

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

MERCK & CO., INC., ELI LILLY AND  
COMPANY, AMGEN INC., and  
ASSOCIATION OF NATIONAL  
ADVERTISERS, INC.,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF  
HEALTH AND HUMAN SERVICES,  
ALEX M. AZAR II, in his official capacity as  
the Secretary of the United States Department  
of Health and Human Services, CENTERS  
FOR MEDICARE & MEDICAID  
SERVICES, and SEEMA VERMA, in her  
official capacity as the Administrator of the  
Centers for Medicare & Medicaid Services,

Defendants.

Case No. \_\_\_\_\_

**EXPERT DECLARATION OF PROFESSOR CRAIG GARTHWAITE**

**JUNE 14, 2019**

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## I. Qualifications

1. I am the Herman R. Smith Research Professor in Hospital and Health Services and a tenured Associate Professor of Strategy at the Kellogg School of Management, Northwestern University. I am also the Director of the Program on Healthcare at Kellogg. At Kellogg, I teach courses in the economics of strategy and healthcare strategy and organize Kellogg's healthcare business curriculum. In addition, I am a Research Associate at the National Bureau of Economic Research, and a Faculty Associate at the Institute for Policy Research at Northwestern University.

2. I received a PhD in Economics from the University of Maryland at College Park, a Master's in Public Policy from the Gerald R. Ford School of Public Policy at the University of Michigan, and a B.A. in Political Science from the University of Michigan.

3. Prior to my graduate studies, I was an Economist at Public Sector Consultants in Lansing, MI, and the Director of Research and Chief Economist at the Employment Policies Institute, in Washington, DC.

4. My research focuses on a variety of issues including drug pricing and innovation, the effect of expanded patent protection on drug pricing, the effects of increases in demand on innovation by U.S. pharmaceutical firms, and the relationship between health insurance expansions and high drug prices. My research has been published in journals such as the *Quarterly Journal of Economics*, the *American Economic Review*, the *Review of Economics and Statistics*, the *Journal of Health Economics*, *The New England Journal of Medicine*, the *Annals of Internal Medicine*, and *Health Affairs*, and has been profiled in media outlets such as the New York Times, the Wall Street Journal, the Washington Post, and Vox.

5. I have testified before the United States House of Representatives and the United States Senate on matters including competition in prescription drug markets, consolidation in

healthcare markets, and healthcare reforms. My full curriculum vitae is attached to this declaration as **Appendix A**.

6. In forming my opinion, I relied on the various materials and documents discussed in this declaration, which are listed in **Appendix B**.

7. I am being compensated at the rate of \$750 per hour. In addition, I receive compensation based on the work that Analysis Group, Inc., performs in support of my declaration. My compensation is not contingent on the nature of my findings or on the outcome of this litigation.

## **II. Background and Assignment**

8. In its recently published final rule, the Centers for Medicare and Medicaid Services (CMS) mandates that Direct-to-Consumer (DTC) television advertisements for prescription drugs and biological products that are reimbursed by Medicare or Medicaid include the so-called “list price,” which is defined in the rule as the Wholesale Acquisition Cost (WAC) for a typical 30-day regimen or typical course of treatment for that product.<sup>1</sup>

9. I have been asked by counsel for Plaintiffs to describe the relationship of that WAC, which is the price for wholesalers,<sup>2</sup> with the price—or out-of-pocket cost—that consumers incur when acquiring prescription drugs. In addition, I have been asked to describe, more generally, the roles played by various stakeholders in the U.S. healthcare system in relation to the pricing of prescription drugs.

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<sup>1</sup> Department of Health and Human Services, Centers for Medicare & Medicaid Services, 42 C.F.R. Part 403, [CMS—4187—F], RIN 0938—AT87, “Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency,” Federal Register, Vol. 84, No. 91, Friday, May 10, 2019, Rules and Regulations, pp. 20732-20758. Hereinafter I refer to this as the “final rule.”

<sup>2</sup> 42 U.S.C. § 1395w-3a(c)(6)(B) (defining WAC as “the manufacturer’s list price” to “wholesalers or direct purchasers,” “not including prompt pay or other discounts, rebates or reductions in price”).

### **III. Summary of Findings**

10. In the following sections of this declaration I show that:

- For more than 120 million Americans, a drug's WAC has no direct relationship to their out-of-pocket costs at the pharmacy counter. These consumers will make only a flat copayment. The amount of that copayment is unrelated to WAC. And it is almost always a small fraction of WAC—particularly for branded medications.
- Even when consumers' out-of-pocket costs are related in some way to WAC, for example, when a consumer has a coinsurance obligation, the consumer's cost is almost always *substantially* lower than WAC. This is due to the nature of different cost-sharing arrangements typically used by health insurers in the United States.
- Moreover, the relationship (or lack of relationship) between WAC and out-of-pocket costs is complex and subject to considerable variation across consumers, and even variation for the same consumers over time. As a result, most consumers are unlikely to be able to reliably predict their true out-of-pocket costs for a specific prescription based on disclosure of WAC alone.
- Therefore, for the overwhelming majority of Americans, WAC will grossly overstate their out-of-pocket costs for prescription drugs and will not provide meaningful information to them.

### **IV. Overview Of The Prescription Drug Supply Chain And Pricing**

11. The actual costs of prescription drugs—both the costs to consumers and to insurance providers—are the result of a patient's unique healthcare needs, the availability of

insurance and the specifics of the insurance plan, and a complex series of negotiations between manufacturers, wholesalers, pharmacies, pharmacy benefits managers, and health insurers.

12. Before explaining how the consumer’s out-of-pocket costs differ from the so-called “list price” for which disclosure is required in the final rule, I first provide an overview of the prescription drug supply chain and the various prices paid by different stakeholders. I then describe the key components of consumer cost-sharing.

**A. WAC captures only one part of the complex prescription drug supply chain**

13. The supply chain of a pharmaceutical drug begins with manufacturers, who research, develop, and produce the drugs. Manufacturers typically sell their pharmaceutical products to wholesale distributors (“wholesalers”).<sup>3</sup> Wholesalers, in turn, distribute the drugs from the manufacturers to pharmacies, hospitals, and other medical facilities.<sup>4</sup> Pharmacies and healthcare facilities purchase drugs directly from wholesalers and ultimately dispense them to consumers.

14. While the physical movement of pharmaceutical products from manufacturer to wholesaler to pharmacy to consumer is straightforward, the calculation of the price paid for the drug at each step in the supply chain is far more complex. First, the pharmaceutical manufacturer sets a price for their product known as the Wholesale Acquisition Cost (WAC)—the cost at which a wholesaler acquires prescription drugs from the manufacturer.<sup>5</sup> WAC is the price that the final

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<sup>3</sup> “Follow the pill: understanding the U.S. commercial pharmaceutical supply chain.” *Prepared for The Kaiser Family Foundation by The Health Strategies Consultancy LLC*, March 2005, at p. 4, available at <https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf> (“KFF ‘Follow the Pill’”), (viewed June 13, 2019).

<sup>4</sup> KFF “Follow the Pill,” p. 8.

<sup>5</sup> Wholesalers may pay a price that is discounted from WAC. Examples of discounts they may receive are “volume discounts, prompt pay discounts, and discounts related to the sale of short-dated products.” The wholesaler may receive a distribution fee from the manufacturer for its services. *See* KFF “Follow the Pill,” p. 18.

rule calls the “list price.” WAC is rarely representative of, and is almost always substantially higher than, the cost incurred by consumers at the pharmacy counter.

15. Pharmacies acquire prescription drugs from the wholesaler. Pharmacies may negotiate an acquisition price directly with wholesalers or with manufacturers, who might extend discounts through the wholesalers. Pharmacies also negotiate with Pharmacy Benefits Managers (PBMs) on the reimbursement amount and inclusion in preferred pharmacy networks—these negotiations can reduce the price paid by the pharmacy for a drug to a cost below WAC.<sup>6</sup> The pharmacies then dispense prescription drugs to consumers and typically receive compensation from two sources: (1) third-party payers (i.e. commercial health insurers or government programs such as Medicare and Medicaid) and (2) consumers themselves.

16. In a separate set of negotiations, PBMs work with third-party payers (i.e., insurance companies) to negotiate a more favorable price for prescription drugs. PBMs pool together many health plans and are able to leverage that scale to negotiate rebates from manufacturers. Rebates, or discounts off a product’s WAC, incentivize volume and market-share-based savings and result in lower prices paid by health plans. They play a particularly important role in the sale of branded (rather than generic) prescription drugs. Plans may also agree to place particular drugs onto preferred formulary tiers in exchange for even deeper discounts.<sup>7</sup> The differential tiers can affect a consumer’s out-of-pocket costs, as preferred tiers are typically associated with lower consumer cost-sharing.

17. These rebate arrangements are specific to particular pharmaceutical products, payers and PBMs. In other words, purchases of one drug could entail a large rebate for one insurer

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<sup>6</sup> KFF “Follow the Pill,” p. 14.

<sup>7</sup> KFF “Follow the Pill,” p. 14.

and a comparatively small rebate for another. Rebates, however, can be substantial, and insurance companies' net costs are therefore often meaningfully lower than WAC.<sup>8</sup> Furthermore, the revenue from these rebates is used to reduce insurance premiums for health plan beneficiaries, and can also be passed on to consumers to reduce out-of-pocket costs at the pharmacy.<sup>9</sup> Hence, WAC does not reflect—and is often considerably higher than—the eventual cost of the drug to the ultimate purchasers.

**B. Consumer cost-sharing structures are varied**

18. Consumers pay a share of the cost associated with obtaining a prescription drug from a pharmacy, hospital, or other medical facility. More than 90% of Americans carry health insurance.<sup>10</sup> For that population, the amount they pay—their out-of-pocket cost—is determined by the particulars of their cost-sharing arrangement with their health insurer, which can vary considerably.

19. Health insurers offer a wide range of health plans that differ in the premiums to be paid by beneficiaries, as well as the magnitude and structure of the cost-sharing arrangements they require. Cost-sharing typically includes one or more of the following elements:

- Copayments—a flat fee per prescription or medical service, unrelated to WAC; copayments for prescriptions will typically vary by formulary tier (e.g., preferred brand, non-preferred brand);

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<sup>8</sup> Dubois, Robert W. “Rx Drug Costs: List Prices Versus Net Prices and The Importance of Staying Within the Data,” *Health Affairs Blog*, March 13, 2019, available at <https://www.healthaffairs.org/doi/10.1377/hblog20190312.446522/full/> (viewed June 5, 2019).

<sup>9</sup> Abelson, Reed. “UnitedHealthcare Says it Will Pass on Rebates from Drug Companies to Consumers,” *New York Times*, March 6, 2018, available at <https://www.nytimes.com/2018/03/06/health/unitedhealth-drug-prices.html> (viewed June 13, 2019).

<sup>10</sup> 9% of Americans are uninsured, see “Health Insurance Coverage of the Total Population,” *Kaiser Family Foundation*, 2017, available at <https://www.kff.org/other/state-indicator/total-population/> (viewed June 5, 2019).



- Coinsurance—a set percentage of a medical service or a drug’s price;
- Deductible—a pre-defined limit up to which the consumer pays the full price charged by the pharmacy.<sup>11</sup>

20. For most insured consumers in the United States, these specific cost-sharing arrangements are limited by a cap on the total out-of-pocket spending for which the consumer can be liable for his or her drug and medical services in a year; 99% of employer-sponsored commercially insured beneficiaries have plans that cap their out-of-pocket spending.<sup>12</sup> As of 2018, the average out-of-pocket maximum for individual coverage among all employer-sponsored commercial plans was \$3,872.<sup>13</sup> In addition, the Patient Protection and Affordable Care Act (ACA) mandates that out-of-pocket spending for an individual be no higher than \$7,350 for ACA-compliant marketplace plans.<sup>14</sup> Medicaid plans cap out-of-pocket spending at 5% of an individual or family’s income.<sup>15</sup>

**V. The Final Rule Requires Disclosure Of WAC, Which Does Not Represent The Price That The Overwhelming Majority Of Consumers Pay For Prescription Drugs**

21. The final rule requires manufacturers to inform consumers of the so-called “list price” of an advertised prescription drug. “List price,” however, is not the price at which prescription drugs are sold to consumers. Instead, “list price” is defined by the final rule as WAC—i.e., the price at which prescription drugs are sold to wholesalers.

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<sup>11</sup> “Cost Sharing,” *Healthcare.gov*, <https://www.healthcare.gov/glossary/cost-sharing/> (viewed June 5, 2019).

<sup>12</sup> Claxton, Gary, Matthew Rae, Michelle Long, Anthony Damico, and Heidi Whitmore, “Employer Health Benefits: 2018 Annual Survey,” *Kaiser Family Foundation*, 2018, p. 130, available at <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018> (“KFF 2018 Employer Health Benefits Survey”)

<sup>13</sup> KFF 2018 Employer Health Benefits Survey, p. 133.

<sup>14</sup> KFF 2018 Employer Health Benefits Survey, p. 130.

<sup>15</sup> Rudowitz, Robin, Rachel Garfield, and Elizabeth Hinton, “10 Things to Know About Medicaid: Setting the Facts Straight,” *Kaiser Family Foundation*, March 2019, available at <http://files.kff.org/attachment/Issue-Brief-10-Things-to-Know-about-Medicaid-Setting-the-Facts-Straight> (viewed June 5, 2019).

22. The price that the vast majority of individual consumers pay for prescription drugs is substantially lower than an amount that resembles the full WAC for their prescription medication. For over 120 million Americans who only have copayment requirements, the *price they pay for prescription drugs has no direct relationship to WAC*. At most, the amount of a copayment is only loosely and indirectly related to WAC, to the extent that an insurer considers WAC and rebates when deciding which copayment tier of its formulary to place a particular product. But even then, drugs with different WACs will be on the same copayment tier. For those transactions for which WAC may be relevant to out-of-pocket costs (e.g., when the consumer is paying coinsurance that is related to WAC), consumers also typically pay substantially less than WAC—particularly for branded drugs.

23. But the price each consumer pays varies considerably based on the particulars of their insurance plans and other variables. Below I discuss how common insurance plans affect a consumer’s out-of-pocket costs.<sup>16</sup>

**A. Commercial Plans: Tens of millions of commercially insured consumers pay drug prices entirely unrelated to WAC**

24. With respect to commercial insurance plans, below I separately discuss employer-sponsored plans from other forms of commercial plans (such as Affordable Care Act-compliant plans).

25. **Employer-sponsored plans.** As of 2017, 156 million Americans (49%) received health insurance coverage through an employer-sponsored plan.<sup>17</sup> As I describe next, as of 2017, between 39% and 51% of employer-sponsored beneficiaries are shielded entirely from a drug’s

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<sup>16</sup> The statistics included in the section that follows rely on national averages based on publicly available information, and may differ for particular manufacturers or particular drugs due to variation in patient segments.

<sup>17</sup> “Health Insurance Coverage of the Total Population,” *Kaiser Family Foundation*, 2017, available at <https://www.kff.org/other/state-indicator/total-population/> (viewed June 5, 2019).

WAC as a result of the cost-sharing and prescription drug coverage in their plans. That percentage may be significantly larger for any particular drug. As a result, WAC is irrelevant to the amount that tens of millions of Americans with employer-sponsored plans pay for prescription drugs.

26. As an initial matter, Americans who receive health insurance coverage through their employers generally do not have to pay a deductible for their prescription drugs and, therefore, are not exposed to WAC on that basis. According to a Kaiser Family Foundation report, 85% of employer-sponsored health insurance beneficiaries have some form of annual deductible.<sup>18</sup> However, the deductible that applies to healthcare services generally does not apply to prescription drugs for 95% of beneficiaries on HMO plans, 92% on PPO plans, 91% on POS plans, and 83% on high deductible health plans.<sup>19</sup> Therefore, the large majority (approximately 90%) of employer-sponsored health insurance beneficiaries have no deductible for prescription drugs.

27. Among all covered workers, the vast majority (82%) are on plans with at least three tiers of cost-sharing for prescriptions (typically generic, preferred brand, and non-preferred brands).<sup>20</sup> For those employees, approximately half to two-thirds of plans use copayments rather than coinsurance for prescription drug cost-sharing, depending on the medication's tier.<sup>21</sup> By definition, a consumer who pays a copayment for a prescription drug pays only a set copayment (i.e., a set fee of, say, \$15, or whatever the fixed amount is set by a plan), irrespective of WAC of the prescription drug.

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<sup>18</sup> KFF 2018 Employer Health Benefits Survey, p. 104.

<sup>19</sup> KFF 2018 Employer Health Benefits Survey, p. 121.

<sup>20</sup> The count of tiers of cost-sharing does not include tiers that cover only specialty drugs. KFF 2018 Employer Health Benefits Survey, p. 155.

<sup>21</sup> The percentage of employees with copayment for second tier ("preferred") drugs is 76% on non-HDHP plans and 52% on HDHP plans. For third tier ("non-preferred") drugs, 73% of employees on non-HDHP plans and 47% on HDHP plans have copayments. For fourth tier drugs, 56% of non-HDHP employees and 43% of HDHP employees have copayments for prescription drugs, *see* KFF 2018 Employer Health Benefits Survey, p. 158.

28. Even those covered workers who do have a coinsurance obligation pay substantially less than WAC. For plans with three or more tiers of drug coverage, the average coinsurance ranges from 19% for first-tier drugs to 36% for third-tier drugs.<sup>22</sup>

29. Thus, considering the percent of workers in each plan type with no deductible applicable to prescription drug purchases and no coinsurance, an estimated 61 million to 80 million (39% to 51%) of employer-sponsored insurance beneficiaries do not incur costs for prescription drugs that have any relation to WAC. This is a conservative estimate, as it does not include individuals on two-tier or single-tier plans, some of whom may also have no coinsurance or deductible.<sup>23</sup>

30. For those few beneficiaries of employer-sponsored plans who do have a deductible for prescription drugs, although their out-of-pocket cost may bear some relation to WAC, their cost can still be far below WAC and cannot be easily calculated simply by knowing WAC. Some of these individuals have a separate prescription drug deductible from their general medical care deductible. For those individuals, a 2017 report found that the average prescription drug deductible was only \$149.<sup>24</sup> This would be quickly satisfied, especially given that the final rule does not apply to prescription drugs with an annual WAC of less than \$420 (or \$35 per month).<sup>25</sup> Across all employer-sponsored plans with a deductible of any kind (either prescription drug, medical, or

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<sup>22</sup> KFF 2018 Employer Health Benefits Survey, p. 159.

<sup>23</sup> More limited information is provided in the KFF 2018 Employer Health Benefits Survey for single and two tier plans, but the vast majority of workers are not on these plans. As noted above, employer-sponsored plans with three or more tiers of prescription drugs are by far the most common, *see* KFF 2018 Employer Health Benefits Survey, p. 155-156.

<sup>24</sup> Claxton, Gary, Matthew Rae, Michelle Long, Anthony Damico, Gregory Forester, and Heidi Whitmore, "Employer Health Benefits: 2017 Annual Survey," *Kaiser Family Foundation*, 2017, p. 159, available at <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017>.

<sup>25</sup> The final rule does not apply to prescription drugs with WAC less than \$35 per month, which is equivalent to \$420 annually. 42 C.F.R. § 403, p. 20732.

both), the average deductible was \$1,573 in 2018.<sup>26</sup> Of the 20 drugs with the highest direct-to-consumer advertising expenditures as specified in the final rule, WAC for a single 30-day supply of nine of these drugs would immediately exceed the \$1,573 average deductible.<sup>27</sup> Moreover, for many consumers, their deductible would also be consumed by other healthcare services over the course of a given coverage year, such as other prescriptions, doctor visits, and the like. Thus, many factors, including a consumer's year-to-date consumption of all medical services, his or her insurance contract design, and the prescription drug's formulary placement all affect out-of-pocket costs.

31. Of those plans that have a deductible for prescription drugs, only a small minority require consumers to pay coinsurance once the deductible is met. However, among beneficiaries of plans with three or more tiers, the average coinsurance is substantially lower than WAC, ranging from an average of 19% for first-tier drugs to 36% for third-tier drugs.<sup>28</sup> In other words, after only the first month of treatment on many of the drugs with the highest DTC advertising expenditures, the consumer with such a coinsurance plan will still only be paying on average 19%-36% of WAC.

32. **Non-employer commercial insurance.** There were 20.5 million Americans (7% of the population) with commercial insurance not provided through an employer in 2017.<sup>29</sup> Of these, approximately 12.2 million were insured through a state health insurance marketplace, while the remainder purchased plans directly from insurance companies.<sup>30</sup> Approximately half (49%) of

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<sup>26</sup> KFF 2018 Employer Health Benefits Survey, p. 103.

<sup>27</sup> 42 C.F.R. § 403, p. 20741.

<sup>28</sup> KFF 2018 Employer Health Benefits Survey, p. 159.

<sup>29</sup> "Health Insurance Coverage of the Total Population," *Kaiser Family Foundation*, 2017, available at <https://www.kff.org/other/state-indicator/total-population/> (viewed June 5, 2019).

<sup>30</sup> "Marketplace enrollment 2014-2019," *Kaiser Family Foundation*, 2019, available at <https://www.kff.org/health-reform/state-indicator/marketplace-enrollment/> (viewed June 5, 2019).

all those enrolled in an ACA-compliant plan in 2016 (purchased both on or off the marketplace) were on high-deductible plans, with an individual deductible of at least \$1,500.<sup>31</sup> Marketplace plans are categorized based on generosity of coverage (silver, gold, and platinum). Currently, of all those enrolled in marketplace plans, 31% are in bronze plans (3.5 million people), 59% in silver (6.8 million people), 8% in gold (960,000 people), and 1% in platinum (106,000 people).<sup>32</sup> As of 2016, the deductible in a large number of marketplace plans (58% of silver plans, 65% of gold, and 93% of platinum) does not apply to prescription drugs.<sup>33</sup>

33. According to a 2016 report from the Commonwealth Fund, both copayments and coinsurance are used for cost-sharing on marketplace plans, with the use of coinsurance increasing across tiers. Specifically—as of 2016—68% of marketplace plans used copayments for generic drugs, while only 14% used coinsurance. For preferred brands, the proportion using copayments was 62%, while coinsurance was used by 23%. For non-preferred brand drugs, 41% of marketplace plans used copayments while 37% used coinsurance, and for specialty drugs, only 16% had copayments while 60% of plans used coinsurance. The specific plans also vary, with platinum plans most often relying on copayments and bronze plans most often relying on coinsurance.<sup>34</sup>

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<sup>31</sup> Hamel, Liz, Jamie Firth, Larry Levitt, Gary Claxton, and Mollyann Brodie, “Survey of Non-Group Health Insurance Enrollees, Wave 3,” *Kaiser Family Foundation*, May 20, 2016, available at <https://www.kff.org/health-reform/poll-finding/survey-of-non-group-health-insurance-enrollees-wave-3/> (viewed June 6, 2019).

<sup>32</sup> Totals on each marketplace plan level do not count those on non-marketplace ACA-compliant plans. “Marketplace Plan Selections by Metal Level.” *Kaiser Family Foundation*, 2019, available at <https://www.kff.org/health-reform/state-indicator/marketplace-plan-selections-by-metal-level-2/?dataView=1&currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (viewed June 10, 2019).

<sup>33</sup> Rae, Matthew, Larry Levitt, and Gary Claxton, “Patient Cost-Sharing in Marketplace Plans, 2016,” *Kaiser Family Foundation*, November 13, 2015, available at <https://www.kff.org/health-costs/issue-brief/patient-cost-sharing-in-marketplace-plans-2016/> (viewed June 5, 2019).

<sup>34</sup> Gabel, Jon, Matthew Green, Adrienne Call, Heidi Whitmore, Sam Stromberg, and Rebecca Oran, “Changes in Consumer Cost-Sharing for Health Plans Sold in the ACA’s Marketplaces, 2015 to 2016,” *The Commonwealth Fund*, May 2016, p. 8, available at [https://www.commonwealthfund.org/sites/default/files/documents/\\_\\_\\_media\\_files\\_publications\\_issue\\_brief\\_2016\\_may\\_1875\\_gabel\\_changes\\_cost\\_sharing\\_marketplaces\\_rb\\_v2.pdf](https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2016_may_1875_gabel_changes_cost_sharing_marketplaces_rb_v2.pdf) (viewed June 11, 2019).

**B. Medicaid: Nearly all Medicaid enrollees have only flat copayments for prescription drugs and are unaffected by WAC**

34. Almost 65 million Americans (21% of the population) receive health insurance from Medicaid—which includes roughly 12 million Americans who are eligible for both Medicare and Medicaid coverage.<sup>35</sup> Almost none of these individuals incur a cost for prescription drugs that is based on or calculated from WAC—and many get access to drugs with no payment at all.

35. Instead, Medicaid beneficiaries have no prescription drug deductibles; rather, their prescriptions are purchased with capped copayments or no payment at all—and at levels that are mere fractions of even the most common copayments in the commercial market.<sup>36</sup> For preferred prescription drugs, all Medicaid enrollees pay a federally mandated *maximum* \$4 copayment—regardless of WAC.<sup>37</sup> For non-preferred drugs, Medicaid beneficiaries at or below 150% of the federal poverty level pay a maximum \$8 copay—again, regardless of WAC.<sup>38</sup>

36. By statute, states are allowed to require Medicaid enrollees above 150% of the federal poverty level to pay up to 20% of the state’s cost (as I discuss next, this would be 20% of the greatly discounted price paid by state Medicaid plans, not WAC).<sup>39</sup> But no state exercises this

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<sup>35</sup> “Health Insurance Coverage of the Total Population,” *Kaiser Family Foundation*, 2017, available at <https://www.kff.org/other/state-indicator/total-population/> (viewed June 5, 2019); “Data Analysis Brief: Medicare-Medicaid Dual Enrollment 2006 through 2017,” *CMS Medicare-Medicaid Coordination Office*, December 2018, p.1, available at <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/DataStatisticalResources/Downloads/MedicareMedicaidDualEnrollmentEverEnrolledTrendsDataBrief2006-2017.pdf>.

<sup>36</sup> “Medicaid Benefits: Prescription Drugs,” *Kaiser Family Foundation*, 2018, available at <https://www.kff.org/medicaid/state-indicator/prescription-drugs/> (viewed June 5, 2019). For comparison, for employer-sponsored commercial plans the average copay was \$11 for first-tier, \$33 for second-tier, \$59 for third-tier, and \$105 for fourth-tier drugs. *See* KFF 2018 Employer Health Benefits Survey, p. 155.

<sup>37</sup> “Cost Sharing Out of Pocket Costs,” *Medicaid.gov*, available at <https://www.medicaid.gov/medicaid/cost-sharing/out-of-pocket-costs/index.html> (viewed June 5, 2019).

<sup>38</sup> “Cost Sharing Out of Pocket Costs,” *Medicaid.gov*, available at <https://www.medicaid.gov/medicaid/cost-sharing/out-of-pocket-costs/index.html> (viewed June 5, 2019).

<sup>39</sup> “Cost Sharing Out of Pocket Costs,” *Medicaid.gov*, available at <https://www.medicaid.gov/medicaid/cost-sharing/out-of-pocket-costs/index.html> (viewed June 5, 2019).

option. All states except Kentucky currently require only fixed copayments for non-preferred drugs regardless of income level. Kentucky is the only exception, but it imposes only a 5% coinsurance on the state's cost of the non-preferred drug for adults above 150% of the poverty line, and even that amount is capped at only \$20 per purchase, with no coinsurance required for children at any poverty level.<sup>40</sup> Currently in Kentucky, there are approximately 650,000 adults enrolled in Medicaid, and only a small subset of them are over 150% of the poverty level.<sup>41</sup>

37. Furthermore, with respect to Medicaid, even the government pays costs that bear little resemblance to WAC. States purchase drugs for Medicaid under the "Best Price Guarantee" whereby they are entitled to pay either 23% off average manufacturer price (for branded medications) or the maximum discounted rebate price, whichever discount is greater.<sup>42</sup> State Medicaid plans may also negotiate additional supplemental rebates.<sup>43</sup> Finally, Medicaid is also guaranteed an adjustment if a drug's price rises faster than inflation, which can translate to sizeable discounts for older drugs with significant price increases.<sup>44</sup>

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<sup>40</sup> "Cost-Sharing Requirements for Selected Medicaid Services for Section 1931 Parents," *Kaiser Family Foundation*, January 1, 2019, available at <https://www.kff.org/medicaid/state-indicator/cost-sharing-requirements-for-selected-medicare-services-for-section-1931-parents-january/> (viewed June 5, 2019); "Premium and Cost-Sharing Requirements for Selected Services for Medicaid Adults," *Kaiser Family Foundation*, January 1, 2019, available at <https://www.kff.org/health-reform/state-indicator/premium-and-cost-sharing-requirements-for-selected-services-for-medicare-expansion-adults> (viewed June 5, 2019).

<sup>41</sup> "Monthly Child Enrollment in Medicaid and CHIP," *Kaiser Family Foundation*, March 2019, available at <https://www.kff.org/medicaid/state-indicator/total-medicare-and-chip-child-enrollment/?currentTimeframe=0&selectedRows=%7B%22states%22:%7B%22kentucky%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (viewed June 5, 2019).

<sup>42</sup> "Medicaid Drug Rebate Program," *Medicaid.gov*, available at <https://www.medicare.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html> (viewed June 5, 2019).

<sup>43</sup> "State Prescription Drug Resources," *Medicaid.gov*, available at <https://www.medicare.gov/medicaid/prescription-drugs/state-prescription-drug-resources/index.html> (viewed June 5, 2019).

<sup>44</sup> Baghdadi, Ramsey, "Medicaid Best Price," *Health Affairs Health Policy Brief*, August 10, 2017. DOI: 10.1377/hpb20171008.000173.



38. As a result, Medicaid plans benefit from the largest rebates in the entire industry. Indeed, the Medicaid and CHIP Payment and Access Commission has reported that in aggregate “[d]rug rebates reduced gross Medicaid drug spending by more than half (54.5 percent) in FY 2017” relative to what cost would be if WAC was paid.<sup>45</sup>

**C. Medicare: Medicare enrollees face a complex set of cost-sharing rules, but rarely incur costs that are close to WAC**

39. In 2017, 42.8 million Americans were covered only by Medicare (14% of the population), with an additional 12 million receiving both Medicaid and Medicare benefits (dual eligibility).<sup>46</sup> I have already addressed the dual-eligible population in my discussion of Medicaid above.

40. Medicare-only enrollees pay out-of-pocket costs that are, at certain times and for certain drugs, calculated as a percentage of the pharmacy negotiated price, which itself is based on WAC. But due to the complexity in cost-sharing rules and their variability across hundreds of available prescription drug plans, as well as changes in cost-sharing calculations depending on features such as year-to-date spending and formulary placement, out-of-pocket costs will vary over the course of the year for the same prescription drug for different consumers on the same Medicare plan—and even for the same consumer, depending on the consumer’s other healthcare costs

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<sup>45</sup> “MACStats: Medicaid and CHIP Data Book,” *MACPAC*, December 2018, p.38, available at <https://www.macpac.gov/wp-content/uploads/2018/12/December-2018-MACStats-Data-Book.pdf> (viewed June 5, 2019).

<sup>46</sup> “Health Insurance Coverage of the Total Population,” *Kaiser Family Foundation*, 2017, available at <https://www.kff.org/other/state-indicator/total-population/> (viewed June 5, 2019); “Data Analysis Brief: Medicare-Medicaid Dual Enrollment 2006 through 2017,” *CMS Medicare-Medicaid Coordination Office*, p. 1, available at <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/DataStatisticalResources/Downloads/MedicareMedicaidDualEnrollmentEverEnrolledTrendsDataBrief2006-2017.pdf>.

accrued year to date. This makes it extremely difficult for Medicare beneficiaries to gauge out-of-pocket cost on the basis of WAC.

41. Medicare Part B includes coverage for medical services as well as for physician-administered prescription drugs for beneficiaries enrolled in traditional fee-for-service Medicare. For Part B drug coverage, Medicare beneficiaries first must meet a standard \$185 deductible. They then typically pay a 20% coinsurance calculated based on the drug's Average Sales Price (ASP) plus a 6% markup.<sup>47</sup> ASP is reported to CMS by manufacturers and reflects the average price charged by manufacturers to purchasers, after accounting for rebates and discounts. For many prescription drugs reimbursed through Part B, ASP plus 6% is considerably lower than WAC, while for others the two may be more similar. Medicare beneficiaries, however, are unlikely to know a drug's ASP, much less know whether WAC provides a reasonable proxy for ASP plus 6%, and therefore will have difficulty predicting their expected coinsurance. In addition, many beneficiaries also purchase Medigap supplemental policies, which provide wraparound coverage, some of which can be used to cover any coinsurance burden from Part B expenses. Approximately 1 in 4 people with traditional Medicare are enrolled in Medigap.<sup>48</sup>

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<sup>47</sup> In general, ASP + 6% is the statutory rate for drugs administered in an outpatient or physician office setting. However, due to sequestration provisions introduced in the 2011 Budget Control Act, the reimbursement is effectively reduced to ASP + 4.3%. Werble, Cole, "Medicare Part B," *Health Affairs*, August 10, 2017, available at <https://www.healthaffairs.org/doi/10.1377/hpb20171008.000171/full/> (viewed June 12, 2019). "Medicare costs at a glance," *Medicare.gov*, available at <https://www.medicare.gov/your-medicare-costs/medicare-costs-at-a-glance> (viewed June 10, 2019); Sachs, Rachel. "Administration Outlines Plan to Lower Pharmaceutical Prices in Medicare Part B," *Health Affairs*, October 26, 2018, available at <https://www.healthaffairs.org/doi/10.1377/hblog20181026.360332/full/> (viewed June 10, 2019); "Part B," *Center for Medicare Advocacy*, available at <https://www.medicareadvocacy.org/medicare-info/medicare-part-b/> (viewed June 10, 2019).

<sup>48</sup> Boccuti, Cristina, Gretchen Jacobson, Kendal Orgera, and Tricia Neuman, "Medigap Enrollment and Consumer Protections Vary Across States," *Kaiser Family Foundation*, July 11, 2018, available at <https://www.kff.org/medicare/issue-brief/medigap-enrollment-and-consumer-protections-vary-across-states/> (viewed June 5, 2019).

42. Approximately 43 million Americans (14% of the population) are enrolled in a Medicare Part D prescription drugs plan, with about half (20.4 million) enrolled in a privately administered Medicare Advantage Plan (MA-PD) and the rest in standalone fee-for-service Medicare Prescription Drug Plans (PDPs). (Some of these individuals, as noted above, are also covered by Medicaid.)<sup>49</sup> Medicare Advantage plans must provide coverage that is at least as generous as traditional Medicare, and nearly 90% of those plans also supply drug coverage.<sup>50</sup>

43. With respect to deductibles, as of 2018, 45% of all Medicare Part D beneficiaries had no deductible at all.<sup>51</sup> For those that have deductibles, both MA-PD and PDP prescription drug plans impose a maximum \$415 deductible (as of 2019), after which beneficiaries pay either a copayment or coinsurance on the next \$3,405 of prescription drugs.<sup>52</sup> The precise cost to consumers of their prescription drugs during this phase varies widely and depends on both the type of drug a consumer is taking, their other healthcare expenses, and the cost-sharing specifics of their plan, making the relationship to a drug's WAC difficult to discern.

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<sup>49</sup> Jacobson, Gretchen, Anthony Damico, and Tricia Neuman, "A Dozen Facts about Medicare Advantage," *Kaiser Family Foundation*, November 13, 2018, available at <https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage/>, (viewed June 5, 2019); Cubanski, Juliette, Anthony Damico, and Tricia Neuman. "Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing," *Kaiser Family Foundation*, May 17, 2018, available at <https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/> (viewed June 5, 2019); "Health Insurance Coverage of the Total Population," *Kaiser Family Foundation*, 2017, available at <https://www.kff.org/other/state-indicator/total-population/> (viewed June 5, 2019).

<sup>50</sup> Graham, Judith, "Medicare Vs. Medicare Advantage: How To Choose," *Kaiser Health News*, October 19, 2017, available at <https://khn.org/news/medicare-vs-medicare-advantage-how-to-choose/>, (viewed June 5, 2019).

<sup>51</sup> Cubanski, Juliette, Anthony Damico, and Tricia Neuman. "Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing," *Kaiser Family Foundation*, May 17, 2018, available at <https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/> (viewed June 5, 2019).

<sup>52</sup> "Yearly deductible for drug plans," *Medicare.gov*, available at <https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/yearly-deductible-for-drug-plans> (viewed June 5, 2019); "Costs in the coverage gap," *Medicare.gov*, available at <https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/costs-in-the-coverage-gap> (viewed June 5, 2019)

44. There are multiple additional reasons why a Medicare Part D beneficiary cannot easily predict what his or her out-of-pocket cost will be for a given prescription.

45. *First*, the amount that a Medicare beneficiary will pay depends on the type of medication and the specific plan.

- a. For preferred brand drugs, only 23% of PDP and 1% of MA-PD plan enrollees are required to pay coinsurance—approximately only 5 million beneficiaries in total.<sup>53</sup>
- b. For non-preferred drugs, although nearly all PDP plan enrollees (25.1 million people) pay coinsurance, 88% of enrollees on MA-PD plans (18.3 million people) have copayments for non-preferred drugs rather than coinsurance.<sup>54</sup>
- c. Finally, for specialty drugs, defined as a drug that costs at least \$670 per month, all Medicare Part D enrollees are subject to some level of coinsurance.<sup>55</sup> However, a CBO report estimates that just 300,000 Medicare

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<sup>53</sup> Cubanski, Juliette, Anthony Damico, and Tricia Neuman. “Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing,” *Kaiser Family Foundation*, May 17, 2018, available at <https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/> (viewed June 5, 2019).

<sup>54</sup> Cubanski, Juliette, Anthony Damico, and Tricia Neuman. “Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing,” *Kaiser Family Foundation*, May 17, 2018, available at <https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/> (viewed June 5, 2019).

<sup>55</sup> Cubanski, Juliette, Anthony Damico, and Tricia Neuman. “Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing,” *Kaiser Family Foundation*, May 17, 2018, available at <https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/> (viewed June 5, 2019).

Part D members (1.4%) who received no other subsidies from Medicaid or an employer took a specialty drug in 2015.<sup>56</sup>

46. *Second*, for those Medicare beneficiaries who are responsible for paying coinsurance on their prescription medication, there are federally-mandated limits on the percentage coinsurance that any consumer would have to pay. For non-preferred brand drugs, the maximum coinsurance allowed for Medicare beneficiaries is 50%, while preferred brand coinsurance is capped at 25% and specialty drugs are capped at 33% coinsurance.<sup>57</sup>

47. *Third*, the price on which the Medicare beneficiary's cost-sharing is based is the price negotiated by the pharmacy, not WAC.<sup>58</sup> This negotiated price is difficult, if not impossible, for a Medicare beneficiary to discern, as it can vary by pharmacy due to preferred pharmacy networks—limited networks of pharmacies that Medicare Part D plan sponsors use to lower costs. One study found considerable variation in the negotiated price paid by Medicare plans at different pharmacies. For example, the study looked at the most common package size and type of the

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<sup>56</sup> Anderson-Cook, Anna, Jared Maeda, and Lyle Nelson, "Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis," *Congressional Budget Office Working Paper Series*, March 2019, p. 29, available at [https://www.cbo.gov/system/files?file=2019-03/55011-Specialty\\_Drugs\\_WP.pdf](https://www.cbo.gov/system/files?file=2019-03/55011-Specialty_Drugs_WP.pdf).

<sup>57</sup> Pearson, Caroline F., Kelly Brantley, and Miryam Frieder, "Majority of Drugs Now Subject to Coinsurance in Medicare Part D Plans," *Avalere*, March 10, 2016, available at <https://avalere.com/press-releases/majority-of-drugs-now-subject-to-coinsurance-in-medicare-part-d-plans> (viewed June 5, 2019).

<sup>58</sup> "Medicare Clarifies 'Negotiated Prices' Under Part D," *CMS.gov*, January 6, 2009, available at <https://www.cms.gov/newsroom/press-releases/medicare-clarifies-negotiated-prices-under-part-d> (viewed June 5, 2019).

cholesterol drug Crestor.<sup>59</sup> For a single day's supply of Crestor, there was variability in price of \$1.32 (with a mean price of \$5.15) between the 25<sup>th</sup> and 75<sup>th</sup> percentile.<sup>60</sup>

48. Therefore, even when Medicare beneficiaries pay coinsurance for prescription drugs, they are paying *at most* 50% of the negotiated price, which itself is may be less than WAC. Their out-of-pocket cost is therefore at most half of WAC. Furthermore, this price will vary by pharmacy and is difficult for consumers to discern in advance based on a WAC they may observe in ads.

49. *Fourth*, the amount a Medicare beneficiary has to pay for one prescription of a particular drug changes depending on how much they have spent in the aggregate so far that year. After a Medicare beneficiary has spent \$3,820 on prescription drugs, he or she enters the coverage gap phase, where the beneficiary pays no more than 25% of the negotiated price of a brand-name drug (with the manufacturer covering an additional 70%) or 37% of the negotiated price of a generic drug.<sup>61</sup> In 2016, approximately 5.2 million Medicare Part D enrollees who were not covered by low-income subsidies reached the coverage gap.<sup>62</sup>

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<sup>59</sup> More specifically, the study looked at the most common National Drug Code (NDC) for Crestor. The NDC uniquely identifies the manufacturer, product strength and dose information, as well as package size and type for a specific version of a drug. "National Drug Codes: What is a National Drug Code (NDC)?" *Idaho MMIS*, February 9, 2018, p. 1, available at <https://www.idmedicaid.com/Reference/NDC%20Format%20for%20Billing%20PAD.pdf> (viewed June 10, 2019).

<sup>60</sup> Starc, Amanda and Ashley Swanson, "Preferred Pharmacy Networks and Drug Costs," *National Bureau of Economic Research*, Working Paper 24862, July 2018, p. 9, available at <https://www.nber.org/papers/w24862.pdf>.

<sup>61</sup> "Costs for Medicare drug coverage: Costs in the coverage gap," *Medicare.gov*, available at <https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/costs-in-the-coverage-gap> (viewed June 5, 2019).

<sup>62</sup> Cubanski, Juliette, Tricia Neuman, and Anthony Damico, "Closing the Medicare Part D Coverage Gap: Trends, Recent Changes, and What's Ahead," *Kaiser Family Foundation*, August 2018, p. 2, available at <http://files.kff.org/attachment/Data-Note-Closing-the-Medicare-Part-D-Coverage-Gap-Trends-Recent-Changes-and-Whats-Ahead> (viewed June 5, 2019).

50. When beneficiaries' drug expenses total \$5,100 in out-of-pocket spending, they enter the "catastrophic coverage" range, where they are responsible for paying only 5% coinsurance on the negotiated price for the remainder of the plan year.<sup>63</sup> Notably, while in the coverage gap, the manufacturer's contribution of 70% of the drug cost counts towards the beneficiary's out-of-pocket cost, which can accelerate the process of reaching catastrophic coverage.<sup>64</sup>

51. Thus, throughout all phases of Medicare drug coverage, beneficiaries pay out-of-pocket costs that are based on the drug's negotiated price, but in ways that are typically heavily discounted and can be difficult to infer for any given prescription fill or refill—i.e., that price will vary for the same product throughout the year.

**D. Uninsured: WAC may not be fully determinative of their out-of-pocket costs**

52. Uninsured Americans represent the population responsible for paying drug costs that most closely resemble WAC. However, as of 2017, only 9% of the population (27.8 million Americans) were without health insurance.<sup>65</sup> Although no formal cost-sharing with an insurer is available to the uninsured, there are a variety of ways in which they can receive cost assistance. For example, most pharmaceutical manufacturers offer programs to provide discounts or free products for need-based, eligible consumers.<sup>66</sup> The programs may be offered directly through the

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<sup>63</sup> Doshi, Jalpa, Amy Pettit, and Pengxiang Li, "Addressing Out-of-Pocket Specialty Drug Costs in Medicare Part D: The Good, The Bad, The Ugly And The Ignored," *Health Affairs Blog*, July 25, 2018, available at <https://www.healthaffairs.org/doi/10.1377/hblog20180724.734269/full/> (viewed June 5, 2019); "Catastrophic Coverage," *Medicare.gov*, available at <https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/catastrophic-coverage> (viewed June 6, 2019)

<sup>64</sup> "Costs for Medicare drug coverage: Costs in the coverage gap," *Medicare.gov*, available at <https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/costs-in-the-coverage-gap> (viewed June 5, 2019).

<sup>65</sup> "Health Insurance Coverage of the Total Population," *Kaiser Family Foundation*, 2017, available at <https://www.kff.org/other/state-indicator/total-population/> (viewed June 5, 2019).

<sup>66</sup> For example, see information about programs for need-based eligible individuals for AbbVie (<https://www.abbvie.com/patients/patient-assistance/program-qualification/humira-program->

manufacturer or through an affiliated foundation. Indeed, every one of the manufacturers of the 20 drugs with the highest DTC advertising spend referenced in the final rule offers an assistance program for patients that provides medication at no cost to eligible consumers. Eligibility for these programs related to the top 20 DTC drugs can reach up to 500% of the federal poverty line, and many offer up to 12 months' worth of coverage. In addition to these no-cost programs, some drugs have more than one patient assistance option, offering uninsured consumers discounts ranging from 36-75% off WAC regardless of income.<sup>67</sup> Importantly, the variability of the structure of these low-income assistance programs means that an uninsured individual watching a commercial listing WAC has no systematic way of predicting how that price reflects what they would be required to pay for the product if they were to seek out a prescription.

#### **VI. Consumers' Out-Of-Pocket Costs Vary Considerably And Are Difficult To Reliably Predict Based On WAC**

53. For the reasons discussed above, the overwhelming majority of Americans do not pay an amount that resembles or is related to WAC when purchasing prescription drugs. The out-of-pocket costs for the same prescription drug vary by consumer—and can vary even for the same consumer over the course of the year—based on whether a consumer has insurance, the design of his or her insurance plan, and his or her other healthcare expenses. As a result of these complexities, without very specific data even the people most knowledgeable about prescription drug pricing and health insurance structures would be challenged to reliably predict a given consumer's out-of-pocket costs in any given year, let alone for any particular transaction. But, unsurprisingly, and as discussed below, most Americans are not well-informed about drug pricing

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selection.html#myabbvie), Lilly (<http://www.lillycares.com/aboutlillycares.aspx>), Amgen (<http://www.amgensafetynetfoundation.com/resources-faqs.html>), and Merck (<https://www.merckhelps.com/>).

<sup>67</sup> For example, *see* Pfizer RxPathways ([https://www.pfizerRxPathways.com/sites/default/files/PfizerRxPathwaysMedicineList1.2.19-0951\\_1.pdf](https://www.pfizerRxPathways.com/sites/default/files/PfizerRxPathwaysMedicineList1.2.19-0951_1.pdf)).



and how their own health insurance works. For these reasons, most Americans cannot be expected to accurately predict their out-of-pocket costs from a prescription drug's WAC, let alone from the disclosure of WAC in a short commercial.

**A. Due to the complexities of drug pricing and cost sharing, out-of-pocket costs generally bear little—or no—relation to WAC**

54. Out-of-pocket costs are generally minimally related—or entirely unrelated—to WAC, such that a consumer may well pay lower out-of-pocket costs for a prescription drug that has a higher WAC. For example, consider two hypothetical drugs that could be used by a consumer. Drug A has a WAC of \$1,000 per month, and Drug B has a WAC of \$900. The manufacturer of Drug A has agreed to give an insurer a rebate of 25%, resulting in a net price to the insurer of \$750. The manufacturer of Drug B is only providing a 10% rebate, for a net price to the insurer of \$810. In this example, Drug A, the preferred drug by the plan, carries a copayment of \$50 per prescription, while Drug B has an \$80 copayment. As a result, a consumer prescribed the drug with higher WAC will have lower out-of-pocket costs than if he or she was prescribed the drug with the lower WAC. Complicating matters, this scenario could be reversed for a consumer insured by a different company; for that consumer's insurance company, it may be that the manufacturer of Drug B offered that insurer the larger rebate, resulting in the insurer placing it on a tier with a lower copayment than Drug A. In that case, the consumer in question will pay lower out-of-pocket costs if prescribed Drug B than Drug A.

55. As an additional example, consider a consumer with a \$1,500 deductible, a 20% coinsurance for a specialty drug he or she needs to treat a chronic condition, and a total out-of-pocket maximum of \$3,000. The drug has a WAC of \$1,500. Even assuming the pharmacy's retail price is close to WAC and the consumer was using no other drugs, this consumer will face at least three different out-of-pocket-costs for the same drug in the same plan year: his or her first

prescription would cost approximately \$1,500; once the deductible is met, the next five prescriptions would cost approximately \$300 each (20% of \$1,500); and for the remainder of the year the out-of-pocket cost would be zero, since the out-of-pocket maximum has been met.<sup>68</sup> To complicate things further, this same consumer would face different costs yet if he or she had other medications or received medical services, which would add to the consumer's overall healthcare spending. The additional spending could bring the consumer to his or her deductible limit or out-of-pocket maximum even sooner, and perhaps before she has paid anything at all for the drug in question.

56. Certain additional complexities further hamper consumers' ability to accurately estimate their costs. First, manufacturers increasingly are making copayment coupons available to beneficiaries of commercial insurance.<sup>69</sup> These can further reduce consumers' out-of-pocket costs, which further complicates predictions of out-of-pocket costs. In addition, certain tax-advantaged tools can affect consumers' out-of-pocket costs. For example, many employers offer flexible spending accounts (FSA), in which pre-tax dollars can be set aside by employees to cover certain healthcare expenses such as copayments, coinsurance and deductibles. Hence, when an FSA is used to finance such expenses, the economic cost to consumers is further reduced due to the tax benefit. Similar logic applies to funds used from health savings accounts (HSAs). It is unclear how salient these tax benefits are for consumers when they consider their spending on specific

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<sup>68</sup> As discussed above, pharmacies can negotiate their own discounts when they purchase drugs. As a result, the retail price they charge would be determined based on this discounted price to the pharmacy, which can vary across pharmacies, and not based on WAC. However, for simplicity, I use WAC in this example.

<sup>69</sup> Van Nuys, Karen, Geoffrey Joyce, Rocio Ribero, and Dana P. Goldman, "A Perspective on Prescription Drug Copayment Coupons," *USC Schaeffer Center for Health Policy & Economics*, February 2018, p. 2, available at [https://healthpolicy.usc.edu/wp-content/uploads/2018/02/2018.02\\_Prescription20Copay20Coupons20White20Paper\\_Final-2.pdf](https://healthpolicy.usc.edu/wp-content/uploads/2018/02/2018.02_Prescription20Copay20Coupons20White20Paper_Final-2.pdf) (viewed June 10, 2019).

prescription drugs throughout the year, and to what degree they explicitly consider them, but they introduce yet another complicating factor for consumers in estimating their out-of-pocket costs.<sup>70</sup>

**B. Claims data from actual individuals demonstrate the variability and lack of predictability of out-of-pocket costs**

57. Examples from actual individuals further illustrate the variability of out-of-pocket costs for prescription drugs—as well as their lack of relationship to WAC. To demonstrate this point, I examined data from OptumHealth Care Solutions, Inc., a large database of health insurance claims data for beneficiaries of employer-sponsored plans.<sup>71</sup> I reviewed the complete medical and pharmacy claims data for select individuals over a one-year period (2016). While these data contain detailed information on spending, they lack detail on many specific features of the insurance design. Therefore, in the analysis below, I infer many of these features from the observed spending of the individuals. For this illustrative analysis, I reviewed claims data for individuals who filled at least one prescription for one of the following four medications: Ibrance, Xeljanz, Lyrica, or Farxiga. These products were selected because they are included in the final rule’s list of top 20 drugs in terms of DTC advertising spending and because they reflect a variety of therapeutic areas and manufacturers. However, these examples are not meant to imply that these individuals are statistically representative of any population. Instead they serve as context for how the complicated design of an insurance plan can influence spending throughout the year.

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<sup>70</sup> See, for example, Consumer Reports, “How to Use FSAs, HSAs, and HRAs to Cut Your Healthcare Costs” (<https://www.consumerreports.org/healthcare-costs/how-to-use-fsas-hsas-hras-to-cut-healthcare-costs/>). In particular, they report that “More companies and insurers are offering these options as a way to combat higher healthcare costs, but people are wary about using them,” and “there’s a serious lack of understanding of how these plans work.”

<sup>71</sup> The database consists of claims data for approximately 20 million privately-insured individuals covered by 84 self-insured Fortune 500 companies with locations in all areas of the United States for services provided during the 17-year period, 1999 through 2017:Q1. The database contains complete medical and pharmaceutical claims for the under age 65 (non-Medicare) population, as well as data for supplemental coverage for beneficiaries eligible for Medicare. The database does not contain claims for people covered solely by Medicare.

58. In the examples below, the relevant claims for an individual beneficiary are grouped by month.<sup>72</sup> Monthly costs are broken out by out-of-pocket categories (copayment, coinsurance, deductible) and amounts paid by the plan. Importantly, the amounts paid by the plan reported in the prescription drug claims data do not reflect any manufacturer rebates, which are processed only after the claim has been adjudicated. Therefore, the total cost reported on prescription drug claims—plan paid plus out-of-pocket costs—reflects the gross price of the prescription as dispensed at the pharmacy.

59. Exhibit 1 shows the monthly cost breakdown for a consumer enrolled in a PPO plan who filled prescriptions for Ibrance, a medication for breast cancer. WAC for Ibrance was \$10,342.50 in 2016, but the consumer paid only a copayment of \$36 for each Ibrance prescription, spending a total of \$468 over the course of the year, or less than 1% of WAC. Knowing WAC for Ibrance would give this consumer no information regarding his or her true out-of-pocket costs, and assuming the consumer paid WAC would wildly overstate the consumer's true out-of-pocket costs.

60. In Exhibits 2(a) and 2(b), the consumer is enrolled in a PPO plan with a health savings account (HSA), which indicates a high deductible health plan.<sup>73</sup> Exhibit 2(a) captures the consumer's prescription drug claims for Xeljanz only, while 2(b) describes all drug claims for the consumer. This consumer begins the year taking a different medication (Enbrel—for which he or she pays \$1,500 in deductible and \$640 in copayments), and only begins taking Xeljanz in May. This plan has a deductible that applies to prescription drug benefits, but because the consumer had

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<sup>72</sup> The exhibit charts may include prescription drug claims for the drug of interest alone, all prescription drug claims, or all claims for prescription drug and medical services—as needed. Below the horizontal axis of each exhibit, I indicate whether a patient filled a prescription for the drug of interest in that month. The WAC prices shown each month correspond to the drug of interest's WAC price on the first day of that month. WAC prices obtained from IBM Micromedex, available at <http://www.micromedexsolutions.com/> (viewed June 13, 2019).

<sup>73</sup> “Publication 969 (2018), Health Savings Accounts and Other Tax-Favored Health Plans,” *IRS.gov*, available at <https://www.irs.gov/publications/p969> (viewed June 8 2019).

already met his or her deductible by that time, his or her out-of-pocket cost for Xeljanz was only a \$160 copayment per prescription (totaling \$1,440), while the plan paid \$3,327.65 to \$3,641.78 per prescription each month (totaling \$31,021.89).<sup>74</sup> There are two main takeaways from this example: (1) as with the consumer in Exhibit 1, this consumer's out-of-pocket costs for his or her medication are a small fraction of WAC (approximately 5%); and (2) had the consumer filled a Xeljanz prescription earlier in the year, he or she might have faced higher out-of-pocket costs due to the deductible.

61. Exhibits 3(a) and 3(b) describe a consumer filling prescriptions for Lyrica. This consumer was also enrolled in a PPO plan with a HSA (indicating a high deductible plan). As seen in the exhibits, that deductible applied to his or her drug benefits. This consumer filled a prescription for Lyrica in 11 months of 2016. As seen in Exhibit 3(a), WAC for Lyrica was \$517.54, but the retail price was only \$431.47. The consumer was responsible for the full cost of the drug in January (\$431.47) before meeting his or her deductible with other prescriptions in February (Exhibit 3(b)). The consumer then paid only a copayment of \$60 for each Lyrica prescription each month through October. For the remainder of the year (two more Lyrica prescriptions), the consumer had no out-of-pocket costs whatsoever for Lyrica because he or she had likely met the annual spending cap due to total healthcare spending. In this example, the retail price varies considerably from WAC, thus even when the consumer is responsible for the full cost due to his or her deductible, the cost is considerably lower than WAC. In addition, the consumer's costs further vary during the year, with three different levels of out-of-pocket spending per Lyrica prescription, the last of which is *zero*.

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<sup>74</sup> WAC for Xeljanz in 2016 increased from \$3,169.19 to \$3,468.36 on June 1, 2016, increasing the price the plan paid for this patient's prescriptions from \$3,327.65 through May 31 to \$3,641.78 for the rest of the year.

62. Finally, Exhibits 4(a), 4(b), and 4(c) show a consumer filling prescriptions for Farxiga. The consumer is enrolled in a PPO plan with a HSA (again, indicating a high deductible health plan). This patient meets his or her deductible with medical and non-Farxiga drug expenses in January and February. As a result, his or her out-of-pocket cost for Farxiga is a monthly flat copayment of \$90 in February and May. In June, however, this consumer appears to meet the plan's out-of-pocket maximum, and incurs no out-of-pocket costs for his or her Farxiga or any other drug or medical expenses for the remainder of the year. Not only did this consumer face changing out-of-pocket costs for Farxiga over the year (which in all instances were substantially lower than WAC and even zero in some months), but also his or her cost-sharing was likely affected by other healthcare spending earlier in the year. It is also worth noting that this consumer was subject to coinsurance for non-Farxiga drugs, while he or she only paid copayments for Farxiga. This further illustrates the difficulty—even for a well-informed consumer—to predict out-of-pocket costs based on WAC for a given prescription.

**C. The literature shows that consumers struggle with cost sharing concepts**

63. Given the complexities of drug pricing and the structures of health insurance plans, unsurprisingly, many consumers are not well-informed about their health insurance coverage. This makes it further unlikely that consumers will be able to predict their out-of-pocket costs based on WAC.

64. Few Americans understand the complex structure of insurance benefits and cost-sharing, and how their own plans would operate in practice with respect to a given prescription. One 2013 study of Americans with private health insurance found that “only 14% of [consumers were] able to answer correctly 4 multiple choice questions about the four basic components of traditional health insurance design: deductibles, copays, coinsurance and maximum out of pocket

costs.”<sup>75</sup> Another 2013 study of employees of one large company found that the vast majority of workers were unable to answer questions about high-level health plan benefits and their own recent healthcare spending.<sup>76</sup> Market research by Consumer Reports corroborated this point. They found that “consumers can’t review ‘traditional’ health plan information like deductibles, co-insurance levels and benefit maximums and figure out what it means for them.”<sup>77</sup> Research found that consumers were unfamiliar with terms like “co-insurance, annual benefit limit, allowed amount, out-of-pocket limit and drug tier . . . Yet these terms are used to describe key features present in almost all health plans.”<sup>78</sup>

65. Additional research indicates that Medicare Part D beneficiaries are no different from the general public—they likewise do not understand their health coverage well. A 2019 report finds that a majority of Part D beneficiaries “find it difficult to determine the current and future formularies of the plans they evaluate.”<sup>79</sup> Another study of Medicare Part D beneficiaries found that “regardless of age, gender, predicted drug expenditures or the predictability of drug demand consumers underweight out of pocket costs relative to premiums and fail to consider the individualized consequences of plan characteristics; as a result, they frequently choose plans . . .

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<sup>75</sup> Loewenstein, George, Joelle Y. Friedman, Barbara McGill, Sarah Ahmad, Suzanne Linck, Stacey Sinkula, John Beshears, et al, “Consumers’ Misunderstanding of Health Insurance,” *Journal of Health Economics* 32, no. 5, 2003, p. 22, available at <http://nrs.harvard.edu/urn-3:HUL.InstRepos:17190506>.

<sup>76</sup> Handel, Benjamin R. and Jonathan T. Kolstad, “Health Insurance for ‘Humans’: Information Frictions, Plan Choice, and Consumer Welfare,” *National Bureau of Economic Research Working Paper*, August 2013, p. 17-18, available at <https://www.nber.org/papers/w19373.pdf>.

<sup>77</sup> “What’s Behind the Door: Consumers’ Difficulties Selecting Health Plans,” *ConsumersUnion Health Policy Brief*, January 2012, p. 4, available at [https://www.mnsure.org/assets/MR-CUConsumerSelect\\_tcm34-183778.pdf](https://www.mnsure.org/assets/MR-CUConsumerSelect_tcm34-183778.pdf).

<sup>78</sup> “What’s Behind the Door: Consumers’ Difficulties Selecting Health Plans,” *ConsumersUnion Health Policy Brief*, January 2012, p. 4, available at [https://www.mnsure.org/assets/MR-CUConsumerSelect\\_tcm34-183778.pdf](https://www.mnsure.org/assets/MR-CUConsumerSelect_tcm34-183778.pdf).

<sup>79</sup> Heiss, Florian, Daniel McFadden, and Joachim Winter, “Who Failed to Enroll in Medicare Part D, And Why? Early Results,” *Health Affairs* Vol 25, No 5, September/October 2006, p. w352, available at <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.25.w344>, (viewed June 5, 2019).

[where] an alternative plan provides better risk protection at a lower cost.”<sup>80</sup> Overall, the research shows that consumers have a great deal of difficulty understanding their health insurance benefits generally, and prescription drug coverage and cost-sharing specifically.

66. As seen in the claims data examples discussed above, even if an individual were well-informed of this complex pricing structure, it would be extremely complicated to predict with much reliability what his or her specific costs would be, as they are often influenced by the utilization of other medical services and prescription drugs (and their associated costs), much of which may be unpredictable (e.g., an accidental fall leading to an Emergency Room visit). To further complicate the analysis, he or she would also need visibility into how his or her specific plan classified a specific drug (i.e., preferred, non-preferred), and how his or her specific treatment plan (i.e., the dosage and frequency he or she was prescribed for a given drug) relate to the typical regimen.

## **VII. Conclusion**

67. Over 120 million Americans pay an out-of-pocket cost for prescription drugs that is entirely unrelated to WAC—a price charged to wholesalers and direct purchasers. These consumers pay a fixed copayment substantially below the cost of the drug to wholesalers. Because WAC is irrelevant to the out-of-pocket costs they incur, the final rule’s required disclosure of the so-called “list price” will be highly misleading to these consumers with respect to their own out-of-pocket costs.

68. For the remaining consumers whose out-of-pocket costs are in some way tied to WAC, their share is typically just a fraction of WAC. And within this group of consumers, the cost

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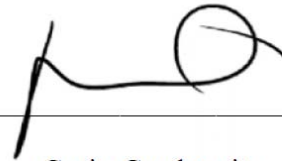
<sup>80</sup> Abaluck, Jason and Jonathan Gruber, “Heterogeneity in Choice Inconsistencies Among the Elderly: Evidence from Prescription Drug Plan Choice,” *American Economic Review*. 2011 May, p.1, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4319794/> (viewed June 5, 2019).



a particular consumer incurs and its relationship to WAC is a complex calculation that is subject to variation over time and across consumers, making WAC a poor benchmark for consumers to predict their out-of-pocket expense.

69. In all, for the vast majority of Americans, the disclosure of WAC will present consumers with information that grossly overstates their out-of-pocket costs for prescription drugs.

I declare and state the foregoing is true and accurate to the best of my knowledge.

A handwritten signature in black ink, appearing to read 'Craig Garthwaite', is written above a horizontal line. The signature is stylized with a large loop at the end.

Craig Garthwaite

June 14, 2019

**APPENDIX A**  
**CURRICULUM VITAE**

**CRAIG GARTHWAITE**

Strategy Department  
Kellogg School of Management, Northwestern University  
2211 Campus Drive, Evanston, IL 60208  
Email: c-garthwaite@kellogg.northwestern.edu

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**APPOINTMENTS**

Kellogg School of Management, Northwestern University  
*Herman Smith Research Professor in Hospital and Health Services*, 2017-Present  
*Associate Professor of Strategy (with tenure)*, 2016 – Present  
*Director, Program on Healthcare @ Kellogg*, 2016 - Present  
*Assistant Professor of Strategy*, 2010 - 2016  
*Senior Lecturer and Donald P. Jacobs Scholar in Management and Strategy*,  
2009 - 2010

National Bureau of Economic Research  
*Research Associate*, 2016-Present  
*Faculty Research Fellow*, 2011-2016

Institute for Policy Research, Northwestern University  
*Faculty Associate*, 2015 - Present

**EDUCATION**

Ph.D. Economics, University of Maryland at College Park, 2009  
M.A. Economics, University of Maryland at College Park, 2008  
M.P.P Gerald R. Ford School of Public Policy at the University of Michigan, 2001  
B.A. Political Science, cum laude, University of Michigan, 2000

**PUBLIC SERVICE**

Member, Congressional Budget Office Technical Review Panel for the Health Insurance  
Simulation Model (2018-Present)

Member, Health Affairs Council on Spending and Value (2018-Present)

Testimony, United States House of Representatives, 2018  
- House Judiciary Committee, Subcommittee on Regulatory Reform,  
Commercial and Antitrust Law: [“Competition in the Pharmaceutical Supply  
Chain: The Proposed Merger of CVS Health and Aetna”](#)

Testimony, United States House of Representatives, 2019  
- House Judiciary Committee, Subcommittee on Regulatory Reform,

Commercial and Antitrust Law: [“Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets”](#)

Testimony, United States Senate, 2019

- Senate Judiciary Committee, Subcommittee on Antitrust, Competition Policy, and Consumer Rights: [“Your Doctor/Pharmacist/Insurer Will See You Now: Competitive Implications of Vertical Consolidation in the Healthcare Industry”](#)

## ACADEMIC PUBLICATIONS

“The Impact of Early Discharge Laws on the Health of Newborns,” (with William Evans and Heng Wei), *Journal of Health Economics*, 2008, 27(4): 843-870.

“The Economic Benefits of Pharmaceutical Innovations: The Case of Cox-2 Inhibitors,” *American Economic Journal: Applied Economics*, 2012, 4(3): 116-137.

“Empirical Evidence on the Value of Pharmaceuticals,” (with Mark Duggan), in *The [Oxford] Handbook of the Economics of the Biopharmaceutical Industry*: Oxford University Press: Oxford, 2012: 463-492.

“The Doctor Might See You Now: The Supply Side Effects of Public Health Insurance Expansions.” *American Economic Journal: Economic Policy* 2012, 4(3): 190-217.

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“Demand Spillovers, Combative Advertising, and Celebrity Endorsements,” *American Economic Journal: Applied Economics*, 2014, 6(2): 76-104.

“Giving Mom a Break: The Effect of Higher EITC Payments on Maternal Health” (with William Evans), *American Economic Journal: Economic Policy*, 2014, 6(2): 258-290.

“Public Health Insurance, Labor Supply, and Employment Lock,” (with Tal Gross and Matthew Notowidigdo), *Quarterly Journal of Economics*, 2014, 129(2): 653-696.

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The Black/White Educational Gap, Stalled Progress, and the Long Term Consequences of the Emergence of Crack Markets, (with William Evans and Timothy J. Moore), *The Review of Economics and Statistics*, 2016, 98(5): 832-847.

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How do Hospitals Respond to Negative Financial Shocks? The Impact of the 2008 Stock Market Crash (with David Dranove and Christopher Ody), *The RAND Journal of Economics*, 2017, 48(2): 485–525.

Insurance Expansion and Hospital Emergency Department Access: Evidence from the Affordable Care Act, (with John Graves, Tal Gross, and Matthew Notowidigdo), *Annals of Internal Medicine*, Feb 7 2017, 166(3):172-179

Success and Failure in the Insurance Exchanges (with John Graves), *New England Journal of Medicine*, March 9, 2017, 376(10):907-910

The Economics of Indication Based Pricing (with Amitabh Chandra), *New England Journal of Medicine*, July 2017, 377(2):103-106.

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The CVS–Aetna Merger: Another Large Bet on the Changing U.S. Health Care Landscape (with Austin Frakt), *Annals of Internal Medicine*, January 9, 2018.

The Orphan Drug Act at 35: Observations and an Outlook for the Twenty-First Century, (with Nicholas Bagley, Benjamin Berger, Amitabh Chandra, and Ariel D. Stern) in *Innovation Policy and the Economy*, 2018, Volume 19, pages 97-137, National Bureau of Economic Research, Inc.

Characterizing the Drug Development Pipeline for Precision Medicine, (with Chandra, Amitabh, Garthwaite, Craig and Stern, Ariel Dora Stern), *Economic*

*Dimensions of Personalized and Precision Medicine*, 2018, National Bureau of Economic Research, Inc.

It's Time to Reform the Orphan Drug Act (with Nicholas Bagley, Amitabh Chandra, and Ariel D. Stern), *NEJM Catalyst*, Dec 19, 2018.

## **WORKING PAPERS**

Guns and Violence: The Enduring Impact of Crack Cocaine Markets on Young Black Males, NBER Working Paper #24819, *under review*, (with Bill Evans and Timothy J. Moore)

Pharmaceutical Profits and the Social Value of Innovation, NBER Working Paper #20212, *under review*, (with David Dranove and Manuel Hermosilla)

Insurance and the High Prices of Pharmaceuticals, NBER Working Paper #22353, *under review*, (with David Dranove and David Besanko)

## **OTHER PUBLICATIONS**

The Impact of the ACA's Medicaid Expansion on Hospitals' Uncompensated Care Burden and the Potential Effects of Repeal (with David Dranove and Christopher Ody), *Commonwealth Fund Issue Brief*, May 2017.

"A Floor and Trade Proposal for Hospital Charity Care," The Hamilton Project working paper.

## **CASES**

*Starbucks: A Story of Growth*, (with Jen Brown and Meghan Busse), 2011. Kellogg Case #5-211-259.

*The Global Aircraft Manufacturing Industry, 2002-2011* (with Jen Brown), 2012. Kellogg Case #5-312-505.

*Sovaldi: Pricing a Breakthrough Drug* (with Meghan Busse), 2015

## **PERMANENT WORKING PAPERS**

"The Effect of In-Utero Conditions on Long Term Health: Evidence from the 1918 Spanish Flu Pandemic," April 2008 (First Draft, July 2007).

## **TEACHING**

Core Business Strategy (STRT 431), Kellogg School of Management, 2009-Present  
Foundations of Strategy, Kellogg-HKUST EMBA, 2016-Present  
Strategy Frameworks Kellogg EMBA, 2017-Present  
Healthcare Strategy (STRT 443), Kellogg School of Management, 2017-Present  
Healthcare Strategy (STRTX 945), Kellogg School of Management EMBA, 2017-Present

## HONORS AND AWARDS

Lavengood Professor of the Year Finalist, 2019  
Lavengood Professor of the Year Finalist, 2018  
Kellogg Faculty Impact Award, Healthcare Strategy, 2018  
*Poets and Quants* 40 Best Under 40 Professors, 2015  
Kellogg Faculty Impact Teaching Award, Business Strategy, 2012  
Kellogg Faculty Impact Teaching Award, Business Strategy, 2012  
Kellogg Chairs' Core Course Teaching Award, 2011-2012  
International Institute of Public Finance (IIPF) Young Economists Award, 2011  
Kellogg Faculty Impact Teaching Award, Business Strategy, 2010  
University of Maryland Third Year Paper Fellowship

## INVITED PRESENTATIONS

2008: University of Notre Dame  
2009: Chicago Booth Graduate School of Business  
2010: University of Wisconsin-Madison, Dartmouth College, University of Notre Dame  
2011: AEA Annual Meeting, University of Illinois-Chicago, Olin Business School at Washington University, Harris School of Public Policy at the University of Chicago, Indiana University SPEA, National Tax Association Annual Meeting, AcademyHealth Research Insights Meeting  
2012: AEA Annual Meeting (Presenter and Discussant), Society of Labor Economists Annual Meeting, NBER Summer Institute, University of Illinois Urbana-Champaign, University of California-Davis, Columbia University  
2013: University of Chicago Health Economics Workshop, University of British Columbia, University of California-San Diego, University of Kentucky, Texas A&M University, Wharton School of the University of Pennsylvania, University of Maryland, Brookings Institution, UC-Davis Poverty Center  
2014: AEA Annual Meeting, Northwestern Law School, RAND Corporation, Rice University/University of Houston, HDMS User Forum, Bates/White Life Science Conference, Vanderbilt University, University of Michigan RWJF Scholars, Northwestern University Economics Department  
2015: AEA Annual Meeting, Stanford University, University of California-Irvine, MIT/BU Health Economics Seminar, Syracuse University, NBER Summer Institute, UT-Austin, University of Maryland

- 2016: Harris School of Public Policy at the University of Chicago, Owen School of Management, Vanderbilt University.  
2017: National Tax Association Annual Meeting  
2018: University of Georgia, Auburn University, Harvard University, Boston University, American Enterprise Institute, University of Southern California  
2019: Ohio State University, Louisville, Emory University, University of Utah  
(Scheduled)

## **ACADEMIC ACTIVITIES**

Co-Editor, *Journal of Public Economics*, (2016 – Present)

Reviewer: *American Economic Review*, *Quarterly Journal of Economics*; *Journal of Political Economy*; *Econometrica*; *Review of Economic Studies*; *New England Journal of Medicine*, *The Journal of Public Economics*; *American Economic Journal: Economic Policy*; *Health Affairs*; *The Review of Economics and Statistics*; *The Journal of Industrial Economics*; *The Journal of Health Economics*; *The Journal of Human Resources*; *Journal of Policy Analysis and Management*; *International Journal of Industrial Organization*; *Health Economics*; *Social Science and Medicine*; *Economic Inquiry*

## **PAST EMPLOYMENT**

Employment Policies Institute, Washington, DC  
*Director of Research and Chief Economist*, 2003-2005  
Public Sector Consultants, Lansing, MI  
*Economist*, 2002-2003

## **OUTSIDE ACTIVITIES**

Affiliated Consultant, Analysis Group (2018-Present)



**APPENDIX B**  
**DOCUMENTS RELIED UPON**

“42 U.S. Code § 1395w–3a. Use of average sales price payment methodology,” *Legal Information Institute*, available at <https://www.law.cornell.edu/uscode/text/42/1395w-3a> (viewed June 13, 2019).

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“Cost-Sharing Requirements for Selected Medicaid Services for Section 1931 Parents,” Kaiser Family Foundation, January 1, 2019, available at <https://www.kff.org/medicaid/state-indicator/cost-sharing-requirements-for-selected-medicaid-services-for-section-1931-parents-january/> (viewed June 5, 2019)

“Costs for Medicare drug coverage: Costs in the coverage gap,” *Medicare.gov*, available at <https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/costs-in-the-coverage-gap> (viewed June 5, 2019).

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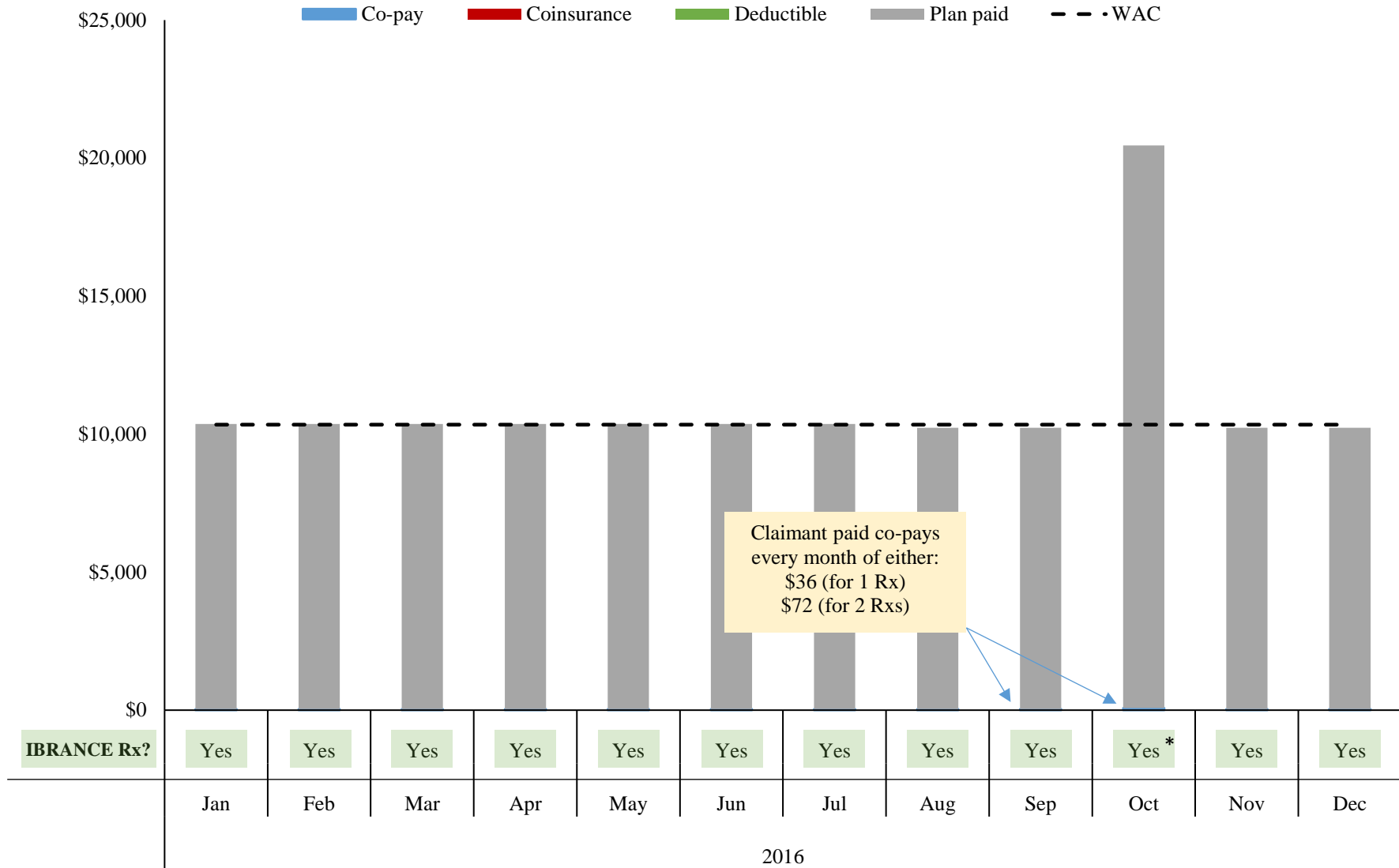
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# **Exhibit 1**

**Exhibit 1 - IBRANCE drug claim cost analysis**  
**IBRANCE patient - PPO - Claimant 25018549301648**



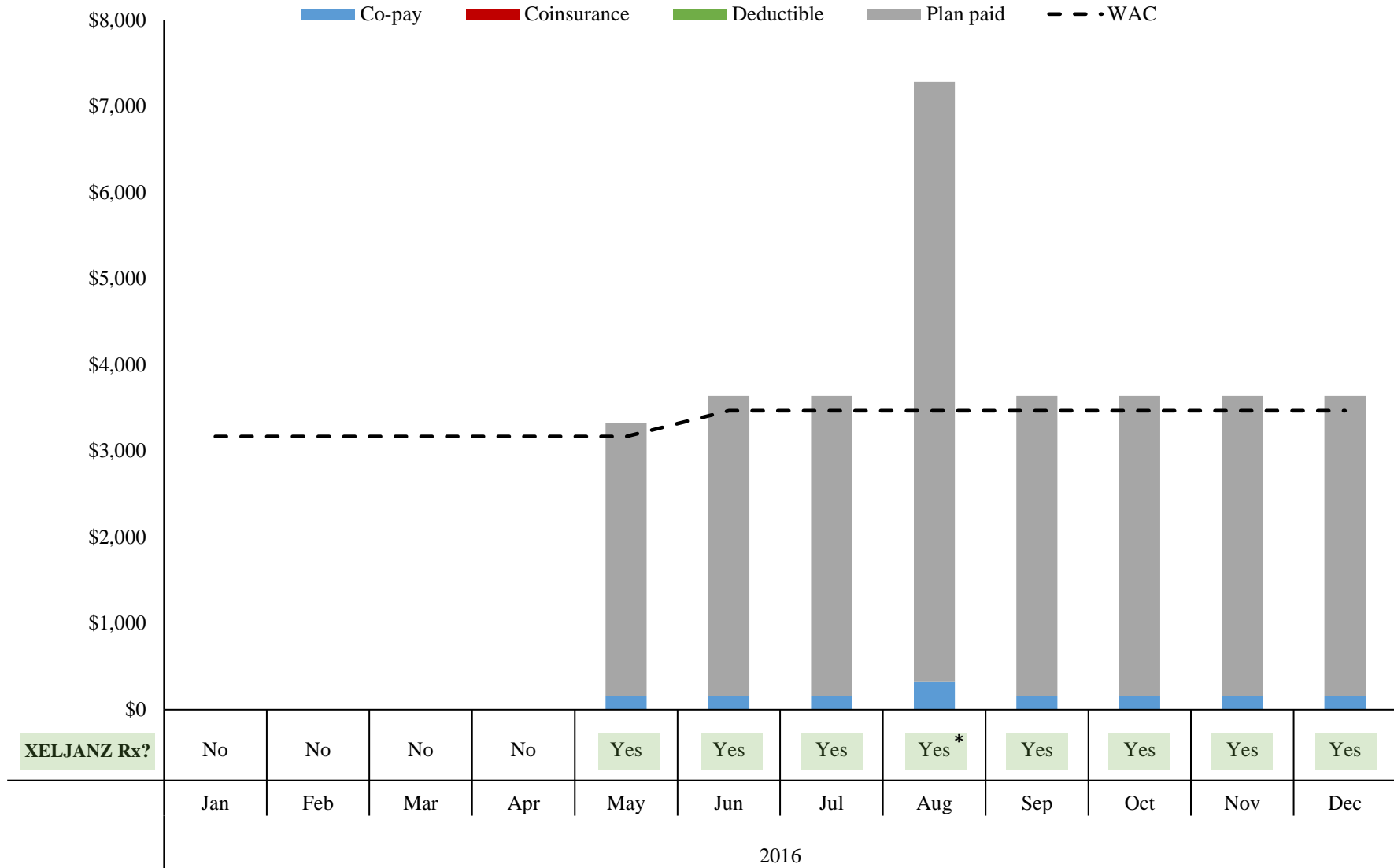
\* Note that in October 2016 the claimant filled two IBRANCE prescriptions

Sources: [A] Micromedex (WAC data); [B] OptumHealth Care Solutions (claims data)



## **Exhibit 2**

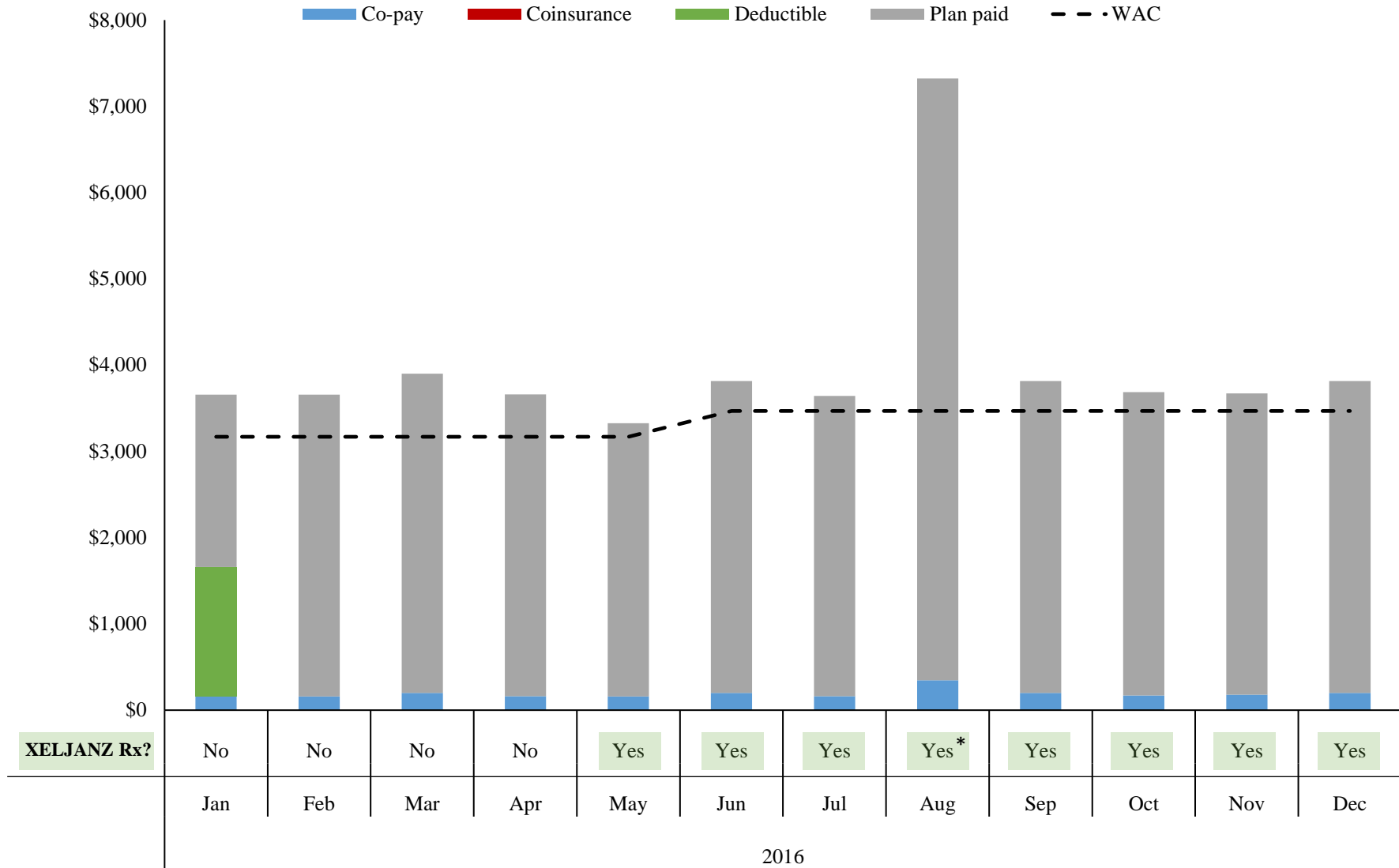
**Exhibit 2(a) - XELJANZ drug claim cost analysis**  
**XELJANZ patient - PPO w/ HSA - Claimant D1003701501458**



\* Note that in August 2016 the claimant filled two XELJANZ prescriptions

Sources: [A] Micromedex (WAC data); [B] OptumHealth Care Solutions (claims data)

**Exhibit 2(b) - Drug claim cost analysis**  
**XELJANZ patient - PPO w/ HSA - Claimant D1003701501458**

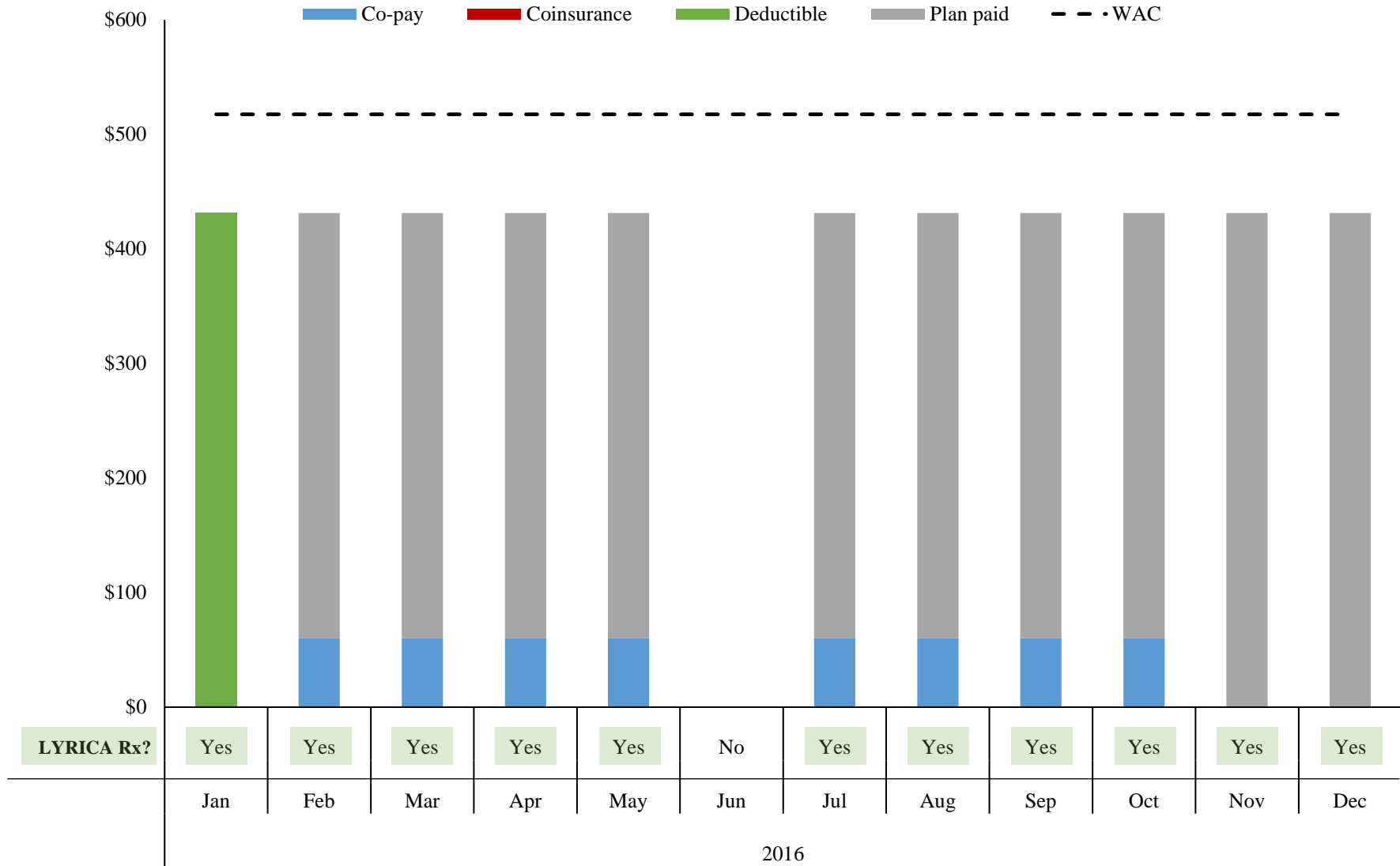


\* Note that in August 2016 the claimant filled two XELJANZ prescriptions

Sources: [A] Micromedex (WAC data); [B] OptumHealth Care Solutions (claims data)

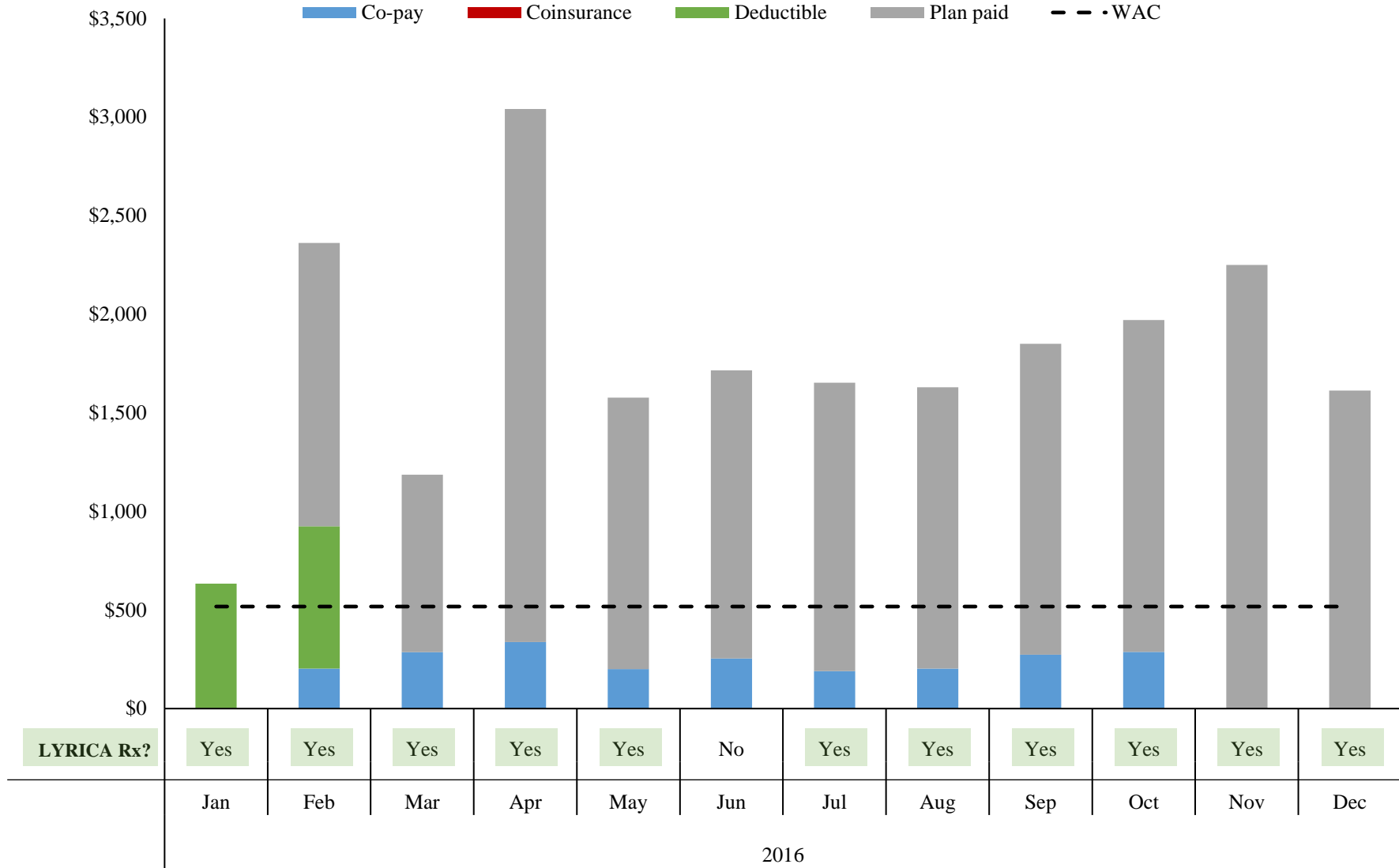
# **Exhibit 3**

**Exhibit 3(a) - LYRICA drug claim cost analysis**  
**LYRICA patient - PPO w/ HSA - Claimant D1002677601853**



Sources: [A] Micromedex (WAC data); [B] OptumHealth Care Solutions (claims data)

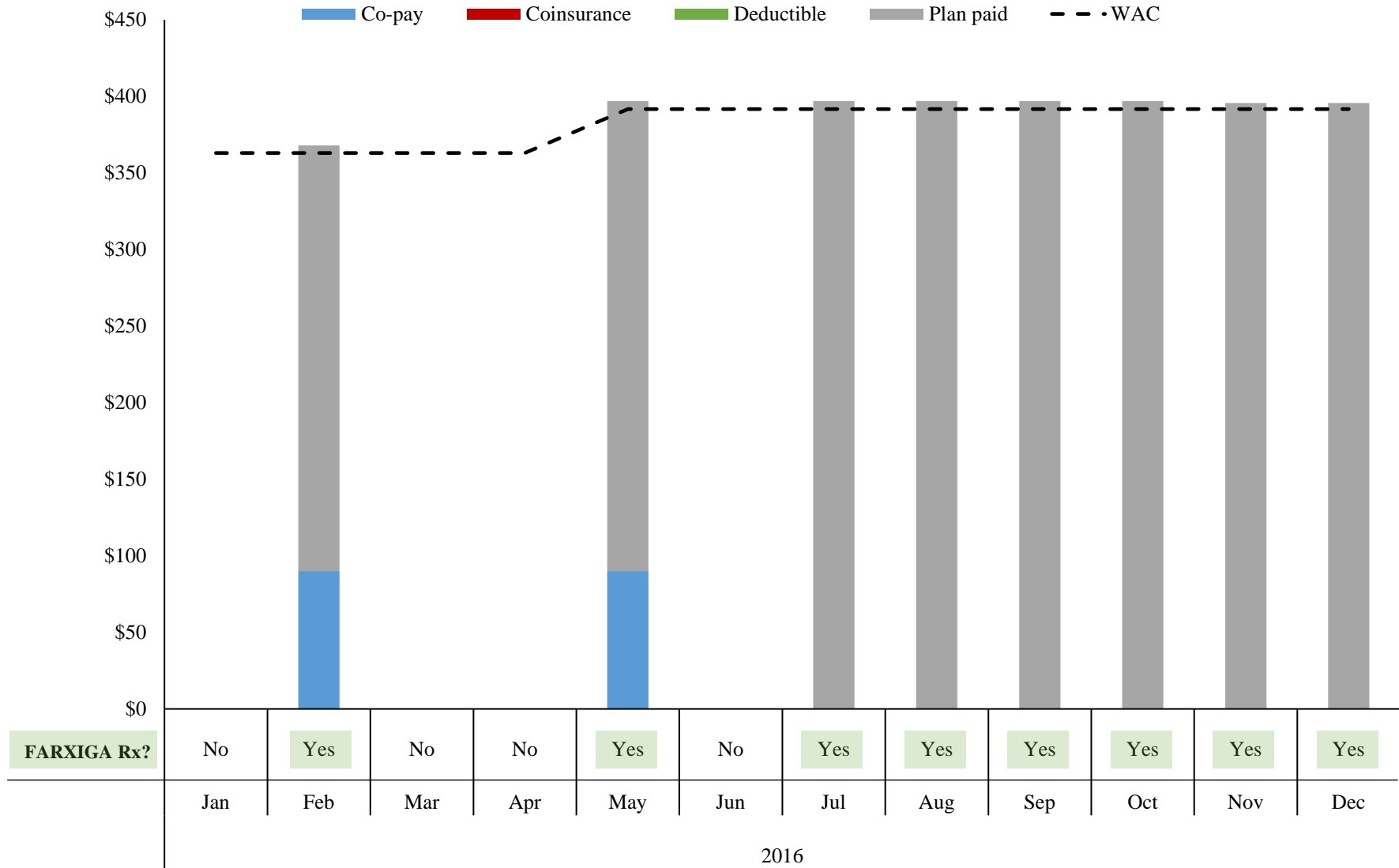
**Exhibit 3(b) - Drug claim cost analysis**  
**LYRICA patient - PPO w/ HSA - Claimant D1002677601853**



Sources: [A] Micromedex (WAC data); [B] OptumHealth Care Solutions (claims data)

# **Exhibit 4**

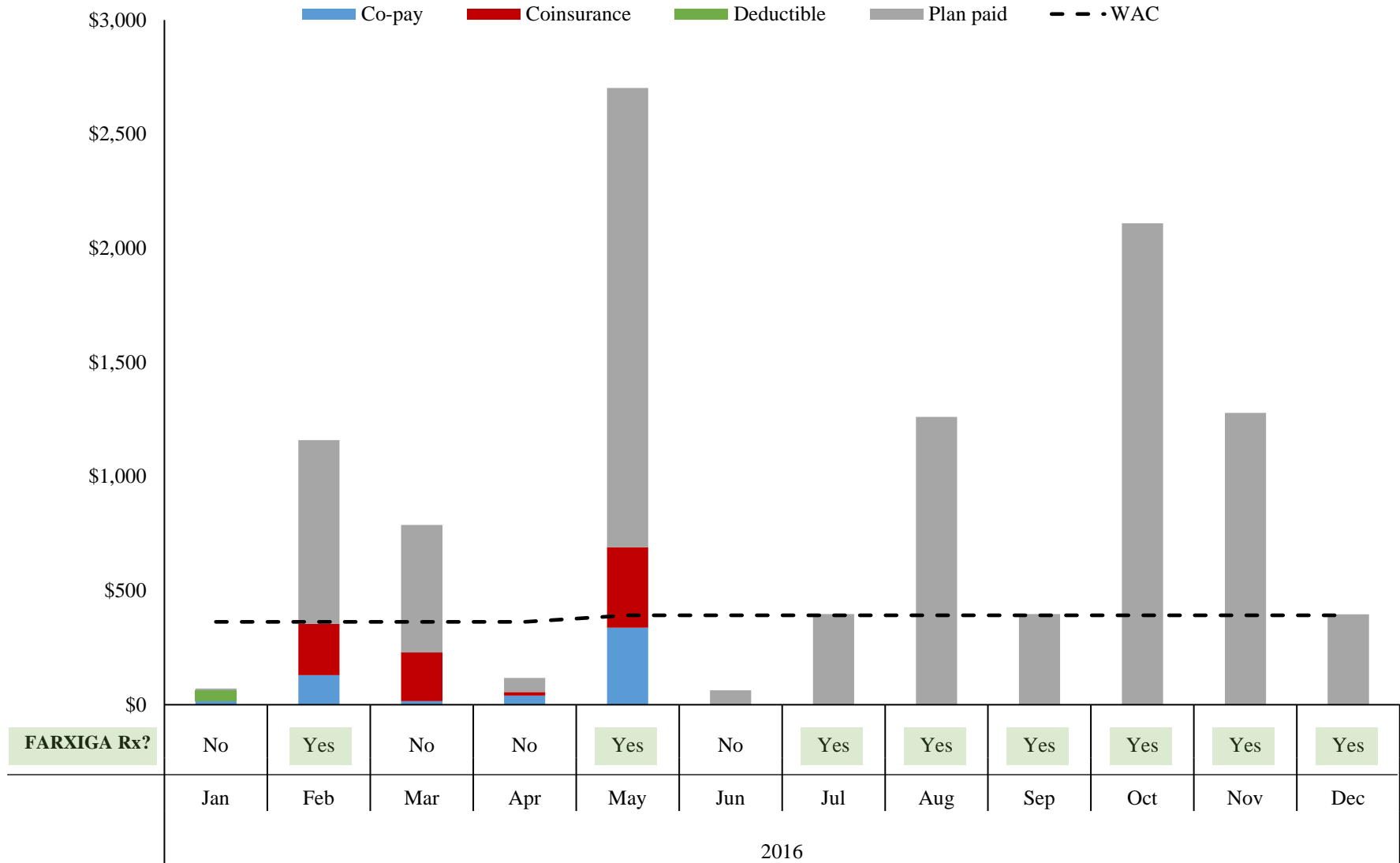
**Exhibit 4(a) - FARXIGA drug claim cost analysis**  
**FARXIGA patient - PPO w/ HSA - Claimant 56010846700246**



Sources: [A] Micromedex (WAC data); [B] OptumHealth Care Solutions (claims data)

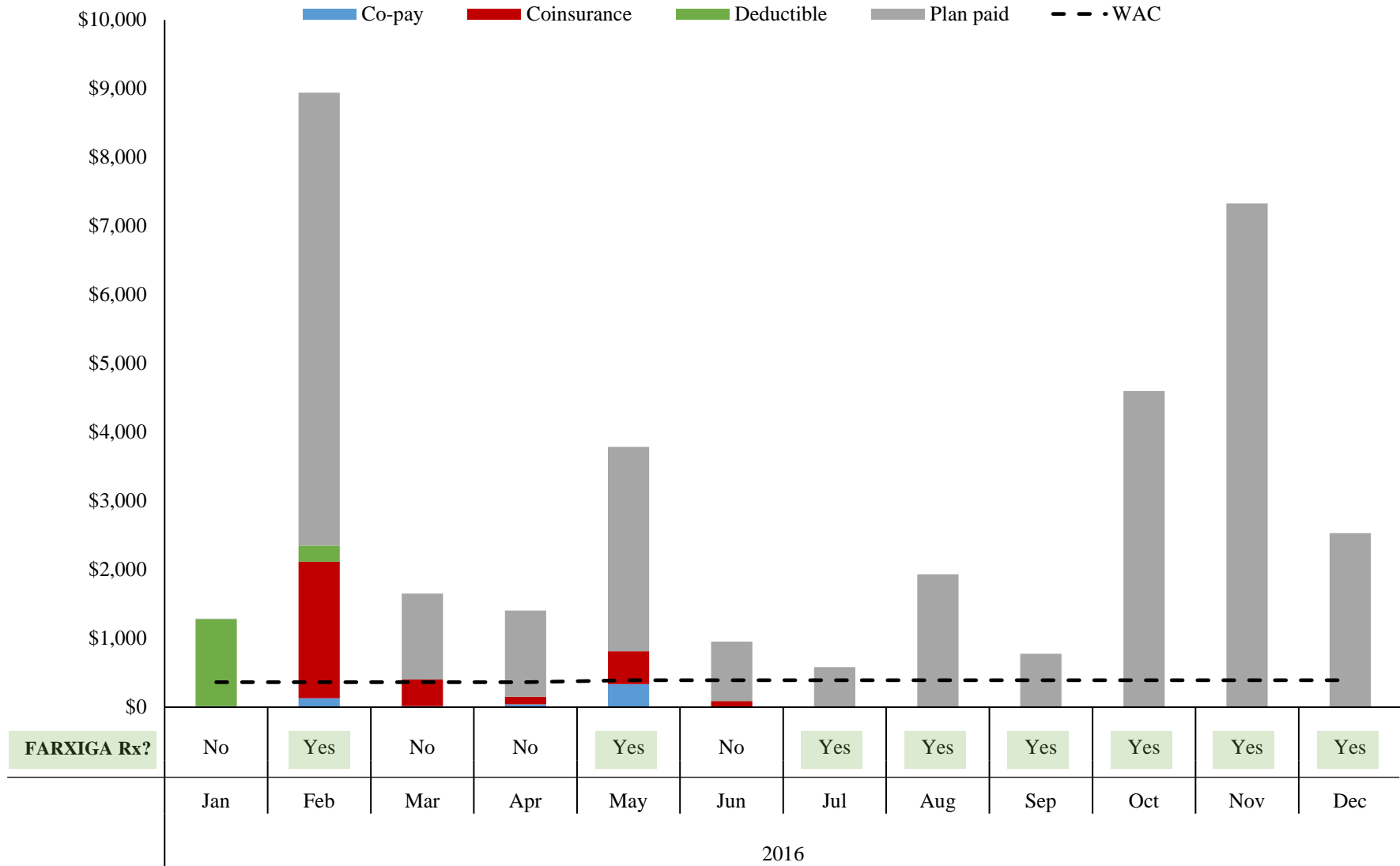


**Exhibit 4(b) - Drug claim cost analysis**  
**FARXIGA patient - PPO w/ HSA - Claimant 56010846700246**



Sources: [A] Micromedex (WAC data); [B] OptumHealth Care Solutions (claims data)

**Exhibit 4(c) - Drug and medical claim cost analysis**  
**FARXIGA patient - PPO w/ HSA - Claimant 56010846700246**



Sources: [A] Micromedex (WAC data); [B] OptumHealth Care Solutions (claims data)