

Academic Articles & Reports Roundup: April 2017

Happy May! This month's Roundup includes articles about 1) prescription drug competition and generic delay|2) the "Big Insurance" merger cases|and 3) the effect of the ACA's risk adjustment and reinsurance programs. In addition to the articles highlighted below, be sure to check out our recent blog post about Public Agenda's [report](#) by David Schleifer, Rebecca Silliman, and Chloe Rinehart on how people use and find health care price information.

Prescription Drug Competition & Generic Delay

In [*A Citizen's Pathway Gone Astray – Delaying Competition from Generic Drugs*](#) (New England Journal of Medicine), Robin Feldman and Connie Wang discuss their research on brand-name drug manufacturers' use of citizen petitions to delay generic drug entry. The authors studied citizen petitions filed between 2000 and 2012 and found that nearly half of citizen petitions were filed toward the end of the FDA approval process for a generic, suggesting that brand-name manufacturers filed the petitions to hold off generic approval and entry. The use of citizen petitions to delay generic entry is on the rise, with the number of citizen petitions doubling since 2003. While some citizen petitions involved real concerns about drug safety, the FDA denied most petitions (80%) filed by brand-name competitors. Unfortunately, the 2007 amendments to the FDA Act that attempted to address this type of generic delay tactic have proven ineffective. Feldman and Wang argue that new procedural blocks, such as requiring delays to be approved only to "protect the public health," would more effectively address delay-related citizen petitions. In addition, they suggest that antitrust actions, such as the FTC's case against

Shire ViroPharma's use of citizen delay petitions, and greater transparency can help prevent this increasingly common form of generic delay.

Also in the pharmaceutical realm, Ann Marie Marciarille published [*The Prescription Drug Pricing Moment: Using Public Health Analysis to Clarify the Fair Competition Debate on Prescription Drug Pricing and Consumer Welfare*](#) (The Journal of Law, Medicine & Ethics), which discusses how public health could help inform consumer welfare analyses in antitrust cases. Marciarille's central claim is that antitrust enforcers should not think of consumer welfare in the pharmaceutical market just in terms of the impact on individuals, but also on the collective population. She contends that public health can provide antitrust law with the vocabulary needed to articulate these collective consumer interests. To show this, she discusses the effects of favored-group pricing schemes, under which the drug price varies depending upon the drug consumer's affiliation with a particular group. For example, federal law dictates that veterans covered by the VA get the lowest priced drugs. She also details the story of Daraprim, the drug that Turning Pharmaceuticals infamously acquired and re-priced at a 5,000 percent increase. Marciarille argues that the drug pricing schemes and story of Daraprim show that public health analysis "could power a consumer welfare analysis of market gaming behavior that extends beyond shifting pharmaceutical acquisitions costs to other payers and, in fact, effectively sets public health priorities."

Big Insurance Merger Cases

Leemore Dafny published [*Good Riddance to Big Insurance Mergers*](#) (New England Journal of Medicine), which explores the impact of the federal district court decisions blocking the Anthem-Cigna and the Aetna-Humana mergers. In addition to halting consolidation in the insurer market, Dafny argues that the

Department of Justice's victory in these two cases may pave the way for stronger enforcement of both health insurance and provider mergers. She points out similarities between the insurer and provider merger cases, including arguments about market definition, the merger's effect on competition, likelihood of new market entry by competitors, and potential efficiencies created by the merger. For instance, Dafny discusses how the government's argument in favor of a narrow market definition prevailed over the merging entities' broader market definition argument in both the Aetna-Humana case and in *FTC v. Penn State Hersey Medical Center*. She hopes that the big insurance merger cases will cause insurers to "devote more energy to growing by offering superior value, rather than by swallowing rivals."

ACA Risk Adjustment & Reinsurance Programs

Paul D. Jacobs, Michael L. Cohen and Patricia Keenan evaluate the impact of the first two years of the ACA's reinsurance and risk-adjustment programs in [*Risk Adjustment, Reinsurance Improved Financial Outcomes for Individual Market Insurers With The Highest Claims*](#) (Health Affairs). The authors compared data about ACA exchange insurer revenue and costs from before and after the implementation of these programs. The reinsurance program reimburses insurers for expenses related to high-cost enrollees. The risk adjustment program aims to make the cost of covering sick enrollees equal to the cost of covering healthy enrollees. To accomplish this, funds from plans with healthier enrollees are reallocated to plans with sicker enrollees. The authors found that prior to implementing the transfers under these programs, as one would expect, insurers with sicker enrollees performed worse financially than insurers with healthier enrollees. Once the programs took effect, financial performance generally equalized between all insurers. Specifically, prior to implementing the risk adjustment program, claims costs exceeded revenue by \$90-\$397

per enrollee per month for insurers with the highest costs. After risk adjustment, those insurers' costs only exceeded revenue by \$0-\$49 per enrollee per month. As the authors' note, this outcome aligns with the goal of risk-adjustment, to equalize spending across insurers regardless of the health of people covered under their plans. In addition, the reinsurance program successfully provided insurers with the highest costs with the most reimbursement revenue.

That's all for this month. 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!