Crossing the Political Divide: Senate HELP Committee Hearings on Drug Prices

On December 12, 2017, the Senate Committee on Health, Education, Labor, and Pensions (HELP) held a bipartisan hearing on the cost of prescription drugs. This hearing was the third in a series of Senate HELP committee meetings on drug prices and was held in response to the release of the National Academies of Science, Engineering, and Medicine's report entitled "Making Medicines Affordable: A National Imperative". At the hearing, Senator Murray (D-WA), ranking member of the Senate Health Committee, noted that the price of prescription drugs was one of the primary concerns to her constituency. She commented on Congress' attempt to increase competition in the pharmaceutical industry with provisions of the Food and Drug Administration Reauthorization Act (FDARA). The FDARA, passed in August 2017, accelerates the review of generic applications (abbreviated new drug applications or ANDAs) for which the reference drug has less than three approved generics and for products on the drug shortage list.[1] The FDARA also increased restrictions on drugs seeking exclusivities through an orphan drug designation.[2] Senator Murray explained, however, that these provisions remain inadequate to address the growing concerns about drug prices. She encouraged the committee to "get at root of the problem[, which is] the high prices set by manufacturers," and to prevent gaming of the patent system and anticompetitive practices by pharma companies.[3]

The committee went on to discuss additional actions that Congress could take to target the problem of increasing drug costs, including the recommendations from the National Academies. In its report, the National Academies provides eight recommendations to ensure affordability and availability of prescription drugs:

1. Foster market entry and effective competition of generics and biosimilars
2. Consolidate and apply governmental purchasing power

3. Assure greater transparency of profits in the pharmaceutical supply chain
4. Discourage direct to consumer advertising and financial incentives (payment coupons) from manufacturers to patients
5. Modify insurance benefits to reduce cost-burden for patients
6. Eliminate inefficiencies in federal programs to aid vulnerable populations (specifically the 340B program)
7. Ensure that protections for drugs to treat rare diseases are not extended to widely sold drugs
8. Ensure that reimbursement incentives align with treatment value and that physicians have information about relative clinical benefits and costs of treatments

Each recommendation from the National Academies also includes multiple implementation actions. The report is remarkable because it contains both very specific actions (e.g. remove tax deductions of direct-to-consumer advertising expenses and seek reciprocal drug approval arrangements for generics and biosimilars between the regulatory agencies of the United States and the European Union) and broader policy changes that could revolutionize the way payers reimburse for drugs (e.g. test and refine methods for determining the "value" of drugs and identify approaches to support value-based payments).

Many of the issues discussed in the report have been discussed in detail on the Source Blog. Previous Source articles include discussions about increasing competition of drugs through increased FDA approvals, eliminating ways that innovator companies keep out generic competition with the CREATES Act, how drug companies exploit the Orphan Drug Act, the need to modify physician reimbursement for drugs to be independent of the cost of the drug, and various other ways that branded drug companies attempt to limit competition.

Overall, both the Senate HELP hearing and the National Academies report recognized the need for both targeted solutions to address specific inefficiencies in the pharmaceutical market that limit competition and systematic reforms to ensure that reimbursement policies emphasize value to patients. Both Democrats and Republicans voiced their support for value-based reimbursement, but also

recognized the difficulty in measuring value. Members of both political parties also agreed that policies should promote competition where possible, but that competition won't solve all of the ills of the healthcare system. Sen. Rand Paul (R-KY) acknowledged in addition that intermediaries between the consumer and seller limit competition in most healthcare markets in the U.S.

In his testimony at the hearing, Norm Augustine, editor of the National Academies report and Chair of the Committee on Ensuring Patient Access to Affordable Drug Therapies at the National Academies, urged Congress to act. He asserted that drugs that are not affordable have no value to patients, and drugs that have not been developed can help no one. With nationwide concern about drug prices and bipartisan support, the time is ripe for bridging the political divide to take action. Congress should consider targeted legislation to address specific actions by drug companies that limit competition and more sweeping legislation to encourage value-based payment reform.

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[1] FDARA §801.

[2] FDARA § 607 amending FDC Act § 527 (see 21 C.F.R. § 316.3(b)(3)).

[3] https://www.help.senate.gov/hearings/the-cost-of-prescription-drugs-an-examination-of-the-national-academies-of-sciences-engineering-and-medicine-report-making-medicines-affordable-a-national-imperative