

Competition

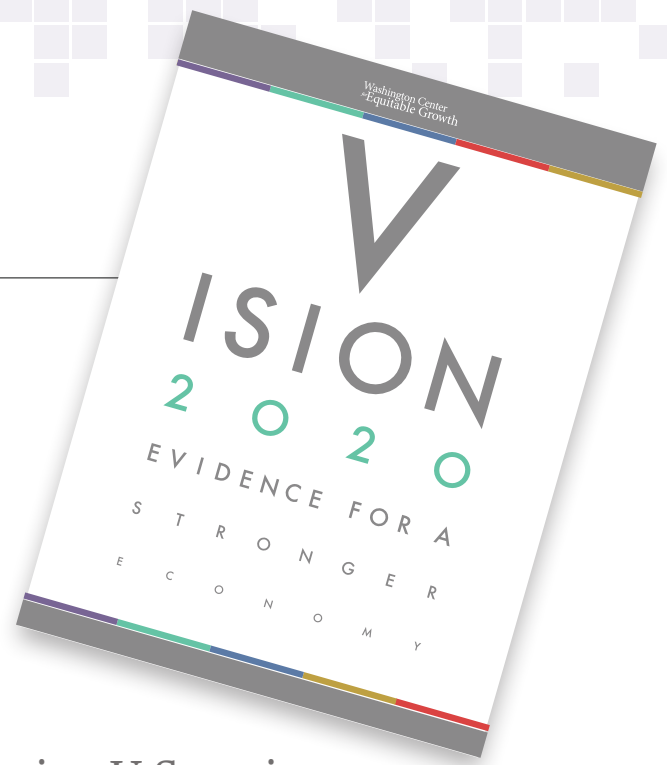
February 2020

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Equitable Growth

Competition is a little like good health: You only appreciate it once you've lost it. Research increasingly shows that the United States suffers from a market power problem that contributes to wider U.S. economic problems such as income and wealth inequality, wage stagnation, stifled innovation and entrepreneurship, and slow growth. Solving the market power problem with evidence-based policies is imperative for delivering the strong, stable, and broad-based growth the country so desperately needs.

There are serious, negative ramifications of high market concentration for our economy. Weak and underenforced antitrust laws justifiably give rise to the increasingly popular, and politically toxic, belief that the rules of the economy are rigged for the rich and powerful. Just as money corrupts the political process, market power corrupts the economy.

As the essays in the competition section of the Washington Center for Equitable Growth's latest book *Vision 2020: Evidence for a stronger economy* underscore, there is substantial research covering both competition policy generally, and drug pricing specifically. Both essays provide more than a laundry list of policy proposals—they provide a vision for how to achieve increased competition and, in turn, more widely shared prosperity for our nation.



Reforming U.S. antitrust enforcement and competition policy

Fiona Scott Morton, Yale University

Competitive markets deliver higher productivity, lower prices, better-quality products, and more innovation, yet firms often seek to restrain competition to obtain monopoly profits. Today, there is increasing evidence that many firms are unrestrained by antitrust enforcement and engage in anticompetitive mergers, anticompetitive exclusion, and collusion with rivals.

Solutions

U.S. antitrust laws need to be strengthened and better enforced, particularly in the areas of mergers and exclusionary conduct, and a new digital regulatory authority that would enforce privacy laws and create conditions conducive to competition would improve outcomes in digital markets. Recommended actions include:

- Approximately double the budgets of the Antitrust Division of the Justice Department and the Federal Trade Commission to allow for greater enforcement activities.

- Appoint leaders of the two enforcement agencies who are prepared to use existing authority to toughen enforcement of the antitrust laws and bring challenging cases to the courts.
- Reform antitrust statutes to guide the courts more closely and thus deter and prevent anticompetitive conduct more effectively. Such changes would:
 - Overturn Supreme Court precedent that has permitted anticompetitive behavior on a large scale
 - Prohibit courts from avoiding examination of the evidence in a case and just assuming that a market is or will become competitive
 - Create simple rules (presumptions) that deter practices that, based on existing evidence, are likely to be anticompetitive
 - Clarify that antitrust violations can result in not only higher prices but also reduced quality, harm to innovation, lower wages, and elimination of potential competition
- Create a new federal agency to regulate digital businesses that could take such actions as establishing standards for a competitive digital marketplace and considering whether consumers should be able to coordinate their use of social media applications or commerce websites (known as interoperability).

Improving competition to lower U.S. prescription drug costs

Aaron S. Kesselheim, **Harvard University**

Rising drug prices are a major driver of U.S. healthcare spending, accounting for a little less than one-fifth of overall spending in 2018. High drug prices can limit the

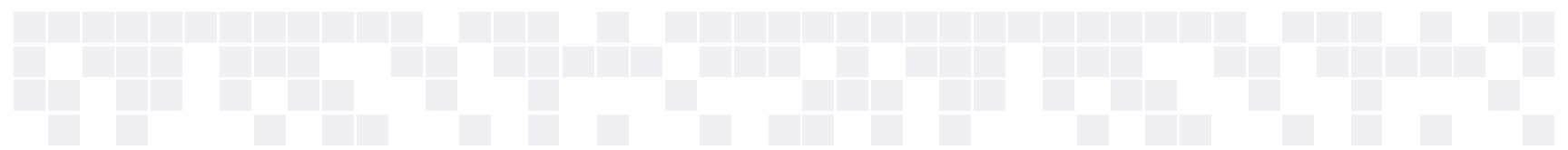
availability of new medications, including gene therapies for devastating illnesses and decades-old products such as insulin and antibiotics.

Solutions

Policy reforms are necessary at all phases of drug development and sales—including the discovery process leading up to approval by the U.S. Food and Drug Administration, the brand-name-only period of market exclusivity, the end of market exclusivity and the transition to a competitive market with generic drugs, and the multi-sourcing of generic drugs—to dramatically lower spending while ensuring continued funding for true innovation.


Potential reforms include:

- When public funding leads to patents covering approved prescription drugs, the U.S. National Institutes of Health could require a reasonable pricing provision in the technology transfer from the public sector to the private sector, requiring that the ultimate price of the product be no greater than its value-based price—a price reflecting the drug’s potential ability to improve patient outcomes over comparable interventions—as determined by independent organizations.
- During the period when a drug exists in its brand-name version only, the most direct way to address excessive drug prices would be for the federal government to negotiate the price of drugs for Medicare and other programs.
- Establish a federal entity to assess a newly approved drug’s clinical value and help determine what a fair price would be based on how well it is expected to perform against other available treatments. Price increases each year should not be able to exceed inflation, unless there is new evidence about the drug’s value. Similarly, future technology that lowers the cost of care should lead to price declines. For particularly essential and high-priced medications for which a negotiated price cannot be reached, the government should have the authority to reimburse pharmaceutical manufacturers at a fair-market-value price for use of their intellectual property.

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- Given the potential dangers of off-label use of prescription drugs, the U.S. Food and Drug Administration must reaffirm its commitment to enforcing current off-label marketing rules, even under the evolving commercial speech doctrine in this area.
 - Enact legislation to combat drug company strategies for delaying generic drugs, such as patenting changes in peripheral aspects of the drug, product hopping, filing Citizen Petitions with the U.S. Food and Drug Administration, restricting supplies of their product for generic manufacturers to use in bioequivalence studies, and entering into settlements with generic manufacturers seeking to challenge patents that include agreements to drop the challenge and delay or terminate plans to market a competing generic product. One proposal is to restrict a brand-name drug's market exclusivity period to a particular time period, barring secondary or tertiary patents from blocking FDA approval of a generic version.
 - Invest greater resources in the U.S. Food and Drug Administration to limit unnecessary delays in generic drug approval and ensure that guidances are produced in a timely fashion for the studies generic manufacturers need to complete in order to receive approval of interchangeable products, particularly for complex small molecule products and biosimilars.
 - In cases of high prices for off-patent drugs, importation is a possible solution. A process for facilitating U.S.-wide imports, followed by an expedited process for formal FDA approval, could help prevent and respond to price spikes. Another solution would be to pursue a system of government-sponsored drug manufacturing.

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