

# The Source Roundup: June 2018 Edition

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Happy June! In this edition of the Source Roundup, we cover five academic articles and reports from April and May. The topics this month include: 1) barriers for generics to lower specialty drug prices, 2) a call to reform pharmaceutical systems in the United States and Canada, 3) efforts by states to stabilize the individual market, 4) Vermont's push for community-driven health care reform, and 5) antitrust lawsuits in the pharmaceutical industry.

## Barriers for Generics to Lower Specialty Drug Prices

The Health Affairs article [\*Generic Price Competition For Specialty Drugs: Too Little, Too Late?\*](#) looks at the pricing and out-of-pocket spending on first-line prescription drug treatments and focuses on the potential barriers to effective generic price competition. Authors Ashley L. Cole and Stacie B. Dusetzina studied the drug Imatinib, one of the most effective cancer treatments. Since its market entry in 2001, the price of Imatinib has increased from \$4,000 to almost \$10,000. Generic price competition has been proposed as a solution for reducing prescription drug spending and increasing drugs' affordability. However, although generic competition entered the market in 2016, prices remain high. There are a few reasons generics struggle to compete with brand-name drugs. First, small patient populations may discourage generic entrants due to limited profitability. Second, generics lack the ability to advertise and promote their products as well as brand-name drugs. Third, regulatory changes by the Food and Drug Administration (FDA) present additional barriers to entry for generic manufacturers as the FDA introduces additional requirements for product testing and production. The authors note that historically, competition from generic drugs has helped drive down the price of brand-name competitors. While this is usually a successful strategy, shifts in pharmaceutical development from drugs used in primary care toward specialty

drugs may present additional barriers to generic competition.

## **A Call to Reform the Broken Pharmaceutical Systems in the United States and Canada**

In [\*Healing an ailing pharmaceutical system: prescription for reform for United States and Canada\*](#), published by BMJ, Adam Gaffney and Joel Lexchin analyze a proposal put forward by a group of doctors, scholars, and advocates to fix the broken health care systems of the United States and Canada. The authors propose six ways to reform the systems. First, medical needs, not financial means, should determine access to medicine. Second, the drugs must be affordable to the society. Third, drug development should be aimed at innovation that maximizes population health. Fourth, the right to health must take precedence over intellectual property such as patents. Fifth, independent and rigorous evaluations should be used to restore safety and effectiveness of medications. Sixth, unbiased information on drugs should be available to prescribers and patients. The group believes that taking power out of the private sector and placing it in the hands of the public would help drive down costs, spur innovation, and expand coverage. Specifically, the authors propose that these reforms can be achieved by increasing government regulation and involvement. While some of these reforms could be implemented through legislation, the authors assert that full implementation of the reform proposal would require the United States to switch to a universal single payer system. The authors note that although Canada already has a single payer system, it still requires reform because the system does not cover prescription drugs out of the hospital.

## **Efforts by States to Stabilize the Individual Market**

In the Health Affairs article [\*Market Stabilization Stalls; States Step In\*](#), Timothy Stoltzfus Jost reviews various Affordable Care Act (ACA) activities that have occurred since Republicans failed to repeal the law in 2017. First, many states have stepped in to propose their own approaches to stabilizing the individual markets

since bipartisan efforts at the federal level failed. Jost notes that some states introduced individual-market plans that violate the ACA or state insurance licensing requirements and regulations, while others acted to support ACA markets by adopting legislation that impose a state individual mandate. Many states are also considering section 1332 reinsurance waivers. Next, Jost examines the 2019 Notice of Benefit and Payment Parameters issued by the Department of Health and Human Services (HHS). The Notice would expand the options states have for defining the essential health benefits (EHB) package that must be offered by all individual and small-group plans. The Notice would also eliminate a number of policies introduced under the Obama administration. Further, the article looks at a number of pending ACA litigation. Two courts have accepted challenges to the technical provisions of ACA regulations. Seventeen states with Democratic attorneys general have moved to intervene in a lawsuit brought by twenty states with Republican attorneys general and governors seeking to declare the ACA unconstitutional. Lastly, a federal judge certified a class action that includes insurers that were denied federal reimbursement for cost-sharing reductions (CSRs) they were required to make under the ACA for 2017 and 2018.

## **Vermont's Push for Community-Driven Health Care Reform**

Vermont is a state that has been committed to achieving health care reform that reduces costs and improves health outcomes. Authors Martha Hostetter, Sarah Klein, and Douglas McCarthy published a case study for the Commonwealth Fund, [\*Vermont's Bold Experiment in Community-Driven Health Care Reform\*](#), which analyzes the state's efforts to implement a value-based all-payer model. Vermont policymakers sought to encourage the state's three largest payers - Medicare, Medicaid, and Blue Cross and Blue Shield of Vermont - to move from fee-for-service to risk-based contracting. OneCare Vermont, a large accountable care organization (ACO), agreed to coordinate care for individuals considered to be high medical risks. OneCare's vision is to unite the physical health, mental health, and social services sectors to provide care to patients with complex needs. The goal is to get patients more engaged in health care, improve health care outcomes, and reduce overall health care spending. Data suggests that the OneCare model is making

progress in achieving the state's population health goals, but the authors stress that OneCare still faces significant hurdles. Specifically, the authors contend that moving cost out of the hospital and redistributing into the community will be challenging. If Vermont is successful, however, its model could be used in other parts of the nation where leaders are looking for more effective ways to address the social determinants of poor health.

## **Antitrust Lawsuits Promote Transparency in the Pharmaceutical Industry**

In [\*Antitrust, Market Exclusivity, and Transparency in the Pharmaceutical Industry\*](#), published by JAMA, authors Michael S. Sinha, Gregory D. Curfman, and Michael A. Carrier, analyze three recent antitrust lawsuits in which pharmaceutical manufacturers sued their competitors, alleging that the rivals' anticompetitive practices of exclusive dealing and bundling prevented competing products from gaining a foothold in the pharmaceutical marketplace. At the core of each case is the claim that restrictive contracts increase the cost of drugs while reducing access to potentially better rival medication. The authors note that antitrust issues are not a concern when a company without market power engages in exclusive dealing and bundling, because purchasers have other choices and the conduct could help small sellers obtain stronger positions in the market. However, antitrust concerns arise when companies with substantial market power engage in these practices. The courts are split on how to determine liability for exclusive dealing. The Third Circuit, which will hear these cases, focuses on exclusionary effects to see if there was exclusive dealing and bundling. In particular, it considers barriers to entry, the plaintiff's inability to gain market share, and harms to patients. In contrast, in *Cascade Health Solutions v. PeaceHealth*, the Ninth Circuit focused on the discount, finding liability when the defendant's price is less than the plaintiff's cost of manufacture. The authors argue that these lawsuits offer two lessons. First, exclusive contracting by drug companies with substantial market power could keep viable competitors out of the market. Second, antitrust lawsuits can reveal crucial information about pricing and the relationships among pharmaceutical manufacturers, pharmacy benefit managers, and third party payers. Even without victories in court, greater transparency from these lawsuits may promote increased

scrutiny of anticompetitive deals by lawmakers and the public, leading to more equitable prescription drug policies.

That's all for this month's Roundup. As always, if you find articles or reports that you think should be included in the monthly Roundup, please send them our way. Enjoy your reading!