AIMED ALLIANCE
Alliance for the Adoption of Innovations in Medicine

Common-Sense Steps to Reduce the Cost of Health Care in the U.S. Part I: Federal Government

About

The Alliance for the Adoption of Innovations in Medicine (Aimed Alliance)

Aimed Alliance is a tax-exempt, not-for-profit organization that works to improve access to quality health care and preserve practitioner-patient relationships. We achieve this mission by conducting legal research and analysis; developing sound, patient-centered recommendations; and disseminating our findings to inform policy makers and increase public awareness.

Visit www.aimedalliance.org and follow @AimedAlliance on Twitter.

Introduction

According to the Centers for Medicare and Medicaid Services ("CMS"), total U.S. health care spending topped $3.3 trillion in 2016,[1] representing almost 18 percent of the entire U.S. economy. This level of spending has strained the budgets of consumers and taxpayers.[2] Many Americans cannot afford health care services and treatments. The costs of medical care not covered by health insurance can lead to significant debt and bankruptcy.[3] For example, individuals with cancer are 2.6 times more likely to declare bankruptcy than individuals without cancer.[4] As such, all stakeholders, including the federal and state governments, insurers and pharmacy benefit managers, the pharmaceutical industry, pharmacies and pharmacists, health care practitioners, hospitals, and consumers, must do their part to reduce the costs of health care.

Aimed Alliance recommends that big-picture reforms be enacted nationally to improve the quality, and reduce the costs, of health care. Specifically, Aimed Alliance set forth principles for health care reform in *Advancing Quality Health Care in the U.S.: A Roadmap for Consumer-Focused Reform*. The proposals in this series are intended to address shortcomings in the current health care system. They are intended to be partial, interim fixes in the absence of system-wide reforms.

Similarly, Aimed Alliance provided state-level recommendations during its May 2016 legislative working group meeting, *Closing Legal Loopholes to Improve Health Care*. This series will not set forth recommendations for state governments.

In this three-part series, Aimed Alliance sets forth common-sense steps multiple stakeholders can take to help reduce the costs of health care for U.S. consumers and taxpayers under the current system. Part one focuses on the federal government. It accounts for the priorities of the Trump Administration and the challenges the U.S. Congress has faced in enacting legislation in 2018.

Part two provides recommendations for the health insurance industry, its pharmacy benefits managers, and the pharmaceutical industry. Part three identifies actions pharmacies, pharmacists, health care practitioners, hospitals, and consumers can take to reduce health care costs without sacrificing the quality of care.

The Federal Government

The federal government influences health care costs in many ways. As the largest single payer of health care in the country, it exerts significant influence on the health care industry.[5] Through Centers for Medicare and Medicaid Services ("CMS"), it determines which treatments and services to cover for Medicare beneficiaries, how much it will pay providers for such treatments and services, and the price at which manufacturers must sell medications to state Medicaid programs. It also regulates the marketing of prescription and non-prescription medication through the Food and Drug Administration ("FDA"). Federal action that aims to align stakeholder incentives towards a more competitive and efficient market for health care products and services, as well as federal trade policies intended to improve the fairness of international pharmaceutical trade, can serve to lower the costs of health care in the U.S.

A. Improve the Fairness and Freeness of Pharmaceutical Trade

The U.S. government should enact trade policies that require other developed countries to pay more toward pharmaceutical research and development costs.

1. Hold Negotiations Pursuant to the Trade Promotion Authority Act

Congress passed the Trade Act of 1974 to "establish fairness and equity in international trading relations."[6] It authorizes the president to negotiate trade agreements that modify existing tariffs or reduce or eliminate non-tariff barriers to trade that unduly burden and restrict the foreign trade of the U.S. or adversely impact the U.S. economy.[7]

Pharmaceutical prices in the U.S. are 20 to 40 percent higher than those in other developed nations.[8] A recent White House report estimates that Americans are responsible for 70 percent of profits stemming from patented pharmaceutical sales, although the U.S. only makes up 34 percent of the combined gross domestic product at purchasing power parity[9] of Organization for Economic Co-operation and Development ("OECD") member nations.[10]

The OECD's 35-member nations include many of the world's most advanced countries, such as Germany, Japan, France, UK, and Canada.[11]

Other OECD nations, where government purchasing and price controls are more prevalent, are imposing below-

market prices on U.S. pharmaceutical manufacturers, causing market prices in the U.S. to be higher than they otherwise would be under a more open global market.[12] According to one analysis, prices for the world's 20 top-selling drugs are, on average, three times higher in the U.S. than in the United Kingdom, where profits on brand drugs sold to the publicly-funded National Health Service in England are regulated through agreements between the country's Department of Health and manufacturers.[13]

U.S. consumers shoulder a disproportionately high proportion of global pharmaceutical research and development costs by paying higher prices compared to other countries, even for countries with stronger economic indicators and quality of life metrics.[14] Published estimates of new drug development costs range between $800 million and $2.6 billion.[15] This range is consistent with a 2014 study's estimate that it takes an average of $2.5 billion in pharmaceutical revenue to support the invention of one new chemical entity.[16] A recent policy report estimated that if drug prices increased in European countries by 20 percent, then there would be "substantially more drug discovery worldwide, assuming that the marginal impact of additional investments is constant."[17] After accounting for the value of health gains from higher quality, longer lives, the 20 percent increase could lead to $10 trillion in welfare gains in the U.S., and $7.5 trillion for Europeans, over the next 50 years.[18]

Given that price controls in other developed nations unfairly raise prices for U.S. consumers, who in turn effectively subsidize global pharmaceutical research and development,[19] the president should exercise presidential authority under the Trade Act of 1974. Specifically, the president should improve fairness and equity in international pharmaceutical trade by renegotiating trade agreements with other developed nations and China so that they contribute fairly to the costs of pharmaceutical research and development.[20]

Section 301 of the Trade Act of 1974 authorizes the U.S. Trade Representative ("USTR")[21] to take certain actions if the USTR determines that "an act, policy, or practice of a foreign country is unreasonable or discriminatory and burdens or restricts United States commerce. . . ."[22] Specifically, the USTR may impose economic sanctions on a foreign country or enter into agreements with a foreign country to eliminate burdens on the U.S. .[23] In March 2018, the USTR exercised this authority by proposing tariffs on $50 billion worth of Chinese imports following an investigation alleging theft of U.S. intellectual property by China.[24]

The USTR prepares an annual "Special 301 Report." The report may include a wide range of issues the USTR believes to limit innovation and investment, including "market barriers [such as] nontransparent, discriminatory or otherwise trade-restrictive, measures that appear to impede access to health care."[25]

Notably, the 2018 Special 301 Report states that the "USTR has been engaging with trading partners, including Algeria, Argentina, Canada, China, Korea, India, Indonesia, Japan, Malaysia, Saudi Arabia, and the United Arab Emirates, to address concerns related to market access barriers with respect to pharmaceuticals and medical devices."[26] The report further states that the USTR has "pressed trading partners" so that they "contribute their fair share,"[27] toward research and development of new treatments and cures. It cites as an example recent talks with Japan to address concerns over pharmaceutical pricing and payment policies.[28]

Given the burdens on U.S. commerce created by price controls in other countries, as described above, the USTR should more aggressively exercise its Section 301 authority to identify countries with trade-restrictive pricing policies, name them in the annual Special 301 Report, and enter trade talks to reduce the proportion of research and development costs currently being shouldered by the U.S.

B. Grant Breakthrough Designation

The FDA should increase the speed at which it approves new drugs by granting breakthrough therapy designation to more orphan drugs.

Currently, it takes approximately 12 years for a drug to go from initial discovery and preclinical research to the U.S. marketplace, including as many as seven years of clinical trials and another two years of FDA review.[29] A 2017 report found no change in the speed of FDA drug approval compared to 20 years ago. It attributed the stagnation to stricter evidence requirements from the FDA and a lack of improvement in the clinical trial process.[30] Delays in drug approval impact patient access to new treatments and also hinder competition for existing treatments.

An orphan drug is a medication that treats a rare disease, and a rare disease is a condition that affects fewer than 200,000 Americans.[31] Many rare diseases are serious or life threatening.[32] Yet, even though there are as many as 7,000 rare diseases, 95 percent of rare diseases do not have an FDA-approved drug indicated to treat them.[33] Rare disease treatments make up the costliest drugs in America.[34] These medications' costs are high because there are fewer patients among whom to spread the costs of research and development.

Increased use of the FDA's breakthrough therapy designation can potentially lower the costs of orphan drug treatments by reducing the amount of capital and time needed for new drug development.[35] A drug can qualify for breakthrough therapy designation if it is intended to treat a serious or life-threatening condition, such as cancer, hemophilia, and multiple sclerosis, and may demonstrate substantial improvement over existing therapies based on

initial clinical evidence.[36] Orphan drugs that treat serious or life-threatening rare diseases should, therefore, qualify for breakthrough therapy designation.

The FDA's breakthrough therapy designation allows for a 60-day expedited review of such drugs.[37] It also allows a drug manufacturer more frequent contact with the FDA to expedite resolution of issues in the approval process,[38] and streamlines the clinical trial process, which can cut the cost of conducting clinical trials by as much as 90 percent.[39] According to a recent study, more than half of the drugs that received breakthrough therapy designation went through the approval process more than two years faster than drugs that did not receive such designation.[40] By reducing their own expenses related to research and development, drug manufacturers can offer breakthrough therapies at lower prices while still recouping development costs.[41]

As FDA Commissioner Scott Gottlieb, M.D. acknowledged, the FDA's cancer division has fully embraced breakthrough therapy designation.[42] As of April 2018, the FDA had approved 91 breakthrough therapy designated products, 52 of which were new cancer medications, since the program's inception in 2012.[43] At the same time, Gottlieb noted that the FDA has not readily embraced "these progressive regulatory constructs" outside of the oncology setting.[44] He attributed this in part to the fact that "rare diseases cut across many different clinical divisions in [the] FDA..., and the willingness to "make certain regulatory accommodations in the setting of terrible and largely untreatable diseases is not as consistently recognized across every part of [the] FDA, or embraced with the same vigor."[45] The FDA has increased the burdensome clinical trial requirements rather than streamlining the approval process for some rare diseases, such as Aldurazyme, Hurler Syndrome and MPS 1.[46]

Orphan drugs that treat rare diseases could be brought to patients sooner, and at lower development costs, if the rare disease division more fully integrated the use of the breakthrough therapy designation into its operations. The rare disease division should use processes similar to those of the FDA's cancer division, including new approaches to evaluating "trial design, statistical analysis, and product issues related to new platforms for pursuing biological targets."[47]

C. Reform 340B to Promote Charity Care

Congress should enact legislation to reform the 340B discount drug program to require participating hospitals to use the medication purchased through the program for treatment of vulnerable patient populations. The 340B program is a federal health care program that allows hospitals with a high proportion of lower-income patients to purchase medications from drug manufacturers at deeply discounted prices in order to provide high-quality treatment for patients.[48] However, some hospitals dispense discounted medications obtained through the 340B program to insured patients at much higher rates and net the difference as profit.[49] To account for the deep discounts that manufacturers provide to hospitals, manufacturers ultimately charge higher prices to other payers.[50]

A 2017 study found that 69 percent of hospitals joining the 340B program in 2015 administered less charity care than in the two years prior.[51] A 2018 study found no evidence that 340B participating hospitals were using financial gains earned from the 340B program toward expanding care or lowering mortality among low-income patients.[52] The program simply is not delivering the discounted care to the patient populations that Congress intended to serve.

The government restricts which hospitals may enter the 340B program but allows the discounted medications to be dispensed to any hospital patient and places no restrictions on profits derived from dispensing discounted medications to patients at high prices.[53] This has led hospitals to treat the 340B program as a means for boosting profits rather than as a lifeline to allow hospitals to provide charity care and serve patient populations with a high proportion of vulnerable patients.

CMS recently promulgated a rule, effective as of January 1, 2018, that reduced Medicare payment for separately payable drugs purchased by 340B hospitals by 28 percent. Medicare payment for such drugs had been historically higher than the price that 340B hospitals paid for the medications, thereby allowing the hospitals to make a profit.[54] The rule received significant backlash from the hospital industry, which filed a lawsuit challenging the law.[55] The lawsuit ultimately was decided in favor of the government. However, the federal government must still go further to ensure that the 340B program is functioning as it was originally intended.

Congress should pass legislation to require participating hospitals to report how they are using their profit margins from the 340B program.[56] By improving transparency, the public can understand how hospitals are using funds obtained through the 340B program.[57] If the transparency requirements bring to light that a significant amount of the discounts are not being used for their intended purposes, further regulations could be promulgated to restrict the 340B program.[58] The increased transparency will motivate participating hospitals to use more of the discounts toward low income patients to avoid such restrictions.

D. Amend Best Price Program to Encourage Outcomes-Based Pricing

CMS should amend the Medicaid "best price" rule to allow for outcomes-based pricing arrangements and to prevent drug price inflation.

The best price rule is a part of the Medicaid Drug Rebate Program, a program through which manufacturers provide discounts to CMS and state Medicaid agencies to help offset the costs of prescription medications for Medicaid beneficiaries.[59] "Best price" is defined as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States . . . inclusive of cash discounts . . . and rebates."[60] The best price rule mandates that manufacturers participating in Medicaid must sell medication to state Medicaid programs at the lowest of (1) the best price offered to other purchasers; or (2) 23.1 percent off the average manufacturer price.[61] The best price regulation further clarifies that this price determination is made on a "unit basis," meaning if one individual receives a lower price than a Medicaid program, then all Medicaid programs are entitled to that same price.[62] If a manufacturer declines to participate, then that manufacturer is excluded from all federal programs, including Medicare.[63]

This payment structure does not allow for sensible outcomes-based pricing for medication, which can be structured so that drug manufacturers offer insurers or pharmacy benefit managers ("PBMs") discounts if a medication turns out to be ineffective for individual plan beneficiaries. Outcomes-based pricing models allow for individualized care based on the value that the medication provides to the unique patient.

The best price rule currently stands in the way of outcomes-based payment mechanisms and should be reformed.[64] The best price rule's statutory provision would be triggered if a drug manufacturer provided a rebate pursuant to an outcomes-based payment model, and the price of the drug with the rebate were lower than the price that the Medicaid program paid.[65] To allow for outcomes-based pricing, CMS should amend the best price regulation to determine the best price based on a weighted average of the medications sold to a payer, rather than individual units sold.[66] This would allow manufacturers more regulatory cover to pursue outcomes-based pricing arrangements with insurers and other payers without unfairly tying the manufacturer to an unreasonable Medicaid sales price.

Conclusion

The federal government can play a meaningful role in reducing the costs of health care. The simple solutions laid out herein can help to achieve that goal. Following the government's lead, Parts II and III of this series will contain further solutions for other industry stakeholders, including insurers, pharmacy benefit managers, pharmaceutical manufacturers, pharmacies and pharmacists, hospitals, health care practitioners, and consumers. Parts II and III are forthcoming in 2018.

Endnotes

1. *National Health Expenditures 2016 Highlights*, Centers for Medicare and Medicaid Services https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf (last visited May 9, 2018).

2. Ian Hathaway & Jonathan Rothwell, *A Cure for Health Care Inefficiency? The Value and Geography of Venture Capital in the Digital Health Sector*, Brookings (Sept 10, 2015), https://www.brookings.edu/research/a-cure-for-health-care-inefficiency-the-value-and-geography-of-venture-capital-in-the-digital-health-sector/.

3. *NCI Dictionary of Cancer Terms*, National Cancer Institute, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/financial-toxicity (last visited May 9, 2018).

4. *Financial Toxicity of Cancer Care*, University of Pennsylvania, Leonard Davis Institute of Health Economics, https://ldi.upenn.edu/50at50/financial-toxicity-cancer-care (last visited May 9, 2018).

5. Tevi D. Troy, *How the Government as a Payer Shapes the Health Care Marketplace*, American Health Policy Institute, http://www.americanhealthpolicy.org/Content/documents/resources/Government_as_Payer_12012015.pdf (last visited May 9, 2018).

6. 19 U.S.C. § 2102(3).

7. 19 U.S.C. § 2101 et seq.

8. Dana Goldman & Darius Lakdawalla, *The Global Burden of Medical Innovation*, USC Schaeffer (Jan. 2018), http://healthpolicy.usc.edu/documents/01.2018_Global%20Burden%20of%20Medical%20Innovation_01.pdf

9. Purchasing power parities "are price relatives which show the ratio of prices in national currencies of the same good or service in different countries," and are frequently used in gross domestic product computations. Paul Schreyer and Francette Koechlin, *Purchasing Power Parities – Measurement and Uses*, OECD (Mar. 2002), https://www.oecd.org/sdd/prices-ppp/2078177.pdf.

10. *Reforming Biopharmaceutical Pricing at Home and Abroad*, The Council of Economic Advisers, Executive of the President of the United States, (Feb. 2018), https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf

11. *Members and Partners*, OECD, http://www.oecd.org/about/membersandpartners/ (last visited May 9, 2018).

12. *Id.*

13. Ben Hirschler, *How the U.S. Pays 3 Times More for Drugs*, Scientific American https://www.scientificamerican.com/article/how-the-u-s-pays-3-times-more-for-drugs/ (last visited May 9, 2018). The United Kingdom's publicly-funded National Health Service (NHS) provides free health care to more than 64 million people. The National Institute for Health and Care Excellence (NICE), a non-departmental public body of the Department of Health responsible for developing health care guidance and quality standards in England, assesses new medications to determine whether they are cost effective and whether they should be covered by NHS. If NICE approves a brand drug, then the Department of Health negotiates a five-year agreement with the manufacturer to regulate how much profit the manufacturer can make on NHS sales. Aine Quinn, *Why Drugs Cost Less in the U.K. Than in the U.S.*, Bloomberg (Sept. 4, 2017) https://www.bloomberg.com/news/articles/2017-09-04/why-drugs-cost-less-in-the-u-k-than-in-the-u-s-quicktake-q-a.

14. *There Is a Better Way to Help U.S. Consumers: Pharmaceutical Price Controls Abroad: An Unfair Trade Policy*, United States Senate, Republic Policy Committee (Nov. 6, 2003), https://sites.hks.harvard.edu/m-rcbg/fellows/T_Christian_Study_Group/Session%204/Republican_Policy_Committee.pdf.

15. *Report to Congress: Prescription Drugs: Innovation, Spending, and Patient Access*, U.S. Department of Health and Human Services (Dec. 7, 2016) https://delauro.house.gov/sites/delauro.house.gov/files/Prescription-Drugs-Innovation-Spending-and-Patient-Access-12-07-16.pdf.

16. Pierre Dubois et al., *Market Size and Pharmaceutical Innovation*, IDEI (Mar. 2014), http://idei.fr/sites/default/files/medias/doc/by/dubois/dmss.pdf.

17. The Global Burden of Medical Innovation (Jan. 2018), http://healthpolicy.usc.edu/documents/01.2018_Global%20Burden%20of%20Medical%20Innovation_01.pdf.

18. *Id.*

19. Jeanne Whalen, *Why the U.S. Pays More Than Other Countries for Drugs*, WSJ (Dec. 1, 2015), https://www.wsj.com/articles/why-the-u-s-pays-more-than-other-countries-for-drugs-1448939481

20. *There is a Better Way to Help U.S. Consumers: Pharmaceutical Price Controls Abroad: An Unfair Trade Policy*, United States Senate Republican Policy Committee (Nov. 6, 2003), https://sites.hks.harvard.edu/m-rcbg/fellows/T_Christian_Study_Group/Session%204/Republican_Policy_Committee.pdf.

21. The United States Trade Representative is appointed by the president and confirmed by the senate. The primary duty of the Trade Representative is "developing, and for coordinating the implementation of, United States international trade policy." 19 U.S.C. § 2171.

22. 19 U.S.C. § 2411(b); 19 U.S.C. § 2411(c).

23. 19 U.S.C. § 2411(c).

24. Jeremy Diamond, *Trump Hits China with Tariffs,*

Heightening Concerns of Global Trade War, CNN Politics (Mar. 23, 2018) https://www.cnn.com/2018/03/22/politics/donald-trump-china-tariffs-trade-war/index.html

25. *2010 Special 301 Hearing*, Office of the United States Trade Representative (2010), https://ustr.gov/issue-areas/intellectual-property/Special-301.

26. *2018 Special 301 Report*, Executive Office of the President of the United States (2018), https://ustr.gov/sites/default/files/files/Press/Reports/2018%20Special%20301.pdf.

27. *Id*

28. *Id.*

29. Shahza Somerville & Jessica Holden Kloda, *FDA's Expedited Review Process: The Need for Speed, Applied Clinical Trials* (Mar. 11, 2015), http://www.appliedclinicaltrialsonline.com/fda-s-expedited-review-process-need-speed; Jennifer Harris, *Why Does it Take So Long to Get New Drugs Approved?* The Bradbury Science Museum (Mar. 5, 2018), http://www.lanl.gov/museum/news/newsletter/2018/03/drug-approval.php.

30. *Why Drug Approval Takes So Long: The Pipeline Has Been Clogged for 20 Years*, Managed Care (Jan. 10, 2017), https://www.managedcaremag.com/dailynews/20170110/why-drug-approval-takes-so-long-pipeline-has-been-clogged-20-years

31. *Orphan Drug*, National Cancer Institute, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/orphan-drug (last visited May 9, 2018).

32. *Id.*

33. *What Is a Rare Disease?*, National Center for Advancing Translational Sciences (Nov. 30, 2017), https://rarediseases.info.nih.gov/diseases/pages/31/faqs-about-rare-diseases; *Rare Diseases: Facts and Statistics*, Global Genes https://globalgenes.org/rare-diseases-facts-statistics/ (May 9, 2018).

34. Megan Brooks, *Rare Disease Treatments Make Up Top 10 Most Costly Drugs*, Medscape (May 2, 2017), https://www.medscape.com/viewarticle/879422.

35. *Remarks by Scott Gottlieb: Accelerating Cures: Addressing Unmet Patient Need or Putting Patients at Risk*, International Society for Pharmacoeconomics and Outcomes Research (May 23, 2016), https://www.aei.org/wp-content/uploads/2016/06/ISPOR-Speech-2016.pdf.

36. *Fact Sheet: Breakthrough Therapies*, U.S. Food and Drug Administration (Mar. 28, 2018), https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDASIA/ucm329491.htm; *CY 2018 CDER Breakthrough Therapy Calendar Year Approvals*, U.S. Food and Drug Administration (Mar. 31, 2018), https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NDAandBLAApprovalReports/UCM494010.pdf.

37. *Fact Sheet, Breakthrough Therapies*, supra 35.

38. *Id.*

39. *FDA Breakthrough Designation and What It Means for Pharma*, Bioassociate (Mar. 26, 2013), http://bio-associate.blogspot.com/2013/03/fda-breakthrough-designation-and-what.html.

40. Melissa Healy, *FDA's Program to Speed Up Drug Approval Shaved Nearly a Year Off the Process*, Los Angeles Times (Dec. 5, 2017), http://www.latimes.com/science/sciencenow/la-sci-sn-fda-expedited-drugs-20171205-story.html; Michael Shea, et al., *Nature- Impact of Breakthrough Therapy Designation on Cancer Drug Development*, Friends of Cancer Research, (Mar. 2, 2016), https://www.focr.org/news/nature-impact-breakthrough-therapy-designation-cancer-drug-development.

41. Id.

42. *Remarks by Scott Gottlieb*, supra note 36.

43. *Breakthrough Therapies*, supra note 38.

44. *Remarks by Scott Gottlieb,* supra note 36.

45. *Remarks by Scott Gottlieb,* supra note 36.

47. *Remarks by Scott Gottlieb,* supra note 36.

47. *Remarks by Scott Gottlieb,* supra note 36.

48. Wayne Winegarden, *Addressing the Problems of Abuse in the 340B Drug Pricing Program*, Pacific Research Institute, (Dec. 2017), https://www.pacificresearch.org/wp-content/uploads/2017/12/340B-Study_FINAL.pdf.

49. *Id.*

50. Conti & Rosenthal, *Pharmaceutical Policy Reform — Balancing Affordability with Incentives for Innovation*, New England Journal of Medicine (Feb. 2016), http://www.nejm.org/doi/full/10.1056/NEJMp1515068.

51. *340B Facilities and Charity Care*, Alliance for Integrity and Reform, (Oct. 2017), http://340breform.org/wp-content/uploads/2017/10/AIR340B-Designed_340B_CharityCare_FINAL.pdf.

52. Sunita Desai & J. Michael McWilliams, *Consequences of the 340B Drug Pricing Program*, The New England Journal of Medicine, (Feb. 2018), http://www.nejm.org/doi/full/10.1056/NEJMsa1706475.

53. *Report to the Congress: Overview of the 340B Drug Pricing Program*, MedPac (May 2015), http://medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-

overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0

54. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Program, 82 Fed. Reg. 52356 (Nov. 13, 2017) (Final Rule).

55. *The American Hospital Association, et al. v. Hargan*, No. 1:17-cv-02447-RC (D.D.C.).

56. Susannah Luthi, *Senate Lays Groundwork for 340B Reporting Legislation*, Modern Healthcare (Mar. 15, 2018), http://www.modernhealthcare.com/article/20180315/NEWS/180319937.

57. *Id.*

58. *Id.*

59. 42 U.S.C. § 1396r–8.

60. 42 U.S.C. § 1396r-8(c)(1)(C).

61. 42 U.S.C. § 1396r–8(c)(1)(B)(i)(VI); 42 CFR § 447.509.

62. 42 CFR § 447.505(d)(2).

63. Ramsey Baghdadi, *Prescription Drug Pricing #7: Medicaid Best Price*, Health Affairs (Aug. 10, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171008.000173/full/.

64. Scott Gottlieb, *What Trump Should Have Said on Drug Prices*, Forbes (Mar. 4, 2016), https://www.forbes.com/sites/scottgottlieb/2016/03/04/why-trump-is-wrong-on-drug-prices/2/#265e82056e81.

65. 42 U.S.C. § 1396r–8(c)(1)(C).

66. Rachel Sachs, et al., *Innovative Contracting for Pharmaceuticals and Medicaid's Best-Price Rule*, 43(1) Journal of Health Politics, Policy and Law 5 (2018).