Academic Articles & Reports Roundup: September 2017

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Happy October! In this Roundup of articles from the past month, we cover four articles from September. The topics this month include 1) actual R&D costs for single cancer pharmaceuticals|2) policy solutions beyond antitrust to promote competition and regulate consolidation|3) reasons behind market exclusivity for prescription drugs|and 4) state policy recommendations curbing healthcare consolidation efforts.

Actual R&D Costs for Single Cancer Pharmaceuticals

A 2017 Tufts University Center for Study of Drug Development and Research estimated the total cost of research and development (R&D) spending is $2.7 billion per drug. Cancer physicians Vinay Prisad and Sham Mailankody challenged this study by studying cancer drugs approved between 2006 and 2015. Using different methodology, they found that the Tufts' figure was incredibly misleading. The report published by JAMA titled, Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval, identified ten companies that each had a single cancer drug on the market and analyzed the drugs' US Securities and Exchange Commission filings to determine the average cost of research and development for cancer pharmaceuticals. The cumulative R&D spending was estimated from initiation of drug development activity due to date of approval. The physicians found the median cost for developing a single cancer drug is $648 million and that the median revenue right after approval for these companies is $1658.4 million. Each product produced seven times as much revenue as it cost R&D. This conclusion rejects the former $2.7 billion price tag for research and development costs and thus challenges the justification pharmaceutical companies rely on to explain their high drug prices. Prisad and Mailankody claim they accounted for cost of failure because their method considered other drugs in development that create company costs but do not produce any revenue. Prisad and Mailankody's report is a great addition to transparency efforts aimed at lowering pharmaceutical drug prices.

Policy Solutions Beyond Antitrust to Promote Competition and Regulate Consolidation

The Health Affairs September issue focused on studies includes a group of studies examining different aspects of health care markets. These articles discuss market concentration, preserving competition, and provider networks. In a particularly compelling article, Sherry Glied and Stuart Altman discussed the unique space occupied by midsized community hospitals in the healthcare industry in their article in Health Affairs, Beyond Antitrust: Health Care and Health Insurance Market Trends and the Future of Competition**.** It is often cheaper and more desirable for midsized hospitals to outsource less complicated diagnostic and surgical services to clinics. On the other hand, large hospitals affirmatively seek out complex patient cases and transfer patients out of midsized hospitals into their care. These factors lead to a declining demand for midsize community hospitals, which are often left with no choice but to merge with a competitor or join a vertically integrated system. Increased competition is also influenced by the development of hospital systems that extend the bargaining power of "must-have hospitals." This leaves insurers with no choice except to compete to have these desirable hospital systems in their networks. Glied and Altman argue that although antitrust enforcement is designed to prevent anticompetitive consolidation, its impact is often limited. Historically, federal antitrust authorities and state attorney generals have not aggressively pursued antitrust enforcement within the healthcare industry. Glied and Altman argue that antitrust enforcement must also be paired with regulatory interventions designed to promote competition and prevent nation-wide consolidation. They recommend two primary policy objectives to achieve this goal. The first addresses regions that could support multiple competing midsize community hospitals and focuses on limiting the bargaining power of must-have institutions. The second strategy recommends price regulation for routine hospital and specialized services in regions that are unable to support a number of competing community hospitals. Giled and Altman raise a valid argument that antirust efforts alone will not be enough to ensure fair competition. However, price regulation efforts will likely meet resistance from healthcare and other industry parties.

Journal of American Medical Association's Reasons Behind Market Exclusivity for Prescription Drugs

Researchers Aaron Kesselheim, Michael Sinha, and Jerry Avorn, determined government granted patents and periods of market and regulatory exclusivity are the biggest contributors to brand name pharmaceutical monopolies. Their article, Determinants of Market Exclusivity for Prescription Drugs in the United States (JAMA), concluded most brand name drug manufacturers have a 12-16 year window during which their products are free from competition from lower-priced generics. Researchers reviewed peer-reviewed medical and health policy studies published between 2006-2016 that were related to prescription drug market exclusivity periods, determinants on their length and effects on drug costs, patient access, and health outcomes. The article determined that brand name drugs generate most of their market exclusivity from the time remaining on a patent after they receive FDA approval. Producers of these brand name drugs can then extend their market exclusivity by applying for up to five additional years in patent-term restoration during the clinical trial period and may receive an additional six months of exclusivity for conducting trials in children. Drug manufacturers also receive a concurrent period of regulatory exclusivity that begins at FDA approval and prevents generic entry. This regulatory exclusivity typically runs for at least six years for new drugs. Policy reforms should ensure that drug market exclusivity periods provide for fair return on investment, but do not indefinitely block availability of low cost generics. Changing the patent framework to allow for more competition is an arduous endeavor. Pharmaceutical companies rely on market exclusivity to help compensate their research and development costs. Some incentive is thus completely justified, but the current federal framework may be generating more harm for consumers than good.

State Policy Recommendations Curbing Healthcare Consolidation Efforts

In her report for the National Academy for State Health Policy , State Strategies to Address Rising Prices Caused by Health Care Consolidations, by Erin Fuse Brown identifies state policy recommendations aimed at lowering healthcare costs associated with industry consolidations. Healthcare consolidations, primarily in the form of horizontal mergers between hospitals and vertical consolidations of hospitals and physicians, are occurring at an increasing rate. Hospital concentration increased by 40% in the past 30 years, leaving nearly 50% of all current hospital markets in the US highly concentrated. Healthcare providers often justify rising

costs associated with new consolidations by referencing improvements in quality and efficiency within the healthcare system. However, these justifications seem to lack merit. Horizontal hospital consolidation leads to 20-40% higher price increases while vertical consolidation leads to nearly 14% higher physician prices. Unfortunately, these price increases are rarely accompanied by improvements in quality. Fuse Brown provides state policy recommendations to combat rising prices caused by healthcare consolidations. The primary methods include promoting price transparency in healthcare services and reference pricing by public purchasers, encouraging state antitrust enforcement, reforming or eliminating certificate of need and facility licensure requirements, expanding the use of telehealth, and utilizing rate review authority held by state insurance commissioners to provide oversight on insurance premiums and hospital rates. States can use their legislative authority to promote competition, which can provide a systemic check on private price increases that arise form consolidation. NASHP's policy goals attack the problem from all sides and thus offer plausible and effective solutions. With the federal government constantly entangled in the federal healthcare debate, state actions will likely have the most impact. However, in accordance with NASHP's recommendation, states must address the problem from all sides and thus undertake multiple legislative efforts in order to successfully reduce industry consolidation.

As always, feel free to send us Articles and Reports you think should be in The Source Roundup. We hope you enjoyed this reading list. See you next month!