsor more for a drug than the PBM paid the pharmacy for dispensing the drug. Similarly, PBMs must, when contracting with a group health plan, pass all rebates and discounts received from a pharmaceutical manufacturer, distributor, or other third party through to the health plan; further, all rebate, discount, and fee data must be made available for audit

by the plan sponsor.

Section 3 of the House Energy and Commerce Committee's H.R. 2296, the METRIC Act, would take this principle even further by requiring pricing information be publicly available. This section mirrors H.R. 2115, the Public Disclosure of Drug Discounts Act, which requires the HHS Secretary to release to the public information regarding PBMs serving Medicare Part D and the aggregate drug manufacturer rebates, discounts, fees, and price concessions they obtain, as well as generic dispensing rates. This bill further requires that this information be provided separately for each PBM. The language does stipulate that the data should be displayed in a manner that prevents the disclosure of information on rebates, discounts, and price concessions at the individual drug or plan level. In order to ensure confidentiality of proprietary information, the information would be required to be aggregated by drug class, but only if the Secretary determines the number of drugs in a class is sufficient to meet the confidentiality requirement. Further, data from a particular year must only be made available after two years have passed.

The Prescription Pricing for the People Act, S. 1227, passed by the Senate Judiciary Committee and included as Section 4 of the METRIC Act (with minor variations following the Judiciary Committee's amendments), also seeks to increase insight into PBM contracting practices by requiring FTC to study the intermediaries in the pharmaceutical supply chain and report on the prevalence of anti-competitive and non-consumer-friendly behaviors. Specifically, FTC would report on the practice of spread pricing, practices to steer patients to particular pharmacies in which the PBM has an ownership interest, the use of formularies to increase use of higher-cost drugs, and whether FTC faces any specific legal or regulatory obstacles in trying to enforce antitrust and consumer protection laws in this field. Last, FTC would make recommendations to Congress as to how to make the market more competitive and transparent and how to help ensure consumers benefit from the discounts and rebates provided to the various industry stakeholders.

Drug Price Transparency: H.R. 2087, the Drug Price Transparency Act, would require drug manufacturers without a rebate agreement in effect for the Medicaid Drug Rebate Program to report average sales price (ASP) information for the purpose of determining the appropriate Medicare Part B payment rate for such a drug. The information provided would be subject to audit by the HHS Office of the Inspector General (OIG) and subject to verifying surveys of wholesalers and manufacturers conducted by HHS. Further, the OIG will be required to submit a report to Congress on the accuracy of ASP data and any recommendations on how to improve it.

Drug Samples: An amended version of H.R. 2064 has also been included in the METRIC Act. This legislation would require drug manufacturers to disclose information on the marketing

samples they give to health care providers. Health care oversight agencies, researchers, and health care payers, including both public and private insurers, would receive this information. Unlike in the original bill, however, the information would not be publicly disclosed.

Empowering Prescribing Providers: Section 7 of the METRIC Act would require providers' electronic health record systems to include particular new tools. These tools would allow providers to access prescription drug information for their patients while making prescribing decisions, including which drugs are on a patient's insurance formulary, the out-of-pocket cost for the drug being considered along with therapeutic alternatives, and whether prior authorization or other utilization management requirements are in place for that drug.

Penalizing High and Rising Prices

One bill specifically targets price increases for drugs.

Justifying Price Increases: The METRIC Act includes a slightly amended version of H.R. 2296, the FAIR Drug Pricing Act, which requires drug manufacturers to report publicly and provide justification for any pending price increases for certain drugs provided to Medicare and Medicaid beneficiaries 30 days prior to the increase. This requirement would be triggered for any drug with a list price of $100 or more if the price is going to increase 10 percent or more in a single year or 25 percent or more within three years.

Reducing Development Costs

A couple of provisions in these bills target the costs of developing and maintaining drugs. Bringing down these costs reduces the pressure for drug manufacturers to raise prices or enter the market at such high price points.

U.S. Pharmacopeial Standards for Biologics: Section 207 of S. 1895 says that biological products will no longer have to comply with U.S. Pharmacopeial (USP) standards. The USP is a non-profit scientific organization that develops and publishes standards, referred to as monographs, regarding the strength, quality, and purity of medicines. Currently, all drugs recognized in the compendia must comply with USP monograph standards, when one exists; if they don't, they will be labeled as adulterated, misbranded, or both, as appropriate. But these standards were developed for small molecule drugs which can be exactly replicated; biological products, in contrast, are complex and variable by nature, and such a standard can be difficult (if not impossible) to meet and may hamper innovation, as explained by the FDA. Eliminating this requirement for biological products will remove a potential market barrier for such products, while not in any way changing the FDA approval process or

standards regarding safety and efficacy.

Allowing for Updated Generic Drug Labels: Drug labels include the indications for which a drug is approved, as well as safety and dosing information. Drug label information must be approved by the FDA, and brand-name drug manufacturers are responsible for keeping labels current; generic manufacturers must use the same label as the brand-name manufacturer. Labeling updates may include new safety information or warnings (which are required if new evidence is found), as well as adding new indications for a drug, although a new indication may only be added if FDA approval for that indication has been granted. After enough time, however, the brand-name drug may no longer be manufactured and thus the manufacturer stops updating the drug's label. The responsibility then falls to the generic manufacturer, but updating a drug's label can be expensive (as just noted, a new indication may only be added after successfully completing the approval process) and there may not be sufficient incentive for the generic manufacturer to do so, unless required by the FDA because it pertains to safety information.

When new uses for a drug are discovered but not formally approved, doctors may prescribe the drug for "off-label" use. Insurers, however, are not required to provide reimbursement for drugs used off-label, which can leave patients on the hook for the full cost of the drug. Off-label use is quite common in cancer treatment.[1] The new authority included in S.1895 would allow the FDA to initiate and require generic manufacturers to update their labels when new scientific evidence regarding use of the drug is available; when there is a relevant accepted use of the drug not reflected in the existing label; or when the label does not reflect current legal and regulatory requirements. This authority will allow generic drug labels to be updated to reflect new uses of drugs, which will increase insurance coverage, without requiring generic manufacturers to endure the expensive approval process.

Conclusion

Several committees in Congress have recently crafted legislation intended to bring down the cost of drugs, almost exclusively by either directly or indirectly increasing competition. The bills that aim to increase competition directly do so primarily by increasing scrutiny of certain tactics sometimes used by first-to-market companies to thwart or delay market entrance by a competing product. Many others would attempt to increase transparency of the pricing practices of manufacturers and PBMs, which aim indirectly to help increase competition. Finally, some of the bills seek to reduce the cost to develop new drugs, which should also indirectly increase competition and hopefully allow the drugs to be provided at a lower price than they otherwise would be if the development costs were higher.

While the nation's health policy woes are numerate, prescription drug costs are a top

concern for Americans. With bipartisan support for many of these bills, this seems to be one area where there is a good chance Congress may very well move forward.

[1] https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/off-label-drug-use.html