THE ACCIDENTAL INNOVATION POLICYMAKERS

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Healthcare policymakers in the United States, particularly at the federal level, have been considering a range of proposals that would lower prices for prescription drugs. The pharmaceutical industry and many politicians have argued that these proposals would harm innovation incentives, resulting in fewer new drugs coming to market in the future. This Article identifies and explores a key problem with this argument: that it is typically deployed both accidentally and asymmetrically in nature. Specifically, this Article considers previous changes to health laws that had the impact of increasing innovation incentives by providing large new subsidies to pharmaceutical companies—chiefly the creation of Medicare Part D and the passage of the Affordable Care Act—but where policymakers appear not to have analyzed these innovation-related aspects of the new laws. By contrasting these laws with others in which policymakers explicitly centered the innovation-related impacts of their actions, such as the Hatch-Waxman Act and the Orphan Drug Act, this Article suggests that policymakers may in some cases be making innovation policy "by accident," without knowledge of their likely results. These innovation arguments are also deployed asymmetrically by interested stakeholders, creating the potential for unbalanced policymaking over time. This Article further analyzes the implications of this accidental, asymmetric policymaking for innovation law and policy.

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INTRODUCTION

Even as Americans are politically divided on many issues, they are united in the belief that prescription drug prices today are unreasonable—and that pharmaceutical companies and their profits are to blame.[1] This is not surprising, as nearly one-fourth of Americans report difficulty affording their prescriptions, and even more report not taking their medication as prescribed due to the cost.[2] Patients facing these financial challenges might delay filling their prescription, cut pills in half, or skip doses entirely.[3] Patients may become sicker or even die as a result of these financial pressures.[4]

Many Americans may be familiar with the story of Martin Shkreli, who increased the price of the rare disease drug Daraprim overnight, from

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[1] Ashley Kirzinger et al., *Kaiser Health Tracking Poll – February 2019: Prescription Drugs*, KAISER FAMILY FOUND. (March 1, 2019), https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/ (noting that 79% of Americans believe drug costs are "unreasonable").

[2] *Id.* (noting that 24% have difficulty affording their medications, and 29% report changing their adherence).

[3] *Id.*

[4] Bram Sable-Smith, *Insulin's High Cost Leads to Lethal Rationing*, NPR (Sept. 1, 2018), https://www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing.

$13.50 a tablet to $750.[5] But Shkreli was far from the only pharmaceutical executive to raise his prices, or to set a high price in the first place. Insulin is a life-saving medication for millions of patients with diabetes today. Although it was first developed in the 1920s, its price has continued to rise over the last several decades.[6] Between 2010 and 2015 alone, the monthly wholesale price of one popular insulin product rose from $258 to $1100.[7] As a recent Senate Finance Committee investigation concluded, insulin manufacturers have *increased* their prices in response to competition, rather than decreasing them.[8]

As another example, Humira, one of the top-selling drugs in Medicare,[9] was first approved by the Food & Drug Administration (FDA) in 2002.[10] But twenty years later, it still retains its monopoly, and will not face competition in the United States until 2023[11] due to the surrounding thicket of over 100 patents constructed by its manufacturer.[12] Over time, its net price has

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[5] Andrew Pollack, *Drug Goes From $13.50 a Tablet to $750, Overnight*, N.Y. TIMES (Sept. 21, 2015), https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html.

[6] Jing Luo, Jerry Avorn, & Aaron S. Kesselheim, *Trends in Medicaid Reimbursements for Insulin From 1991 Through 2014*, 175 J. AM. MED. ASS'N INTERNAL MED. 1681 (2015).

[7] Elisabeth Rosenthal, *When High Prices Mean Needless Death*, 179 J. AM. MED. ASS'N INTERNAL MED. 114 (2019).

[8] SENATE FINANCE COMM., INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG, at 6 (2021), https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf. Although older products like insulin would typically experience generic competition, manufacturers have continued to introduce new versions of insulin products over time, particularly by altering the delivery device for the drug, in ways that have limited the ability of competitors to enter the market. *See, e.g.*, Reed F. Beall & Aaron S. Kesselheim, *Tertiary Patenting on Drug-Device Combination Products in the United States*, 36 NATURE BIOTECH. 142 (2018).

[9] Juliette Cubanski & Tricia Neuman, *Relatively Few Drugs Account for a Large Share of Medicare Prescription Drug Spending*, KAISER FAMILY FOUND. (April 19, 2021), https://www.kff.org/medicare/issue-brief/relatively-few-drugs-account-for-a-large-share-of-medicare-prescription-drug-spending/.

[10] Food & Drug Admin., Letter to Abbott Laoratories (Dec. 31, 2002), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/BLA_125057_S000_HUMIRA_APPROV.PDF.

[11] Jason Mast, *Pfizer Gets Biosimilar Approved for Humira, Setting Up Competition – in 2023*, ENDPOINTS (Nov. 18, 2019), https://endpts.com/pfizer-gets-biosimilar-approved-for-humira-setting-up-competition-in-2023/.

[12] I-MAK, HUMIRA: OVERPATENTED, OVERPRICED 3 (Oct. 2020), https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf.

increased from $19,000 in 2012 to over $38,000 in 2018.[13] Further, the prices of drugs like these are far higher in the United States than in other countries,[14] which typically use some form of centralized negotiation to drive down prices.

For the federal government, these high prices have led to increases in spending over time that may be difficult to sustain. Federal spending on drugs through Medicare Part B—the program covering specialty drugs administered in a doctor's office—more than doubled over a decade, increasing from $15.4 billion in 2009 to $35.0 billion in 2018.[15] For Medicare Part D, the program's standard pharmacy benefit covering medications seniors pick up at their local pharmacy, spending rose from $46.2 billion to $79.9 billion between 2007 and 2017.[16] But for small employers who provide insurance to their employees, a single employee with an expensive medication can jeopardize their ability to offer coverage at all. A 2019 *New York Times* article told the story of a family with a rare genetic disease, where the cost for three family members to take just a single medication led to a $6 million annual bill for the insurance provided through their union.[17] As the *Times* noted, "for every hour that one of the union's 16,000 members worked, 35 cents of his or her pay went to" pay for this single drug.[18]

These developments also impact Americans who do not themselves need high-priced prescription drugs. In November 2021, Medicare announced that all seniors' Part B premiums for 2022 would increase by nearly $22 per month, due in significant part to the FDA's 2021 approval of a new, costly Alzheimer's drug, Aduhelm.[19] In approving Aduhelm, the FDA had overruled

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[13] Danny Hakim, *Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher.*, N.Y. TIMES (Jan. 6, 2018), https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html.

[14] U.S. HOUSE OF REPRESENTATIVES COMM. ON WAYS & MEANS, A PAINFUL PILL TO SWALLOW: U.S. VS. INTERNATIONAL PRESCRIPTION DRUG PRICES 4, 18 (Sept. 2019), https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf.

[15] MEDPAC, A DATA BOOK: HEALTH CARE SPENDING AND THE MEDICARE PROGRAM 139 (July 2020), http://medpac.gov/docs/default-source/data-book/july2020_databook_entirereport_sec.pdf?sfvrsn=0.

[16] MEDICARE PAYMENT ADVISORY COMM'N (hereinafter MEDPAC), REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 409 (March 2019), http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf.

[17] Reed Abelson & Katie Thomas, *The $6 Million Drug Claim*, N.Y. TIMES (Aug. 26, 2019), https://www.nytimes.com/2019/08/25/health/drug-prices-rare-diseases.html.

[18] *Id.*

[19] Centers for Medicare & Medicaid Servs., *Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rates, and Annual Deductible Beginning January 1, 2022*, 86 Fed. Reg. 64205, 64205, 64208 (Nov. 17, 2021). At the end of 2022, Biogen announced that they would cut the drug's price in half, but it is not yet clear whether that announcement came too late to translate into lower premiums for seniors.

its own independent advisory committee, which voted nearly unanimously that the drug's clinical trials had not demonstrated sufficient evidence of efficacy to merit approval. In response to the approval, three of the advisory committee members resigned in protest.[20] Yet existing law limits Medicare's ability to negotiate for the drug's price or to decline to cover FDA-approved drugs, even those with little efficacy.[21] All seniors' premiums—not only those taking the drug—will increase accordingly.

Politicians in both parties have attempted to respond to these concerns. President Trump, who railed against pharmaceutical companies who were "getting away with murder"[22] and who had "rigged the system against American consumers,"[23] introduced several ambitious regulations in the drug pricing area. His administration introduced policies to bring down prices in Medicare Part B through international reference pricing, permit states to create programs to import prescription drugs from Canada, and reform the Medicare Part D payment system.[24] Although he failed to implement these reforms,[25] his attention to the issue of prescription drug pricing reflected the public interest on this topic.

After taking back control of the House of Representatives in the 2018 midterm elections, Democrats began constructing their own prescription drug pricing reform bills. In 2019, House committees drafted and passed

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Jessica Rinaldi, *Medicare Asked to Reassess 2022 Premium Hikes After Aduhelm Price Cut*, REUTERS (Jan. 10, 2022), https://www.reuters.com/business/healthcare-pharmaceuticals/medicare-asked-reassess-2022-premium-hikes-after-aduhelm-price-cut-2022-01-10/.

[20] Pam Belluck & Rebecca Robbins, *Three FDA Advisers Resign Over Agency's Approval of Alzheimer's Drug*, N.Y. TIMES (June 10, 2021), https://www.nytimes.com/2021/06/10/health/aduhelm-fda-resign-alzheimers.html.

[21] Rachel E. Sachs, *Delinking Reimbursement*, 102 MINN. L. REV. 2307, 2314–15 (2018). CMS has proposed to use its National Coverage Determination process to limit coverage for Aduhelm, but the decision has not yet been finalized. Centers for Medicare & Medicaid Servs., *Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease* (January 11, 2022), https://www.cms.gov/medicare-coverage-database/view/ncacal-tracking-sheet.aspx?NCAId=305.

[22] Dylan Scott, *Trump Promises Reforms on Drug Prices, Saying Companies "Getting Away With Murder,"* STAT NEWS (Jan. 11, 2017). https://www.statnews.com/2017/01/11/trump-drug-prices-news-conference/.

[23] Donald Trump, *Remarks by President Trump on Prescription Drug Prices* (Oct. 25, 2018), https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-prescription-drug-prices/.

[24] For more on each of these policies, see generally Rachel E. Sachs, *The Rhetorical Transformations and Policy Failures of Prescription Drug Pricing Reform Under the Trump Administration*, 46 J. HEALTH POLITICS POL'Y & L. 1053 (2021).

[25] *See id.*

comprehensive drug pricing reform legislation,[26] though then-Senate Majority Leader Mitch McConnell refused to take up the bill. The Democrats' reform legislation, known as H.R. 3,[27] had three major components: it restructured Medicare Part D to make it easier for seniors to afford their medications,[28] required pharmaceutical companies to pay rebates back to the government if they raised their prices too quickly over time,[29] and instructed the Secretary of Health & Human Services (HHS) to negotiate for the price of prescription drugs using international reference pricing, creating an average international market price as the target fair price in negotiations.[30] The Congressional Budget Office (CBO) estimated that the negotiation provisions alone would save the government $456 billion over a decade.[31]

One common argument against proposals like these is that they would harm future innovation. If drug pricing reforms succeed in lowering drug prices, they may lower pharmaceutical firm revenues, leading industry to reduce R&D investments going forward and translating into fewer approved drugs. To be sure, there are disputes about when these R&D investment impacts begin, and how large they are. President Trump's HHS Secretary Alex Azar, himself a former pharmaceutical company executive, criticized the "tired talking point" that "if one penny disappears from pharma profit margins, American innovation will grind to a halt."[32] Secretary Azar argued that the administration's international reference pricing proposal would not reduce innovation, comparing the size of program's estimated savings to overall pharmaceutical investments in research and development.[33] However, in 2019, CBO estimated that the more ambitious H.R. 3 could lead to eight fewer drugs coming to market over the next decade (a number it later revised downward,

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[26] Yasmeen Abutaleb, *House Democrats Pass Broad Prescription Drug Price Bill as Election Marker*, WASH. POST (Dec. 12, 2019), https://www.washingtonpost.com/us-policy/2019/12/12/house-democrats-pass-broad-prescription-drug-price-bill-election-marker/.

[27] Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2019).

[28] *Id.* at § 301.

[29] *Id.* at § 201-202.

[30] *Id.* at § 101.

[31] Phillip L. Swagel, Director of the Cong. Budget Office, *Letter to Chairman Frank Pallone Jr. Re: Budgetary Effects of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act*, at 2 (Dec. 10, 2019), https://www.cbo.gov/system/files/2019-12/hr3_complete.pdf.

[32] Alison Kodjak, *Trump Administration's 3 Biggest Ideas for Lowering Drug Prices*, NPR (May 14, 2018), https://www.npr.org/sections/health-shots/2018/05/14/611075950/trump-administrations-3-biggest-ideas-for-lowering-drug-prices.

[33] Alex Azar, *Remarks on Medicare Drug Pricing Proposals*, THE BROOKINGS INSTITUTION, at 8 (Oct. 26, 2018), https://www.brookings.edu/wp-content/uploads/2018/10/es_20181026_hhs_medicare_transcript.pdf.

to two).[34] The pharmaceutical industry's trade association, PhRMA, put the number much higher, at 56 fewer new drugs.[35]

These arguments highlight the important theoretical relationship between health insurance and incentives for innovation in new pharmaceuticals, one I have identified and explored in previous work.[36] Insurance reimbursement functions similarly to a prize system, in which insurer decisions to reimburse manufacturers for a new class of products expand the potential returns on investment in that area. On the other side, insurer decisions to decline or limit coverage for a set of products reduce potential returns on investment in that area. Economists have found that both types of decisions impact future innovation incentives.[37] These decisions about whether and how much insurers reimburse for particular new pharmaceuticals must therefore be understood not only as decisions that implicate whether patients can *access* these medications, but also about whether companies will have incentives to *develop* them in the future. Just as scholars of innovation policy debate the role of patents,[38] regulatory exclusivity,[39] grants,[40] tax

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[34] Swagel, *supra* note 31, at 6 (noting that "about 300 drugs might be approved over the next 10 years," for comparison). In 2021, CBO released an updated version of this model in which it projected that a policy like H.R. 3 would lead to only two fewer drugs in the first decade after its passage. CONG. BUDGET OFFICE, CBO'S SIMULATION MODEL OF NEW DRUG DEVELOPMENT, at 1 (Aug. 2021), https://www.cbo.gov/system/files/2021-08/57010-New-Drug-Development.pdf.

[35] Tom Wilbur, *What You Need to Know About H.R. 3*, PHRMA: THE CATALYST (Dec. 12, 2019), https://catalyst.phrma.org/what-you-need-to-know-about-h.r.-3. Republican members of Congress have echoed these arguments as they relate to H.R. 3, as well. *See, e.g.*, Kevin Brady, *CBO Confirms Democrats' Drug Pricing Plan Will Crush Innovation* (Oct. 11, 2019), https://gop-waysandmeans.house.gov/brady-cbo-confirms-democrats-drug-pricing-plan-will-crush-innovation/.

[36] *See, e.g.*, Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J.L. & TECH. 153, 193, 201–08 (2016); *see also* Mark A. Lemley, Lisa Larrimore Ouellette, & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 NYU L. REV. 75 (2020).

[37] *See, e.g.*, text accompanying notes 58–59.

[38] *See, e.g.*, Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to Market*, 61 UCLA L. REV. 672, 719 (2014).

[39] Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. TECH. L. REV. 345, 352 (2007); Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals — Do We Really Need Both?*, 18 MICH. TELECOMM. TECH. L. REV. 419 (2012).

[40] W. Nicholson Price II, Grants, 34 BERKELEY TECH. L.J. 1, 3–4 (2019).

credits,[41] and other policy levers[42] in providing innovation incentives for new drugs, they should also consider the role that insurance reimbursement may play as a demand-side innovation policy lever.

Yet this relationship between insurance and innovation incentives is complex in ways that call into question industry's arguments. Economists may agree that a drug pricing reform on the scale of H.R. 3 may well reduce the number of drugs coming to market in the future. But implicit in these arguments is a claim that the *number* of new drugs and *amount* of innovation is the key metric that matters, to patients and for society. Instead, scholars have argued that the *kind* and *value* of innovation is truly what matters for patients, and that the number of new drugs is one (flawed) proxy for assessing clinical value.[43] A new drug that provides a clinical breakthrough for a disease where patients lack good treatments today (such as Alzheimer's or ALS) would be more important—and should be understood as more "innovative"—than a new dosage of an existing medication, or a new drug in a class where patients already have many treatment options.[44] Yet even where analysts have attempted to estimate a reduction in the number of new drugs coming to market as a result of drug pricing reform, they typically disclaim any effort to determine what the value of those drugs would have been to patients.[45]

Other complexities of this issue stem from the way these innovation arguments are made in practice. First, these arguments are typically made asymmetrically. Political stakeholders argue about potential harm to innovation incentives when a proposal will reduce industry revenues, but they do not tout the potential benefits for innovation incentives when a proposal will increase those revenues. These arguments are then supported by asymmetrically performed analyses from important actors like CBO. Second, in situations where innovation arguments are not made at all, policymakers are

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[41] Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents—Prizes Debate*, 92 TEX. L. REV. 303 (2013).

[42] *See, e.g.*, W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023 (2016) (discussing the issue of trade secrets in manufacturing).

[43] Rachel E. Sachs & Austin B. Frakt, *Innovation-Innovation Tradeoffs in Drug Pricing*, 165 ANNALS OF INTERNAL MED. 871, 871 (2016); *see also* House Comm. on Energy & Commerce, Health Subcomm., Hearing: Drug Patent Restoration, No. 97-17, at 424-25 (April 1, 1981).

[44] One extension of this set of arguments is that if it is true that paying more for drugs across the board results in more new drugs in development, it may also be true that paying more for drugs that represent therapeutic advances—and less or not at all for drugs that don't add new clinical value for patients—may also encourage the development of *valuable* new drugs.

[45] CONG. BUDGET OFFICE, *supra* note 34, at 24 ("CBO has not determined the overall effect of the policy on health outcomes.").

often making innovation policy accidentally. When Congress was considering the passage of important health-related laws that set our current level of innovation incentives—such as Medicare Part D and the Affordable Care Act (ACA)—public debates focused on the need to give uninsured patients access to prescription drugs specifically or healthcare more generally. The debate around the passage of the ACA was not focused on the importance of providing pharmaceutical companies with a large federal subsidy, in other words, but one practical implication of these laws was to create such a subsidy.

This Article identifies and analyzes the implications of this phenomenon, in which policymakers appear to be making health innovation policy both "by accident," without knowledge of their likely results, and asymmetrically, focusing on innovation arguments made only in one direction. To be sure, this problem is not limited to the health innovation policy context, and scholars have written about this type of accidental legislation in other substantive areas.[46] But policymakers' silence about this issue in the health policy field is notable relative to their recognition of its visibility in non-health areas, such as defense spending or the space program.[47] In response to criticisms about the lack of consideration of environmental impacts of legislation, multiple members of Congress have proposed bills which would require CBO or other actors to report on and account for climate impacts in different ways.[48] Also problematically, as noted above, actors like CBO have begun to report on the innovation impacts of relevant legislation—but only in one direction, reporting that a bill may result in *fewer* new drugs coming to market but never (to date) reporting that a bill may result in *more* new drugs coming to market. This asymmetric analysis poses harms that may not be present in other substantive contexts.

Part I examines the passage of two important pieces of healthcare legislation in which key policymakers appear to have made health innovation policy "by accident." This Part documents how Congressional discussions leading up to the passage of Medicare Part D in 2003 and the Affordable Care Act in 2010 focused primarily on the ways in which those bills would promote access to health care, but avoided discussing the ways in which the bills would encourage pharmaceutical companies to invest in the development of new pharmaceuticals. Part I additionally makes the case that when innovation-

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[46] *See, e.g.*, Seth W. Stoughton, *The Incidental Regulation of Policing*, 98 MINN. L. REV. 2179, 2181 (2014).

[47] Nicholas Bloom et al., *A Toolkit of Policies to Promote Innovation*, 33 J. ECON. PERSP. 163, 178 (2019).

[48] *See, e.g.*, Carbon Pollution Transparency Act of 2014, S. 2905, 113th Cong. (2014); Climate Equity Act of 2020, H.R. 8019, 116th Cong. (2020); HOUSE SELECT COMMITTEE ON THE CLIMATE CRISIS, SOLVING THE CLIMATE CRISIS: THE CONGRESSIONAL ACTION PLAN FOR A CLEAN ENERGY ECONOMY AND A HEALTHY, RESILIENT, AND JUST AMERICA, at 15-16 (2020).

related arguments do surface, they do so asymmetrically, only when a policy change is likely to decrease prices or spending. Part II presents a contrasting view, exploring the history of two pieces of legislation which were purposefully designed to promote innovation: the 1983 Orphan Drug Act and the 1984 Hatch-Waxman Act. In exploring the legislative history behind these bills, Part II illustrates the type of language important legislative stakeholders used and the type of inquiries they engaged in when making innovation policy purposefully.

Part III investigates the implications of these descriptive findings for innovation policymaking. In short, it asks what consequences should follow from these observations about accidental, asymmetric innovation policymaking. Part III argues that this observation should have ramifications for both policy and politics, suggesting not only that policymakers re-evaluate the innovation impacts of various access-promoting policies but also that they ought to reject asymmetric political arguments. Part III closes by considering the ways in which the different areas of law underlying each of these pieces of legislation may have contributed to these differing legislative dynamics.

Part IV lays out three potential reforms to the legislative process that would have the effect of informing legislators about the innovation-related consequences of their actions in both directions, addressing the problems of accidental and asymmetric policymaking. Specifically, Part IV considers three types of legislative actors—the CBO, existing legislative agencies with health expertise, and the former Office of Technology Assessment—and explores the ways in which the institutional design of these entities have strengths and weaknesses from this information-generation perspective.

I. ACCIDENTAL INNOVATION POLICYMAKING IN CONGRESS

This Part considers two important pieces of health care legislation which resulted in large subsidies to the pharmaceutical industry: the creation of Medicare Part D in 2003[49] and the passage of the Affordable Care Act (ACA) in 2010.[50] Both of these laws gave the pharmaceutical industry tens of millions of new customers and tens or hundreds of billions of dollars in new annual revenue—revenue that industry in at least some cases used to support new research and development initiatives. But members of Congress on the committees with jurisdiction over these bills appear not to have considered their possible innovation implications. Transcripts of the major legislative documents underlying each law are focused on the importance of expanding

[49] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

[50] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 310 (2010).

access to prescription drug coverage or health insurance more generally, rather than the impact this expansion will have on pharmaceutical companies themselves. As a result, this Part argues that both Part D and the ACA are examples in which policymakers made health innovation policy "by accident": they did not appear to publicly consider the innovation-related impacts of these laws at the time they were being debated and enacted.

A. Medicare Part D

Although the Medicare program was first created in 1965, Congress only established a standard pharmacy benefit plan for seniors in 2003, with the creation of Medicare Part D.[51] At the time, although nearly 90% of seniors were taking prescription drugs,[52] more than a quarter of seniors had no drug coverage, a figure which was even higher for low-income seniors.[53] More than a third of seniors without drug coverage reported not taking their medications as prescribed due to the costs, with some skipping doses, taking smaller doses, or simply declining to fill their prescriptions altogether.[54]

The creation of Medicare Part D provided prescription drug coverage to tens of millions of seniors who previously lacked such coverage,[55] delivering more reliable customers to the pharmaceutical industry. Industry also reaped financial benefits from seniors who already had insurance, as for many seniors already eligible for Medicaid, Part D replaced their existing coverage in ways that provided higher reimbursements to pharmaceutical

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[51] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

[52] Dana Gelb Safran et al., *Prescription Drug Coverage and Seniors: Findings from a 2003 National Survey*, HEALTH AFF. (Web Exclusive) (Apr. 19, 2005).

[53] JANET LUNDY, KAISER FAMILY FOUND., PRESCRIPTION DRUG TRENDS 5 (2010) ("[A]bout one-quarter (27%) of seniors age 65 and older, and one-third of poor (34%) and near-poor (33%) seniors, had no drug coverage in 2003 [when Congress passed Part D].").

[54] Safran et al., *supra* note 52

[55] Kaiser Family Found., *An Overview of the Medicare part D Prescription Drug Benefit* (Oct. 14, 2020), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.

companies for already-prescribed drugs.[56] Today, total Part D expenditures exceed $100 billion annually.[57]

Economists have argued that this large new governmental subsidy of the pharmaceutical industry served as an innovation incentive, though not one with particularly targeted effects. Scholars studying the impact of the creation of Medicare Part D on innovation found that after its establishment, pharmaceutical companies increased research and development investments into drug classes with higher consumption among the Medicare population.[58] However, most of this investment occurred in diseases which already had multiple existing treatments,[59] suggesting that only some of this innovation may have provided truly novel treatment options for patients.

But this innovation framework was not a public focus for healthcare policymakers during the creation of Part D. Policymakers were principally focused on the role Part D would play in increasing access to prescription drug coverage for seniors, and they did not appear to explicitly contemplate the innovation-related impacts of their actions. President George W. Bush, in signing the law, praised it as "the greatest advance in health care coverage for America's seniors since the founding of Medicare."[60] His administration

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[56] Richard G. Frank & Joseph P. Newhouse, Sh*ould Drug Prices Be Negotiated Under Part D of Medicare? And If So, How?*, 27 HEALTH AFF. 33 (2008). Although it is difficult to estimate this figure exactly due to the confidential nature of these prices, the increase are likely to be significant. Pfizer alone experienced a $325 million increase in revenues in the first half of 2006 as compared with 2005, an eight percent increase in net revenue, apparently due to the shift of some patients from Medicaid to Medicare. *Id.*

[57] MEDICARE PAYMENT ADVISORY COMM'N (hereinafter MEDPAC), REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 407 (March 2021), http://www.medpac.gov/docs/default-source/reports/mar21_medpac_report_ch13_sec.pdf?sfvrsn=0.

[58] Margaret E. Blume-Kohout & Neeraj Sood, *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research & Development*, 97 J. PUB. ECON. 327, 327 (2013); *see also* Daron Acemoglu & Joshua Linn, *Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry*, 119 Q.J. ECON. 1049, 1084 (2004).

[59] David Dranove et al., *Pharmaceutical Profits and the Social Value of Innovation* 2–3, 6–7 (Nat'l Bureau of Econ. Rsch., Working Paper No. 20212, 2014).

[60] George W. Bush, *President Signs Medicare Legislation* (Dec. 2003), https://georgewbush-whitehouse.archives.gov/news/releases/2003/12/text/20031208-2.html. The potential expansion of Medicare to include prescription drug coverage had been a topic of debate in the 2000 Presidential election, with both President Bush and then-Vice President Al Gore proposing expansion plans. *See* JONATHAN OBERLANDER, THE NEW POLITICS OF MEDICARE 190-192 (2003).

would later tout the accomplishments of Part D as "giving seniors and people with disabilities better access to the prescription drugs they need."[61]

In Congress, key committees in both chambers held hearings[62] to discuss different aspects of the law. These hearings were similarly focused on the importance of expanding access to prescription drug insurance, rather than on the impact such an expansion would have on the pharmaceutical industry itself. For example, during an April 2003 hearing before the Health Subcommittee of the House Energy & Commerce Committee,[63] Subcommittee Chairman Michael Bilirakis opened the session by declaring that "while prescription drugs have improved the lives of many beneficiaries there are still too many without prescription drug coverage," and that "we must find a way to help Medicare beneficiaries."[64] The House Committee on Ways & Means, which shares jurisdiction with Energy & Commerce in this area,[65] was similarly focused on the access-enhancing features of Part D. Committee Chairman Bill Thomas' opening statement in an April 2003 hearing criticized Medicare by saying that "it really isn't 21st century-ready, it isn't even the last

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[61] White House, *Empowering Medicare Beneficiaries With Affordable Options* (2008), https://georgewbush-whitehouse.archives.gov/infocus/bushrecord/factsheets/medicare.html.

[62] The development and passage of Part D was a lengthy process spanning multiple years and multiple sessions of Congress. I focus here on hearings that were held in 2003 and committee reports issued to support these bills, though there were additional hearings and discussions held in the years before as well, which I reference where they bring in additional points of view. *See* Thomas R. Oliver, Philip R. Lee, & Helene L. Lipton, *A Political History of Medicare and Prescription Drug Coverage*, 82 MILBANK Q. 283, 306–16 (2004).

[63] U.S. House Comm. on Energy & Commerce, *Jurisdiction* (2021), https://energycommerce.house.gov/about-ec/jurisdiction. At the time, the Committee as a whole was led by Chairman Billy Tauzin, a Republican from Louisiana. In 2005, Tauzin would begin to serve as president of PhRMA, the pharmaceutical industry's trade association. He would leave in 2010, amid criticism that the deal he had negotiated with the Obama Administration over the Affordable Care Act (discussed in more detail *infra*, in text accompanying notes 100-104), was not favorable enough to industry. David Kirkpatrick & Duff Wilson, *Health Reform in Limbo, Top Drug Lobbyist Quits*, N.Y. TIMES (Feb. 11, 2010), https://www.nytimes.com/2010/02/12/health/policy/12pharma.html.

[64] House Comm. on Energy & Commerce, Subcomm. on Health, Hearing: Designing a Twenty-First Century Medicare Prescription Drug Benefit, No. 108-25, at 1-2 (Apr. 8, 2003). Representative Mike Ferguson (a Republican from New Jersey) put it more starkly, arguing that "few things that we do in this committee could be more important than crafting a proposal to bring the miracles of prescription drug medication to more seniors throughout our country." *Id*. at 8.

[65] U.S. House Comm. on Ways & Means, *Jurisdiction & Rules*, https://waysandmeans.house.gov/about/jurisdiction-and-rules.

quarter of the 20th century-ready, because it doesn't provide a meaningful prescription drug coverage to seniors… Clearly something has to be done."[66]

In the Senate, the story was similar. During a June 2003 hearing in the Senate Finance Committee (which has jurisdiction over Medicare),[67] Chairman Chuck Grassley described the "historic" nature of their task, "to create a prescription drug benefit within Medicare."[68] That hearing featured testimony from Tom Scully, the Administrator for the Centers for Medicare and Medicaid Services, who emphasized President Bush's focus on this issue. As he stated, "in our debates over this in the last 12 months, the number one thing [the President] has consistently said is, make sure we provide prescription drug coverage, especially for the lowest income."[69]

The Committee reports explicitly echoed these arguments. The House Committee on Energy & Commerce's Report describes the "significant burden on those who cannot afford the sometimes substantial out-of-pocket costs associated" with medications in explaining the need for the law, which aims "to provid[e] seniors with access to a Medicare prescription drug benefit."[70] The House Committee on Ways & Means decried the anachronistic nature of Medicare benefits, noting that "[n]obody today with a blank sheet of paper would design a health care program for seniors that excluded prescription drugs" and describing the new benefit as "long overdue."[71]

Given that CBO's primary reports on the House Democratic caucus' prescription drug pricing bill have included an estimate of how many fewer drugs CBO expects to come to market as a result of the bill,[72] it might be expected that CBO's report on the bill establishing Part D would have included an estimate of how many *more* drugs might be expected to be produced as a result of the large new subsidy created by Medicare Part D. Particularly since CBO's cost estimates for bills are intended to show how a law would "affect

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[66] House Comm. on Ways & Means, Hearing: Expanding Coverage of Prescription Drugs in Medicare, No. 108-7, at 4 (Apr. 9, 2003).

[67] U.S. Senate Rules, Rule 25(i), https://www.rules.senate.gov/rules-of-the-senate (noting that the Finance Committee has jurisdiction over "health programs under the Social Security Act"). As in the House, however, this jurisdiction is typically shared, in this case with the Committee on Health, Education, Labor, and Pensions (HELP). *See id*. at 25(m) (establishing jurisdiction over "measures relating to education, labor, health, and public welfare").

[68] Senate Comm. on Finance, Hearing: Strengthening and Improving the Medicare Program, S. Hrg. 108-339, at 1 (June 6, 2003).

[69] *Id.* at 5.

[70] House Comm. on Energy & Commerce, Report: Medicare Prescription Drug and Modernization Act of 2003, H.Rep. 108-178 Pt. 1, at 152 (2003).

[71] House Comm. on Ways & Means, Report: Medicare Prescription Drug and Modernization Act of 2003, H.Rep. 108-178 Pt. 2, at 144 (2003).

[72] Swagel, *supra* note 31, at 6.

spending or revenues,"[73] if Part D were expected to lead to the creation of new pharmaceuticals targeted at seniors, this might well increase spending under the program. But neither of CBO's pre-enactment cost estimates[74] expressly considers the topic of innovation or new drugs that might result from the program.[75] CBO's lengthy July 2003 report does consider the implications of various elements of the House and Senate bills on drug *pricing*,[76] noting for instance that "[t]he new Medicare benefit might also give manufacturers greater room to raise prices on certain drugs."[77] But the report does not connect these issues regarding pricing to overall innovation. CBO's failure to consider these issues is particularly puzzling in light of a 1998 report in which the agency explicitly connects the demand for drugs as mediated by insurance to incentives for new innovation.[78]

Interestingly, CBO's post-enactment cost report does contain a single parenthetical reference to the topic of innovation. In the context of discussing the noninterference clause—the provision of the Medicare Part D statute prohibiting HHS from negotiating for the price of prescription drugs[79]—CBO noted the following:

> For HHS to use the greater market share of the entire Medicare population as a source of leverage to secure deeper price discounts and greater cost savings, it would probably have to threaten similar exclusions and limitations on coverage for that entire population—a threat that could be difficult to make credible given the potential impact on stakeholders. *(Other policy objectives, such as encouraging the*

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[73] Cong. Budget Office, *Products: Cost Estimates* (2021), https://www.cbo.gov/about/products.

[74] CONG. BUDGET OFFICE, A DETAILED DESCRIPTION OF CBO'S COST ESTIMATE FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT preface (July 2004), https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/07-21-medicare.pdf ("[CBO] provided analysis to the Congress … and issued in July 2003 federal cost estimates for H.R. 1 and S.1 as passed by the House and Senate as well as an estimate of the conference agreement on H.R. 1 in November 2003.").

[75] Douglas Holtz-Eakin, Letter from the Cong. Budget Office to House Committee on Ways & Means Chairman William M. Thomas (Nov. 20, 2003), https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/costestimate/11-20-medicareletter0.pdf; CONG. BUDGET OFFICE, COST ESTIMATE: H.R. 1 AND S. 1 (July 22, 2003), https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/costestimate/hr1s11.pdf.

[76] CONG. BUDGET OFFICE, *supra* note 75, at 9, 15, 50-52, 52-53.

[77] *Id*. at 9.

[78] CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY, at 1 (July 1998), https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf. I discuss this report in more detail *infra*, in Part IV.A.

[79] 42 U.S.C. § 1395w-111(i) (2012).

> *development of new drugs, also could be adversely affected as a result of securing deeper discounts.)*[80]

CBO therefore recognized that empowering Medicare to obtain deeper discounts on covered medications might "adversely affect" the "development of new drugs." But nowhere does CBO consider the converse: the potential for Part D to result in an *increased* number of new drugs, even as CBO expressly recognized that Part D would result in changes to drug pricing and spending.[81]

This asymmetrical argument was also alluded to during committee hearings on the bill, given that Democratic versions had included elements aimed at lowering drug prices, including one which would have required Medicare to negotiate drug prices.[82] In the above-described April 2003 Energy & Commerce hearing, then-Representative (now-Senator) Sherrod Brown criticized members of Congress who argued simultaneously against government price controls and in favor of delegating prescription drug insurance to private plans, partly on the grounds that private plans would have greater ability to drive down prices:

> Just to clarify, the price a public purchaser like Medicare demands is a draconian price control, the price a private purchaser, like an HMO, demands is an all American discounted price per figure. According to private plan proponents, Medicare price controls would jeopardize the drug industry's ability to conduct life-saving research and development…. Yet, the proponents claim that private plans would secure lower drug prices for seniors than would the old tired Medicare program. Private drug plans would be better at controlling drug costs than traditional Medicare, they tell us, but the drug industry's future is in

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[80] CONG. BUDGET OFFICE, A DETAILED DESCRIPTION OF CBO'S COST ESTIMATE FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT 16 (2004), https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/07-21-medicare.pdf (emphasis added).

[81] *See, e.g.*, *id*. at 15 ("[T]he most likely effect of a Medicare drug benefit would be modest price increases for the subset of drugs that had patent protection or exclusive marketing rights."). It is possible that CBO was unsure whether the Part D legislation would in fact increase or decrease returns to the pharmaceutical industry. The post-enactment report discusses in detail the ways in which Part D would be expected to replace existing coverage (or not) for beneficiaries, and the cost and spending effects of that replacement. The report clearly states that "CBO's estimates also assume that, rather than simply rearrange who pays for drug spending, the new benefit will change the level of total spending in various ways," *id*. at 6, but it does not explicitly state in which direction CBO thinks that level is likely to change. However, even at the time, financial markets and the pharmaceutical industry itself made clear that *they* believed the law would result in higher future revenues for industry. Blume-Kohout & Sood, *supra* note 58, at 327–28. As a result, it may be unlikely that CBO thought the result would be to decrease industry revenues.

[82] House Comm. on Energy & Commerce, Subcomm. on Health, *supra* note 64, at 7.

> jeopardy if we go to traditional Medicare rather than through private plans.[83]

Professor Mark Pauly, testifying as a witness in the above-described April 2003 Ways & Means hearing, confronted this innovation downside explicitly in his testimony, arguing that "the part of the government that wants to contain medical costs is at war with the part that wants to foster medical progress," and framing the policy question as "what tradeoffs should we make between inexpensive drugs today and better drugs for the future?"[84] More generally, in these hearings, no witness or member of Congress appears to consider the innovation *upside* of the bill as it was being debated and finalized. Further, the final version of the law contained no significant cost-control elements.[85]

Representatives of the pharmaceutical industry deployed these asymmetric arguments as well. In Congressional hearings about the creation of a Medicare prescription drug benefit as early as 1999, the President of PhRMA argued that "command-and-control big government approaches would stifle innovation and would lead to restrictions on access to medicines."[86] In later hearings, PhRMA representatives stated plainly that "government price controls are unacceptable" because "they would inevitably harm our ability to bring new medicines to patients."[87] These concerns about "price controls that harm innovation" were echoed by representatives of BIO in separate hearings.[88] These arguments spilled over into public-facing media as well: a June 2003 episode of the PBS series *Frontline* focused on the high prices of prescription drugs and the struggle to pass a Medicare prescription

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[83] *Id*. at 3.

[84] House Comm. on Ways & Means, *supra* note 66, at 84–85. No member of Congress asked Professor Pauly to discuss these issues further in the hearing.

[85] Oliver, Lee, & Lipton, *supra* note 62, at 342–43.

[86] Senate Comm. on Finance, Hearing: Medicare Prescription Drug Benefit, S. Hrg. 106-211, at 33 (June 23, 1999).

[87] Senate Comm. on Finance, Hearing: Prescription Drug Benefit in the Medicare Program, S. Hrg. 106-842, at 27 (March 22, 2000); *see also* House Comm. on Ways & Means, Hearing: Legislation to Cover Prescription Drugs Under Medicare, No. 106-113, at 116 (June 13, 2000).

[88] House Comm. on Energy & Commerce, Subcomm. on Health, Hearing: Medicare Reform: Providing Prescription Drug Coverage for Seniors, No. 107-28, at 84 (May 16, 2001); *see also* House Comm. on Ways & Means, Hearing: Integrating Prescription Drugs Into Medicare, No. 107-65, at 99 (April 17, 2002). These officials typically urged reliance on "the private marketplace and competition," *id.*, as an alternative to governmental involvement. Although it is not clear why one mechanism of cost control ought to be preferred to another for innovation purposes, as then-Representative Brown argued above, scholars argued that industry "believes it will have stronger negotiating power vis-à-vis private organizations … than it would if it had to deal directly with the federal government." Oliver, Lee, & Lipton, *supra* note 62, at 339–40.

drug benefit.[89] During that episode, a PhRMA representative stated that "when government imposes price controls on an industry, innovation dries up."[90]

Industry representatives did not present the other side of the analysis: that the new benefit might significantly increase their revenues, and innovation incentives accordingly. Importantly, the central goal of Part D—increasing seniors' access to prescription drugs—was by definition intended to substantially increase the quantity of medications seniors were able to purchase. When balanced against this quantity increase, it's not at all clear that allowing the government to negotiate for lower prices in its capacity as an insurer would have resulted in overall lower revenues for industry.

Ultimately, it appears that none of the key documents surrounding the passage of Medicare Part D—hearing transcripts and reports from Congressional committees, budgetary projections from the CBO, and presidential remarks—contain significant references to the innovation aspect of the program. Scholarly accounts of the law's passage similarly reveal an overall rhetorical focus on the law's relationship to access, not innovation.[91] It appears as if the relevant policymakers were making innovation policy by accident, without knowledge of the foreseeable results of their actions.

B. The Affordable Care Act

The ACA fundamentally transformed the American healthcare system in many ways, and its signature elements (the individual healthcare markets and the Medicaid expansion) have provided 31 million Americans with health insurance coverage who did not previously have it.[92] But the expansive law

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[89] PBS, *The Other Drug War*, FRONTLINE (June 13, 2003).

[90] *Id.*

[91] *See, e.g.*, Jonathan Oberlander, *Through the Looking Glass: The Politics of the Medicare Prescription Drug, Improvement, and Modernization Act*, 32 J. HEALTH POLITICS, POLY' & L. 187 (2007); Oliver, Lee, & Lipton, *supra* note 62.

[92] Dep't of Health & Human Servs., *New HHS Data Show More Americans than Ever have Health Coverage Through the Affordable Care Act* (June 5, 2021), https://www.hhs.gov/about/news/2021/06/05/new-hhs-data-show-more-americans-than-ever-have-health-coverage-through-affordable-care-act.html. As of this writing, though, only 39 states (including DC) have implemented the ACA's Medicaid expansion, Kaiser Family Found., *Status of State Action on the Medicaid Expansion Decision* (May 26, 2021), https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/, and millions more Americans in the remaining states could gain coverage if expansion was fully implemented. Rachel Garfield, Robin Rudowitz, & Anthony Damico, *How Many Uninsured Adults Could Be Reached If All States Expanded Medicaid?*, KAISER FAMILY FOUND. (June 25, 2020), https://www.kff.org/uninsured/issue-brief/how-many-uninsured-adults-could-be-reached-if-all-states-expanded-medicaid/.

did include many different provisions specifically impacting prescription drug availability, pricing, and spending.[93] For example, the ACA improved patient access both by closing Medicare Part D's so-called "donut hole,"[94] making it easier for many seniors to afford their medications, and by requiring all ACA-compliant plans to cover certain "essential health benefits," including prescription drugs.[95] The law also struck a compromise between exclusive rights and price competition in the biologic drug[96] context,[97] aiming to extend the idea behind the Hatch-Waxman Act (considered in more detail in Part II.A, *infra*) more broadly. The ACA also extracted some price concessions from drug manufacturers, increasing the mandatory minimum discounts they must offer to Medicaid programs (referred to as rebates)[98] and creating some

[93] For a review of several additional provisions not discussed here, *see* Rena Conti, Stacie B. Dusetzina, & Rachel Sachs, *How the ACA Reframed the Prescription Drug Market and Set the Stage for Current Reform Efforts*, 39 HEALTH AFF. 445, 445–46 (2020).

[94] *See id*. at 445–46 ("The doughnut hole was created at the time of Part D's enactment … The act required beneficiaries to pay the full cost of their prescription drugs for drug spending between $2,830 and $6,440 (in 2010), after which they reached the benefit's catastrophic phase (in which they paid only 5 percent of drug costs through the end of the year).").

[95] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1302, 124 Stat. 163–64 (2010) (defining "essential health benefits" to include "prescription drugs").

[96] A biologic drug—such as many of today's cutting-edge cancer therapies—is made by living cells, as compared to a small-molecule drug like aspirin, made through chemical synthesis techniques. As Professors W. Nicholson Price and Arti Rai have put it, "if an aspirin were a bicycle, a small biologic would be a Toyota Prius, and a large biologic would be an F-16 fighter jet." W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1026 (2016).

[97] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7001, 124 Stat. 804 (2010) (creating the Biologics Price Competition and Innovation Act). Like the Hatch-Waxman Act, the BPCIA guaranteed a certain period of exclusivity for innovator biologic drugs (12 years, rather than 5), but created a simplified path to approval for biosimilar versions of those drugs. 42 U.S.C. § 262(k) (2012). The full competition-generating promise of the BPCIA has yet to be achieved, though, in part because of scientific challenges and in part because of regulatory gamesmanship on behalf of innovator biologic firms. *See, e.g.*, Ameet Sarpatwari et al., *The US Biosimilar Market: Stunted Growth and Possible Reforms*, 105 CLINICAL PHARMACOLOGY & THERAPEUTICS 92 (2018).

[98] 42 U.S.C. § 1396r-8(c)(1)(B)(i)(V)-(VI) (increasing the mandatory minimum rebate from 15.1% to 23.1%); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2501, 124 Stat. 306 (2010).

financial responsibility for manufacturers to offset reduced beneficiary spending in the donut hole.[99]

This combination of policy changes was the result of an explicit political compromise. The Obama Administration aimed to marshal important interest groups in support of the legislation, including the pharmaceutical industry.[100] The pharmaceutical industry agreed to a deal allowing them to "mak[e] up in volume what they'd be giving up on price":[101] in exchange for tens of millions of new customers, industry would make particular price concessions, including in Medicaid rebates and the Medicare donut hole.[102] At the same time, though, the White House reportedly agreed not to seek further drug pricing reforms as part of the ACA, including empowering Medicare to negotiate for the price of prescription drugs.[103] This deal angered advocates for more structural drug pricing reform, and although not all members of Congress felt constrained by the White House's deal,[104] the ACA ultimately did not include more substantial reforms like those.

As with Medicare Part D, then, "more people with insurance meant more paying customers,"[105] and the pharmaceutical industry was projected to make more money as a result of the passage of the law, despite their isolated pricing concessions.[106] Within the Medicaid program alone (to say nothing of the individual marketplace), states that chose to expand Medicaid increased

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[99] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3301, 124 Stat. 461 (2010) (creating the Medicare Coverage Gap Discount Program).

[100] JONATHAN COHN, THE TEN YEAR WAR 142–43 (2020).

[101] *Id*. at 143.

[102] Ryan Grim, *Internal Memo Confirms Big Giveaways in White House Deal with Big Pharma*, HUFFINGTON POST (Sept. 13, 2009), https://www.huffpost.com/entry/internal-memo-confirms-bi_n_258285; Brett Norman & Sarah Karlin-Smith, *The One That Got Away: Obamacare and the Drug Industry*, POLITICO (July 13, 2016), https://www.politico.com/story/2016/07/obamacare-prescription-drugs-pharma-225444.

[103] Grim, *supra*; COHN, *supra* note 100, at 143.

[104] COHN, *supra* note 100, at 144 ("Waxman announced that he didn't feel bound by the agreement"); Grim, *supra* note 102 ("In the Senate, Democrats Sherrod Brown (Ohio) and Byron Dorgan (N.D.) pressed White House officials at a closed-door meeting last week, asking whether the White House had tied the Senate's hands.").

[105] COHN, *supra* note 100, at 143.

[106] *Id.* ("Baucus brought on an accounting expert, Tony Clapsis, who made projections of just how much extra the drugmakers, for example, would make because the newly insured could afford to pay for their prescriptions."). Without knowing more about the specifics of these projections, it is difficult to say how close they came to reality. But because the Supreme Court subsequently rendered the Medicaid expansion optional for states, Nat'l Fed'n Indep. Bus. v. Sebelius, 567 U.S. 519, 585 (2012), and many states have yet to expand their Medicaid programs, industry likely obtained fewer new customers than projected. *Cf.* Garfield, Rudowitz, & Damico, *supra* note 92.

their drug spending by about 10% more in the year after expansion than did states that chose not to expand Medicaid.[107] Nationwide, net Medicaid expenditures on prescription drugs were $3.6 billion higher in the first year of expansion,[108] even though many states were slow to expand and innovator pharmaceutical companies were providing larger minimum rebates.

Given the ACA's broad focus on expanding access to insurance for all products and services, not only prescription drugs, it is not surprising that many of the hundreds of Congressional hearings[109] and other policy documents focused primarily on access to health care generally. Even prior to the 2008 presidential election, key committees in both houses were hosting hearings entitled "Charting a Course for Health Care Reform: Moving Toward Universal Coverage"[110] and "Living Without Health Insurance: Why Every American Needs Coverage."[111]

After the 2008 election, this focus on improving access to and affordability of health insurance and medical care in general continued. The Subcommittee on Health of the House Energy & Commerce Committee alone hosted five hearings in March and April 2009 on the topic of "Making Health Care Work for American Families."[112] Subcommittee Chairman Frank Pallone

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[107] MACPAC, MEDICAID SPENDING FOR PRESCRIPTION DRUGS 5 (Jan. 2016), https://www.macpac.gov/wp-content/uploads/2016/01/Medicaid-Spending-for-Prescription-Drugs.pdf (showing that non-expansion states experienced a 14.1% increase in gross prescription drug spending, and expansion states experienced a 24.6% increase in gross spending).

[108] *Id*. at 4. Although the percentage increase is likely due to expansion, this numerical increase is due both to the expansion and to the introduction of new high-cost drugs. *Id*. at 1.

[109] Timothy Jost, *Examining the House Republican ACA Repeal and Replace Legislation*, HEALTH AFFAIRS BLOG (March 7, 2017), https://www.healthaffairs.org/do/10.1377/hblog20170307.059064/full/ ("In considering the Affordable Care Act in 2009 and 2010, the House held 79 hearings over the course of a year… The Senate adopted the Affordable Care Act only after approximately 100 hearings, roundtables, walkthroughs and other meetings.").

[110] Senate Comm. on Finance, Hearing: Charting a Course for Health Care Reform: Moving Toward Universal Coverage, S. Hrg. 110-406 (March 14, 2007).

[111] House Comm. on Energy & Commerce, Health Subcomm., Hearing: Living Without health Insurance: Why Every American Needs Coverage, No. 110-34 (Apr. 25, 2007).

[112] House Comm. on Energy & Commerce, Health Subcomm., Hearing: Making Health Care Work for American Families: Designing a High Performance Health System, No. 111-11 (March 10, 2009); House Comm. on Energy & Commerce, Health Subcomm., Hearing: Making Health Care Work for American Families: Ensuring Affordable Coverage, No. 111-16 (March 17, 2009); House Comm. on Energy & Commerce, Health Subcomm., Hearing: Making Health Care Work for American Families: Improving Access to Care, No. 111-20 (March 24, 2009); House Comm. on

opened the first of these hearings by emphasizing how "our Nation's growing uninsured crisis impacts us all," aiming to "ensure access to quality and affordable coverage for every American."[113] The second hearing's focus on "issues surrounding the affordability of health coverage"[114] and the third hearing's focus on access and "eliminat[ing] the inequities and disparities in health care"[115] struck a similar tone. But none of these five hearings featured representatives of the pharmaceutical industry, and prescription drugs were rarely singled out for discussion.[116]

A subsequent series of three hearings before the Health Subcommittee in June 2009[117] did include one witness representing Johnson & Johnson (out of 60 witnesses testifying).[118] Yet as the vice president for health policy there, her testimony ranged broadly, emphasizing the importance of wellness and prevention and the role of Johnson & Johnson as an employer as well as articulating support for the closure of the Part D donut hole.[119] Importantly, she did briefly object to the idea of a public insurance option by expressing concern that "a government plan that negotiates prices of pharmaceuticals would be more likely to use price controls that would undermine risky and long-term research in important new treatments."[120] In other words, her

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Energy & Commerce, Health Subcomm., Hearing: Making Health Care Work for American Families: The Role of Public Health, No. 111-24 (March 31, 2009); House Comm. on Energy & Commerce, Health Subcomm., Hearing: Making Health Care Work for American Families: Saving Money, Saving Lives, No. 111-27 (Apr. 2, 2009).

[113] House Comm. on Energy & Commerce, Health Subcomm., Hearing: Making Health Care Work for American Families: Designing a High Performance Health System, No. 111-11, at 1-2 (March 10, 2009).

[114] House Comm. on Energy & Commerce, Health Subcomm., Hearing: Making Health Care Work for American Families: Ensuring Affordable Coverage, No. 111-16, at 1 (March 17, 2009).

[115] House Comm. on Energy & Commerce, Health Subcomm., Hearing: Making Health Care Work for American Families: Improving Access to Care, No. 111-20, at 1 (March 24, 2009).

[116] The fifth and final hearing featured testimony by a prescription drug regulation and pricing expert, Dr. Jerry Avorn of Harvard Medical School. His testimony focused on the development and transmission of information about prescription drugs, however, rather than about their pricing. House Comm. on Energy & Commerce, Health Subcomm., Hearing: Making Health Care Work for American Families: Saving Money, Saving Lives, No. 111-27, at 67 (Apr. 2, 2009).

[117] House Comm. on Energy & Commerce, Health Subcomm., Hearing: Comprehensive Health Care Reform Discussion Draft, No. 111-54 (June 23, 24, 25 2009).

[118] *Id.* at V-VIII.

[119] *Id.* at 510-11.

[120] *Id.* at 517.

testimony explicitly raised the prospect that health care reform might *decrease* incentives for innovation. But she did not recognize the ways in which reform might *increase* innovation incentives. She did not extend this innovation theme to her support for the Medicaid expansion, which she noted would "improve access for uninsured individuals."[121]

The House Committee on Ways & Means similarly held a six-part series of hearings between March and June 2009, on the subject of "Health Reform in the 21st Century."[122] Committee Chairman Charles Rangel announced the first of these hearings (entitled "Expanding Coverage, Improving Quality, and Controlling Costs") by noting that the "uninsured crisis is not just affecting those families without coverage: it affects costs and quality for everyone," identifying problems of both access and affordability of services system-wide.[123] But no pharmaceutical industry representatives were featured, and outside of AARP advocacy to improve drug affordability for Medicare beneficiaries,[124] drug pricing was rarely discussed.

In the Senate, important committees of jurisdiction also held healthcare reform roundtable discussions in the middle of 2009. Senator Chris Dodd, presiding over the hearings before the Committee on Health, Education, Labor, and Pensions (HELP),[125] stated the mission of the Committee simply:

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[121] *Id.*

[122] House Comm. on Ways & Means, Hearing: Health Reform in the 21st Century: Expanding Coverage, Improving Quality and Controlling Costs, No. 111-5 (March 11, 2009); House Comm. on Ways & Means, Hearing: Health Reform in the 21st Century: Reforming the Health Care Delivery System, No. 111-13 (Apr. 1, 2009); House Comm. on Ways & Means, Hearing: Health Reform in the 21st Century: Insurance Market Reforms, No. 111-14 (Apr. 22, 2009); House Comm. on Ways & Means, Hearing: Employer-Sponsored Insurance, No. 111-17 (Apr. 29, 2009); House Comm. on Ways & Means, Hearing: Health Reform in the 21st Century: A Conversation with Health and Human Services Secretary Kathleen Sebelius, No. 111-18 (May 6, 2009); House Comm. on Ways & Means, Hearing: Health Reform in the 21st Century: Proposals to Reform the Health System, No. 111-26 (June 24, 2009).

[123] House Comm. on Ways & Means, Hearing: Health Reform in the 21st Century: Expanding Coverage, Improving Quality and Controlling Costs, No. 111-5, at 2 (March 11, 2009).

[124] House Comm. on Ways & Means, Hearing: Health Reform in the 21st Century: Proposals to Reform the Health System, No. 111-26, at 128 (June 24, 2009).

[125] The Committee was officially chaired at the time by Senator Ted Kennedy, for whom, as Senator Dodd put it, "reforming our system so that every American has access to affordable, high-quality healthcare has been the cause of his life." Senate Comm. on Health, Ed., Labor, & Pensions, Hearing: Healthcare Reform Roundtable (Part 1), S. Hrg. 111-974, at 2 (June 11, 2009). Senator Kennedy had been diagnosed with brain cancer and Senator Dodd presided over the committee in his absence. COHN, *supra* note 100, at 170. When the HELP Committee passed a healthcare reform bill out of committee in July, Senator Kennedy had Dodd read a statement on his

> If there is no other message out of today's hearing, it should be this: we will act to cut the skyrocketing costs of healthcare to our healthcare system, and we will at long last make quality affordable health insurance available to every man, woman and child in the United States of America.[126]

The HELP Committee's hearings featured representatives from large insurers, business groups, medical societies, hospital systems, unions, and other entities.[127] But outside of an isolated discussion of the importance of creating a path to market for biosimilar versions of innovator biologic drugs, a topic brought up by the representative from the AARP,[128] prescription drugs were infrequently mentioned.

The Senate Finance Committee similarly held three roundtable discussions on health care reform.[129] Like the HELP Committee, the Finance Committee also heard testimony from representatives of large insurers, business groups, medical societies, hospital systems, unions, and other stakeholders. The trade associations for hospitals and for insurers were also represented.[130] But the only witness to focus on prescription drugs was Dr. Robert Greenstein, the Executive Director of the Center on Budget and Policy Priorities. Dr. Greenstein laid out several of the drug pricing policies that would ultimately be included in the ACA, including increases to the mandatory minimum Medicaid rebates, as well as some that would not be included.[131] But these policy ideas were framed as "loopholes that can be closed" or ideas to address assumptions in earlier pieces of legislation that had turned out to be incorrect, rather than significant changes to drug pricing in a way that would impact innovation incentives.[132]

Even when hearings or other legislative documents focused on the prescription drug aspects of the ACA *as drug pricing policies*, they again primarily discussed the ways in which the law might increase access to medications, not on the innovation impacts it might have. Informational sheets released by key House committees touted the benefits of the law for

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behalf, stating, "As you vote today, know that I am with you in heart and mind and soul." Senator Kennedy would pass away in August 2009. *Id.*

[126] Senate Comm. on Health, Ed., Labor, & Pensions, *supra*, at 3.

[127] *Id.* at 3; Senate Comm. on Health, Ed., Labor, & Pensions, Hearing: Healthcare Reform Roundtable (Part 2), S. Hrg. 111-974, at III (June 12, 2009).

[128] Senate Comm. on Health, Ed., Labor, & Pensions, *supra* note 127, at 31.

[129] Senate Comm. on Finance, Hearings: Roundtable Discussions on Comprehensive Health Care Reform, S. Hrg. 111-25 (April 21, May 5, and May 12, 2009). As with the other committees, though, these hearings followed significant prior work in the area. *See id.* at 2 ("In the past year, we held a dozen hearings, held a day-long health reform summit.").

[130] *Id.* at III-V.

[131] *Id.* at 160-61 (relating to patients eligible for both Medicare and Medicaid).

[132] *Id.*

"protect[ing] consumers and taxpayers from rapid drug price increases,"[133] "clos[ing] the Part D donut hole,"[134] and "improv[ing] access and information for low-income beneficiaries."[135] Further, there is a post-enactment CBO letter focused solely on how the ACA would be likely to impact prescription drug pricing. The letter goes into detail about the ways in which the closure of the donut hole, increase in Medicaid minimum rebates, and creation of a biosimilar approval pathway might impact drug prices—but there is no mention of the innovation impacts of the law as a whole.[136]

Both Part D and the ACA delivered tens of millions of new customers to the pharmaceutical industry and expanded markets for pharmaceuticals in other ways that redounded to industry's financial benefit. But in neither case were key actors in the legislative process—members of Congress, CBO, or the President—focused on the innovation-promoting aspects of the laws, centering instead their access-enhancing goals. In these examples, in many ways it appears as if key policymaking stakeholders were making innovation policy "by accident," without important information about the innovation impacts of the laws. But Congress often makes innovation policy "on purpose." And considering how and why Congress makes laws *intending to* impact pharmaceutical innovation forms an important contrast with the ways in which Congress makes innovation policy seemingly by accident.

II. PURPOSEFUL INNOVATION POLICYMAKING IN CONGRESS

This Part considers two pieces of legislation which were deliberately designed with an eye toward prescription drug innovation: the 1983 Orphan Drug Act[137] and the Hatch-Waxman Act, more formally known as the Drug

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[133] House Comms. on Energy & Commerce and Ways & Means, *H.R. 3962 Protects Consumers and Taxpayers from Rapid Drug Price Increases* (Nov. 17, 2009).
[134] House Comms. on Ways & Means, Energy & Commerce, and Ed. & Labor, *Health Insurance Reform at a Glance: Medicare Part D* (March 18, 2010).
[135] *Id.*
[136] Cong. Budget Office, Letter to Representative Paul Ryan regarding the prescription drug price impacts of the Patient Protection and Affordable Care Act (Nov. 4, 2010), https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/reports/11-04-drug_pricing.pdf. To be sure, there are also pre-enactment cost estimates projecting the impact of particular provisions on bills up for consideration which would affect drug pricing and spending. *See, e.g.*, Douglas W. Elmendorf, Letter to the Hon. John D. Dingell Re: Budgetary Impact of H.R. 3962, the Affordable Health Care for America Act, at 4, 8, 11 of report (Nov. 20, 2009), https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/costestimate/hr3962revised0.pdf. However, these estimates do not focus on pricing or innovation.
[137] Pub. L. No. 97-414, 96 Stat. 2049 (1983).

Price Competition and Patent Term Restoration Act of 1984.[138] Unlike Medicare Part D or the ACA, each of these laws was explicitly motivated by the promotion of innovation, though in Hatch-Waxman's case the law balances innovation against price competition efforts. Exploring the legislative history and contemporary debates around these laws provides an important contrast to the previous Part. Examining the passage of these laws reveals how important stakeholders acted and spoke when changing patent law and FDA law with the express purpose of impacting pharmaceutical innovation. Members of Congress actively understood that these changes to patent law and FDA law would have impact pharmaceutical innovation, unlike the later changes they would make to health law with Part D and the ACA.

A. The Orphan Drug Act

The Orphan Drug Act of 1983 was enacted with the explicit purpose of promoting innovation into new drugs for rare conditions, those that affect a small number of patients.[139] The law's purpose and goals are stated clearly in the enacted legislative findings that accompany the law:[140]

> The Congress finds that … there is reason to believe that some promising orphan drugs will not be developed unless changes are made in the applicable Federal laws to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs; and it is in the public interest to provide such changes and incentives for the development of orphan drugs.[141]

Representative Henry Waxman, who led the development of the Orphan Drug Act as chairman of the House Energy & Commerce Committee's Subcommittee on Health and the Environment,[142] wrote about the issues that led him to pursue this legislation. After hearing from constituents whose families were impacted by rare conditions without treatment options, Representative Waxman began studying the problem, and he concluded that "our country's system of discovering and developing new drugs… did not account for the inherent financial disincentives to producing orphan drugs."[143] Waxman's team developed a bill that "encompassed three major incentives for

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[138] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[139] The Act specifically defines "rare conditions" as those affecting fewer than 200,000 Americans. 21 U.S.C. § 360bb(a)(2) (2012).

[140] As Professor Jarrod Shobe has explained, enacted legislative findings like these provide "detailed rationales for congressional action and explanations of Congress's expectations for the legislation." Jarrod Shobe, *Enacted Legislative Findings and Purposes*, 86 U. CHI. L. REV. 669, 671 (2019).

[141] Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983).

[142] HENRY WAXMAN, THE WAXMAN REPORT 65–67 (2009).

[143] *Id*. at 54-55.

pharmaceutical companies, each addressing a specific impediment to orphan drug development that we had uncovered in our survey and hearings."[144]

Representative Waxman and other legislators expressed similar views during the hearings held before the Health Subcommittee of the House Energy & Commerce Committee. Waxman's opening statement in the first hearing on the topic, in June 1980,[145] began with his focus on the importance of "provid[ing] all necessary incentives for investment in research and development."[146] Subsequent committee hearings featured the same themes. A March 1981 hearing featured many witnesses from pharmaceutical companies, with Representative Waxman's goal of learning more about whether barriers to orphan drug development were primarily governmental or corporate in nature.[147] Ranking Member Edward Madigan expressed his support for the efforts, agreeing that "not enough is being done" on orphan drugs and that the Committee ought to "explore ways through which Government and industry can work together to remedy the problem of orphan drugs once and for all time."[148]

Although the bill was revised as it moved through the committee process, the purpose behind it remained the same. The report on the bill from the House Energy and Commerce (which voted unanimously to approve the bill and send it to the full House for a vote)[149] stated its purpose clearly: "The purpose of the Orphan Drug Act is to facilitate the development of drugs for rare diseases or conditions."[150] In the Committee's view, "this country's system of financing and conducting biomedical research and for discovering and developing new drugs does not adequately account for the inherent disincentives in orphan drug development."[151] President Ronald Reagan echoed these sentiments in his statement accompanying the signing of the bill

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[144] *Id*. at 63.
[145] *Id.* at 57.
[146] Subcomm. On Health & the Environment of the Committee on Interstate and Foreign Commerce, *Hearing on How Can We Best Use our Limited Resources and at the Same Time Insure Safe and Effective Drugs to Diseases Which Occur Infrequently*, No. 96-216, at 1-2 (June 26, 1980). The hearing even featured testimony from Representative Elizabeth Holtzman, who (though she was not on this committee) had also introduced a bill with the purpose of "encourag[ing] and facilitate[ing] the development of these drugs by having the Government assist in overcoming obstacles… or assist in subsidizing certain costs." *Id*. at 3-4.
[147] Subcomm. On Health and the Environment of the Committee on Energy & Commerce, *Hearing on Orphan Drugs – H.R. 1663*, No. 97-17, at 1 (March 9, 1981).
[148] *Id*. at 10.
[149] WAXMAN, *supra* note 142, at 64.
[150] U.S. House Committee on Energy & Commerce, *Report: Orphan Drug Act*, H. Rept. 97-840 Pt. 1, at 5 (Sept. 17, 1982).
[151] *Id*. at 7.

in January 1983, noting that "the bill provides incentives for the private sector to develop drugs to treat these rare diseases."[152]

The final legislation provided several benefits to pharmaceutical companies pursuing drugs for the treatment of rare diseases. Most importantly, the law provided manufacturers with seven years of market exclusivity for their products, beginning upon FDA approval. During those seven years, the FDA is prohibited from approving another manufacturer's application for approval of the same drug for the same disease, even if no patents or other exclusive rights existed.[153] The law also created a significant tax credit, for 50% of the cost of clinical trials for such products, on top of existing research and development tax credits.[154] Finally, the law created a special grants program with the goal of developing new drugs for rare diseases.[155]

These innovation incentives are of two different types, as Professors Daniel Hemel and Lisa Larrimore Ouellette have noted.[156] The tax credit and grants program are classic "push" incentives, reducing the high costs of R&D and helping to de-risk the innovation process.[157] But the patent-like exclusivity period also rewards companies with an ex post "pull" incentive,[158] providing manufacturers with financial incentives once their products have been approved.[159] Although it is difficult to disentangle the relative effects of these different innovation incentives,[160] experts have argued that the Act itself was highly successful. In the 25 years after the Orphan Drug Act's passage, 326

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[152] Ronald Reagan, Statement on Signing H.R. 523 Into Law, at 8 (Jan. 4, 1983).

[153] Orphan Drug Act, Pub. L. No. 97-414, § 527, 96 Stat. 2050 (1983) (codified at 21 U.S.C. § 360cc(a)). As a result, this exclusivity is stronger in nature than the data exclusivity provisions in the subsequently-enacted Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(F)(ii), or BPCIA, 42 U.S.C. § 262(k)(7)(A), which prevent the follow-on applicant from relying on the innovator company's clinical trial data.

[154] Orphan Drug Act, Pub. L. No. 97-414, § 44H, 96 Stat. 2053-56 (1983). This tax credit was reduced to 25% in the 2017 Tax Cuts and Jobs Act. Tax Cuts and Jobs Act, Pub. L. No. 115-97, § 13401(a) (2017) (codified at I.R.C. § 45C(a)). Originally, the tax credit was even larger: the original bill included "a 90 percent tax credit designed to pay most of the cost of clinical trials." WAXMAN, *supra* note 142, at 63. The version of the bill analyzed by CBO includes this 90% tax credit. U.S. House Committee on Energy & Commerce, *supra* note 150, at 15.

[155] Orphan Drug Act, Pub. L. No. 97-414, § 5, 96 Stat. 2056-57 (1983).

[156] Hemel & Ouellette, *supra* note 41, at 378–81.

[157] *See id*. at 334 n. 145; Rachel E. Sachs, *Administering Health Innovation*, 39 CARDOZO L. REV. 1991, 1997 (2018).

[158] Sachs, *supra*, at 1997, 2007.

[159] As noted above, *see supra* text accompanying notes 36–42, health insurance coverage serves as an *ex post* pull incentive of this type, because it guarantees financial returns to companies obtaining FDA approval for their products.

[160] *See* Hemel & Ouellette, *supra* note 41, at 379–81.

drugs for orphan conditions were approved, representing a thirteen-fold increase over the pace in the decade prior to the Act.[161]

Despite the drafters' explicit focus on innovation into drugs for orphan conditions, CBO's pre-enactment cost estimate contains no explicit projection about how many drugs are likely to come to market as a result of the bill, or about how much those drugs might cost public payers.[162] It does, however, include a projection as to how much the law's R&D tax credit would cost to implement. CBO estimated that the cost of the tax credit would be $9 million in the first year, $18 million per year until 1989, and $9 million again in 1990.[163] But if CBO was able to project how much money the tax credit might cost, they would likely have had a view as to how many clinical trials those expenditures would represent—and therefore how many new drugs we might expect to come to market. Yet CBO was silent on this point.

The Orphan Drug Act provides a clear example of what it looks like when Congress has the goal of making innovation policy. Members of Congress were explicit about the problem they aim to solve, and their strategy for doing so. And they used more traditional tools of innovation policy—grants, tax credits, and patent-like exclusivity periods—to accomplish those goals. The passage of the Hatch-Waxman Act just a year later, though, adds nuance to the clear case of the Orphan Drug Act.

B. The Hatch-Waxman Act

The Hatch-Waxman Act sought to accomplish two different goals. Title I of the law created a new, simpler path to market for generic versions of FDA-approved innovator small-molecule drugs,[164] with the goal of more easily introducing lower-cost competitors to innovator prescription drugs. At the same time, though, Title II enabled innovator pharmaceutical firms to restore a portion of the patent terms for their products that were lost during the FDA review process.[165] The law also contained a five-year period of FDA-

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[161] M. Miles Braun et al., *Emergence of Orphan Drugs in the United States: A Quantitative Assessment of the First 25 Years*, 9 NATURE REVS. DRUG DISCOVERY 519, 522 (2010).

[162] To be sure, as the Orphan Drug Act predates Medicare Part D by twenty years, the federal expenditures back then would have been much smaller. Still, there would have been some federal expenditures through Medicaid.

[163] U.S. House Committee on Energy & Commerce, *supra* note 150, at 15.

[164] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585-86 (1984).

[165] *Id*. at § 201, 98 Stat. 1598-99. For doctrinal reasons, patents are typically filed early in the process of developing a new pharmaceutical. *See, e.g.*, 35 U.S.C.§ 102(a) (2012); Jacob S. Sherkow, *Patent Law's Reproducibility Paradox*, 66 DUKE L.J.845, 850, 883 (2017). As a result, several years of the patent term have elapsed once the

administered data exclusivity, similar to the Orphan Drug Act's seven-year period of market exclusivity.[166]

Many have argued that the Hatch-Waxman Act therefore reflects a compromise between interest groups, both providing additional incentives for innovation among pharmaceutical firms and ensuring patient access to affordable generics.[167] These arguments are supported by the law's legislative history. Its patent term extension element had been presented previously as a stand-alone bill, but it was not able to become law on its own.[168] Only when re-envisioned as a compromise did the package garner sufficient legislative support to pass through Congress.[169] As Representative Robert Kastenmeier, then chair of the House Judiciary Committee Subcommittee on Courts, Civil Liberties, and the Administration of Justice said during a June 1984 hearing on the bill, "these parallel developments led the conflicting parties to a negotiated settlement of their differences," noting that the bill they were discussing "is a product of that negotiation process."[170] A June 1984 hearing before the Senate Committee on Labor and Human Resources featured testimony from the presidents of the trade associations representing both

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drug is approved. Eisenberg, *supra* note 39, at 352; C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 330 (2012). The Hatch-Waxman Act enabled manufacturers to recover at least a portion of that time.

[166] In practice, these different exclusivity periods function quite similarly. Technically, though, they are different. The Orphan Drug Act's market exclusivity provision prevents the FDA from approving the same drug for the same indication for seven years, 21 U.S.C. § 360cc(a), while the Hatch-Waxman data exclusivity merely prevents other applicants from relying on the innovator company's clinical trials package. 21 U.S.C. § 355(j)(5)(F)(ii).

[167] *See, e.g.*, Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1358 (Fed. Cir. 2003) ("The Hatch-Waxman Act was accordingly a compromise between two competing sets of interests: those of innovative drug manufacturers, who had seen their effective patent terms shortened by the testing and regulatory processes; and those of generic drug manufacturers, whose entry into the market upon expiration of the innovator's patents had been delayed by similar regulatory requirements."); Eisenberg, *supra* note 39, at 356 (referring to the Act as a "legislative compromise[]"); Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 417 (2011) ("The Act was a compromise designed to balance the competing interests of research-based pharmaceutical companies . . . and generic drug manufacturers . . . .").

[168] Rachel Sachs, *The New Model of Interest Group Representation in Patent Law*, 16 YALE J.L. & TECH. 344, 382 (2014).

[169] *See id*.

[170] House Comm. on Judiciary, Subcomm. on Courts, Civil Liberties, and the Administration of Justice, Hearing: Innovation and Patent Law Reform, No. 105 Pt. 1, at 383 (June 27, 1984).

innovator and generic pharmaceutical companies, and Chairman Orrin Hatch thanked both men for their "great efforts in bringing together competing forces in this compromise bill."[171] The presidents themselves referred to the bill as a "compromise" in each of their testimonies.[172]

Key committee reports explicitly articulate these dual purposes. As the 1984 House Energy & Commerce Committee Report noted, "[t]he purpose of Title I of the bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962."[173] Additionally, "[t]he purpose of Title II of the bill is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket governmental approval. The incentive is the restoration of some of the time lost on patent life while the product is awaiting pre-market approval."[174]

Under the leadership of Democratic Representative Henry Waxman, important hearings in the Health Subcommittee of the House Energy & Commerce Committee focused on these twin goals of innovation and access. Representative Waxman opened a July 1983 hearing focusing only on the generic drug provisions of the law by emphasizing not only that "all consumers will benefit from lower drug prices," but also that "the bill will also save the Federal Government money."[175] An April 1981 hearing focusing on the patent term restoration provisions noted that "the purpose of that legislation is to increase pharmaceutical research and development leading to innovations in needed new drugs."[176] Importantly, Representative Waxman recognized that "the trade off for extending patent term and encouraging additional research and development expenditures is higher prices to consumers and reduced availability of generic drugs," wanting to ensure not only that patent term restoration would in fact increase innovation but also that it would "be used to find important breakthrough drugs" rather than "minor modifications of currently marketed drugs."[177]

Republican Senator Orrin Hatch, Representative Waxman's Senate counterpart, emphasized these same issues as he led the Senate Committee on Labor and Human Resources at this time. Senator Hatch opened a June 1984 hearing by stating that the Drug Price Competition and Patent Term

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[171] Sen. Comm. on Labor & Human Res., Hearing: Drug Price Competition and Patent Term Restoration Act of 1984, S. Hrg. 98-1102, at 36 (June 28, 1984).
[172] *Id.* at 36, 52.
[173] House Comm. on Energy & Commerce, Report: Drug Price Competition and Patent Term Restoration Act of 1984, H.Rep. 98-857 Pt. 1, at 14 (1984).
[174] *Id.* at 15.
[175] House Comm. on Energy & Commerce, Health Subcomm., Hearing: Drug Labeling and Advertising and New Drug Application, No. 98-67, at 1 (July 25, 1983).
[176] House Comm. on Energy & Commerce, Health Subcomm., *supra* note 43, at 275.
[177] *Id*. at 276.

Restoration Act of 1984 would respond "to dual problems our country has experienced in the pharmaceutical field," both in the high prices of off-patent drugs and in the decrease in pharmaceutical innovation. As he put it, the law "addresses both problems by striking a balance among the varying interests of research drug firms, generic firms, and consumers."[178] He expected the generic drug provisions of the law to lead to lower drug prices, and the patent term extension to lead to increased research and development expenditures.[179]

The CBO cost estimate for the law is quite sparse, however.[180] Although pharmaceutical companies themselves stated that the law "would create a significant, new incentive which would result in increased expenditures for research and development, and ultimately in more innovative drugs,"[181] CBO did not attempt to estimate how many new drugs might be produced as a result of the law, or how much those new drugs might cost the federal government in its capacity as an insurer. A 1981 Office of Technology Assessment[182] (OTA) report on the topic of patent term extension similarly did not project the innovation consequences of patent term restoration, even questioning the premise that innovation would increase as a result of patent term extensions.[183] The OTA report did, however, provide a range of numerical projections as to what the cost of patent-term extension to consumers (though not payers) might be.[184]

CBO's cost estimate also did not attempt to project how much money the generic drug elements of the bill were likely to save. CBO did note that those provisions may "result in savings if cheaper, generic drugs are made available for purchase by the federal government" through Medicare and Medicaid,[185] but did not specify a number because it did not attempt to project either which eligible drugs might be introduced in generic versions or the prices at which those generics would be sold.[186]

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[178] Sen. Comm. on Labor & Human Res., *supra* note 171, at 1.
[179] *Id.* at 2. Hearings before the House and Senate Judiciary Committees, which have jurisdiction over the patent law portions of the law, sounded similar themes. *See, e.g.*, Sen. Comm. on Judiciary, Hearing: The Patent Term Restoration Act of 1981 – S.255, No. J-97-21, at 2 (April 30, 1981) (noting that "the objectives of the patent restoration bill" are "to help innovative pharmaceutical companies to recover the investment they make in developing new therapies and to correct disincentives to innovative research).
[180] House Comm. on Energy & Commerce, *supra* note 173, at 19–20.
[181] *Id.* at 18.
[182] This Article returns to consider the Office of Technology Assessment in greater detail in Part IV.C, *infra*.
[183] *See* OFFICE OF TECH. ASSESSMENT, PATENT-TERM EXTENSION AND THE PHARMACEUTICAL INDUSTRY, at 4, 45 (Aug. 1981).
[184] *Id.* at 42-43.
[185] House Comm. on Energy & Commerce, *supra* note 173, at 20.
[186] *Id.* at 19.

The Energy & Commerce Committee itself provided more information on the potential cost savings from the law, though it provided no estimate as to how many new drugs might be produced as a result of the legislation. (Representative Waxman had asked the president of the pharmaceutical manufacturers' trade association how much his members could be expected to increase their research and development investments as a result of patent term restoration. The president would not identify a specific amount, though he did state that he anticipated an increase.)[187] The Committee noted that American consumers could save up to $920 million over 12 years if generic versions of drugs approved after 1962 were made available.[188] The Committee went on to point out that "the Department of Defense saved approximately $1.2 million in one year when a lower priced generic version of metronidazole became available," concluding that the law would "result in significant cost savings to the Federal government."[189]

III. IMPLICATIONS FOR INNOVATION POLICYMAKING

Given this descriptive picture, in which key healthcare policymakers have in important cases impacted innovation policy accidentally and asymmetrically, this Part identifies and describes three implications of this phenomenon for innovation policymaking more generally. First, in the case of innovation policy made "by accident," scholars and policymakers should consider whether access-focused policies might be creating innovation harms, as well as benefits, and ask whether this balance of benefits and harms of those policies might be recalibrated in the future. Second, particularly in the case of asymmetric policymaking, these examples suggest a warning about the role of interest group lobbying. The pharmaceutical industry has incentives to present one particular view of innovation policy, but it is generally not matched by constituencies explaining alternative views, in ways that may be problematic. Third, scholars ought to investigate *why* policymakers and other political stakeholders have treated these types of examples so differently, with an eye toward potential reform options.

A. Reevaluating the Innovation Impacts of Access Policies

To the extent that the innovation-related impacts of access-promoting policies like Medicare Part D and the ACA may have been accidental, it is important to ask whether those impacts are positive or negative ones. If these

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[187] House Comm. on Energy & Commerce, *supra* note 43, at 368 ("I don't know that anyone can sit here and give you a specific number.").
[188] House Comm. on Energy & Commerce, *supra* note 173, at 17.
[189] *Id.* at 18.

laws may have resulted in some negative consequences for innovation, policymakers might consider investigating whether the access-promoting goals of those policies might be served in ways that create fewer negative innovation consequences. One possible example comes from the ACA.

I have argued in prior work that the interplay between the ACA's general coverage expansions and its specific drug pricing provisions may have had an unintended consequence of creating a specific innovation *disincentive* for pharmaceutical companies, even as the law as a whole likely increased their revenues.[190] First, as noted above,[191] the ACA expanded access to health insurance for more than 30 million Americans, and one consequence of that expansion is to provide new customers for the pharmaceutical industry, likely increasing innovation incentives. But second, at the same time, the ACA increased the mandatory minimum rebates pharmaceutical companies owe to Medicaid:[192] innovator pharmaceutical companies after the ACA were now required to provide discounts to Medicaid of at least 23.1% of the average manufacturer price, up from 15.1% before the law's passage.[193]

These mandatory minimum rebates are unique to Medicaid—Medicare and private insurance do not have them—and along with other inflation-based Medicaid-specific rebates,[194] they contribute to Medicaid's ability to obtain substantially lower prices for prescription drugs than do Medicare Part D or commercial payers, in the majority of cases.[195] As a result, though, increasing the mandatory minimum Medicaid rebate has the effect of exacerbating the disparity in drug pricing reimbursement for pharmaceutical manufacturers. Those manufacturers were already largely able to charge higher prices in the private market and to Medicare than they were to Medicaid, and the ACA may have increased that disparity on a per-patient basis, even as it significantly expanded the Medicaid program.

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[190] *See* Sachs, *supra* note 36.

[191] *See supra* text accompanying notes 92.

[192] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2501, 124 Stat. 306 (2010).

[193] 42 U.S.C. § 1396r-8(c)(1)(B)(i)(V)-(VI).

[194] Medicaid is also entitled to additional rebates when pharmaceutical manufacturers increase the prices of their drugs more quickly than the rate of inflation. 42 U.S.C. § 1396r-8(c)(2)(A). These inflation-based rebates contribute significantly to the lower prices Medicaid is able to obtain. DEP'T OF HEALTH AND HUMAN SERVS. OFFICE OF INSPECTOR GEN., MEDICAID REBATES FOR BRAND-NAME DRUGS EXCEEDED PART D REBATES BY A SUBSTANTIAL MARGIN 7 (2015). Unlike the mandatory minimum rebates, however, the inflation-based rebates were not increased by the ACA.

[195] *See, e.g.*, DEP'T OF HEALTH AND HUMAN SERVS. OFFICE OF INSPECTOR GEN., *supra*, at 7; CONG. BUDGET OFFICE, A COMPARISON OF BRAND-NAME DRUG PRICES AMONG SELECTED FEDERAL PROGRAMS, at 20, 22 (Feb. 2021), https://www.cbo.gov/publication/57007.

This pricing disparity may result in a concomitant innovation disparity. A pharmaceutical company considering where to make R&D investments will no doubt be cognizant of the lower per-patient revenues they will be able to obtain in Medicaid relative to other payers, and they may deprioritize research on diseases that are more prevalent among low-income Americans.[196] Even as the ACA may deliver more patients and profits (and thus increase innovation incentives) to pharmaceutical companies in the abstract, the innovation impacts of the ACA on diseases that primarily affect low-income Americans may be more complex, and potentially problematic.

Policymakers could have achieved their goals of providing access to healthcare to a new population without creating this potentially concerning innovation bias. In seeking to extract concessions from pharmaceutical manufacturers as part of the negotiated deal for their support of the law, negotiators might have focused on different drug pricing reforms, ones that would not differentially impact Medicaid. Rather than widening the disparity in payments between Medicaid and other insurers, reforms could have equalized other insurers down toward Medicaid's payment rates, mitigating this innovation distortion.[197]

B. Guarding Against the Potential for Asymmetric Policymaking

When policymakers at the state and federal level have proposed changes to our existing system of prescription drug pricing that would reduce prices or spending from our current levels, a common response from the pharmaceutical industry[198] and often from Republican politicians[199] has been that these proposed changes will harm innovation. The debates around the House Democratic caucus' prescription drug pricing bill, H.R. 3, provide just one example. PhRMA has argued that H.R. 3's wide-ranging reforms "threaten[] patients' access to medicines, future innovation and American

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[196] *See* Sachs, *supra* note 36, at 200.

[197] Kevin Outterson & Aaron S. Kesselheim, *How Medicare Could Get Better Prices on Prescription Drugs*, 28 HEALTH AFF. w832, w833 (2009).

[198] Michael A. Carrier & Genevieve Tung, *The Industry That Cries Wolf: Pharma and Innovation*, STAT (Sept. 26, 2019), https://www.statnews.com/2019/09/26/innovation-boy-cried-wolf-pharma-industry/.

[199] *See, e.g.*, Sen. Finance Comm., *Open Executive Session to Consider an Original Bill Entitled "The Prescription Drug Pricing Reduction Act of 2019,"* at 7, 60 (July 25, 2019), https://www.finance.senate.gov/imo/media/doc/7-25-19%20--%20RX%20Drug%20Pricing%20Reduction%20Act%20of%202019.pdf (statements of Senator Chuck Grassley & Tim Scott). To be sure, not all Republican politicians have endorsed these arguments. *See* Azar, *supra* note 33 (pushing back on criticisms that the Trump Administration's own policies would be harmful to innovation).

jobs."[200] Similarly, Republican members of Congress have argued that H.R. 3 would "crush innovation."[201] But these arguments have also been levied against much smaller-scale reforms. Stakeholders have argued that smaller-scale legislation addressing specific anticompetitive actions such as product hopping[202] or pay-for-delay settlements[203] would also harm innovation.[204]

More specifically, the claim is that drug pricing reforms would decrease spending on prescription drugs by empowering patients and payers to pay less for each unit of the drugs they purchase. Several of these reforms would have the effect of reducing pharmaceutical industry revenues,[205] and reductions in industry revenues could translate to decreased R&D investments and a decrease in the number of new drugs coming to market in the future. Most observers agree that drug pricing reforms on the scale of H.R. 3,

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[200] PhRMA, *H.R. 3 Could Have Devastating Consequences for Americans* (2021), https://www.phrma.org/en/HR3.

[201] *See, e.g.*, Brady, *supra* note 35; Joe Grogan & Tom Philipson, *We Can Lower Drug Prices and Spur Medical Innovation. Pelosi's H.R. 3 is Not the Answer.*, FOX BUSINESS (Dec. 6, 2019), https://www.foxbusiness.com/money/lower-drug-prices-medical-innovation-pelosi-hr3-grogan-philipson ("The Pelosi bill would kill the innovation and access that have benefited patients worldwide and made the American life sciences the envy of the world.").

[202] *See* Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 N.D. L. REV. 167, 168 (2018) (describing "product hopping" as occurring when "[a] brand-name pharmaceutical company switches from one version of a drug (say, capsule) to another (say, tablet)").

[203] These settlements have become more complex over time, evolving from simpler settlements in which the branded manufacturer pays a generic competitor to stay off the market, into more complex arrangements, involving more complex arrangements "resulting in a net benefit for the generic firm but without any large, conspicuous payment." *See* Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEG. 499, 504–05 (2016); *see also* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 NYU L. REV. 1553, 1571 (2003).

[204] *See* Carrier & Tung, *supra* note 198.

[205] It is important to note that this is not the case for every pharmaceutical reform. Reforms that reduce what patients pay for their medications *without* reducing what the government pays for those medications might well result in greater revenues for the pharmaceutical industry, if more patients are able to afford their medications and increase the rate at which they fill them. *See, e.g.*, Michael E. Chernew et al., *Impact of Decreasing Copayments on Medication Adherence Within a Disease Management Environment*, 27 HEALTH AFF. 103, 103 (2008) (finding that reducing copays for five chronic disease medication classes increased adherence for four of the five classes); Niteesh K. Choudhry et al., *Eliminating Medication Copayments Reduces Disparities in Cardiovascular Care*, 33 HEALTH AFF. 863, 863 (2014) (finding that reducing copayments after heart attacks may not only increase adherence but also reduce racial and ethnic disparities).

projected to lead to $456 billion in savings over a decade,[206] would in fact lead to fewer prescription drugs being developed. But there are wide disparities in the scale of these projections. In August 2021, CBO released a revised model of drug development suggesting that a policy like H.R. 3 would lead to the development of just two fewer drugs over the next decade,[207] compared to President Trump's own Council of Economic Advisors, which put the figure at 100 fewer drugs.[208]

Scholars have pushed back on the merits of some of these claims. Instead of focusing on the number of new drugs approved, scholars and advocates argue that our focus should be on the clinical value those drugs provide to patients, including whether they provide new treatment options that were not previously available.[209] Given economists' findings that the passage of Part D was followed by an increase in R&D for products with high market share among seniors, but that these findings were concentrated in disease classes with multiple existing treatments,[210] allowing Part D to negotiate for these medications might discourage the development of drugs in already crowded classes, with less impact on more novel products. Particularly when smaller-scale reforms are proposed, advocates have often pushed back on whether innovation would be impacted at all. As noted above, even President Trump's HHS Secretary Alex Azar argued in support of his prescription drug pricing reforms in Medicare Part B, rejecting industry's innovation arguments as "prima facie implausible" and "mathematically unbelievable."[211]

But scholars should also ask questions about the *accidental* and *asymmetric* aspects of this argument. The innovation argument implicitly assumes that our current level or composition of innovation is "better" than the level or composition of innovation after a change that would decrease

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[206] Swagel, *supra* note 31, at 3.

[207] CONG. BUDGET OFFICE, *supra* note 34, at 1.

[208] Council of Economic Advisors, *House Drug Pricing Bill Could Keep 100 Lifesaving Drugs from American Patients* (Dec. 3, 2019), https://trumpwhitehouse.archives.gov/articles/house-drug-pricing-bill-keep-100-lifesaving-drugs-american-patients/.

[209] *See, e.g.*, Sachs & Frakt, *supra* note 43, at 871.

[210] *See supra* text accompanying notes 58–59.

[211] *See* Azar, *supra* note 33 ("These savings, while very substantial for American patients and American taxpayers, cannot, therefore, possibly pull out more than 1 percent of R&D. Of course, that's assuming that companies cannot drive somewhat higher prices in Europe and Japan, which they almost certainly can do. And if they can't, they ought to get new people negotiating. And it assumes there's nowhere in their operating budgets to find a few hundred million dollars across an entire industry in new savings or efficiencies.").

pricing or spending.[212] However, if our current level of innovation—maintained by current patterns of pricing and utilization—was arrived at accidentally, this assumption requires justification, not mere assertion. Choices that depart from our existing, accidentally constructed set of incentives are not automatically suspect, merely because they come with awareness of their innovation impacts. In fact, many of our access- and innovation-related choices have created potentially perverse innovation incentives, as Part III.A noted.

To be sure, it is commonly argued that more—more spending, and more approved drugs—is always better than fewer, and that whatever an optimal level of innovation may look like, we have yet to reach that point. In one sense, this is surely true. I do not take the position that we are, in general, over-incentivizing innovation.[213] But I have argued elsewhere that the *type* and *quality* of innovation we are receiving under our current incentive system is not a good match for the health needs of Americans.[214] One illustration of this argument comes not from the successful passage of an innovation-related bill, but from a legislative defeat. Accounts of the attempts to pass comprehensive healthcare reform during the Clinton Administration featured innovation-related arguments. The primary goal of the Clinton plan would have been to "guarantee comprehensive health benefits" to all Americans, and in doing so would have also provided a prescription drug benefit to Medicare enrollees.[215] But the plan also called for allowing Medicare to "use its negotiating power to get discounts from the pharmaceutical companies."[216] Pharmaceutical firms were "pleased" that the plan "would add an estimated 70 million people" with insurance coverage for their medications—but simultaneously argued that the price negotiation provisions "would cripple research budgets, delaying the discovery of cures for scourges like AIDS, cancer and Alzheimer's disease."[217]

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[212] This assumption suggests (though does not require) a further argument that more drugs and higher prices are necessarily better for innovation than fewer drugs or lower prices, an argument to which I return in Part III.B.

[213] This Article also puts aside the broader question about the optimal "mix" of innovation as between drugs, devices, services, and other interventions.

[214] *See* Sachs & Frakt, *supra* note 43.

[215] Oliver, Lee, & Lipton, *supra* note 62, at 301.

[216] WHITE HOUSE, HEALTH SECURITY: THE PRESIDENT'S REPORT TO THE AMERICAN PEOPLE, at 55 (1993) (Washington, D.C.). Part D would formally prohibit this a decade later. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1860D-11, 117 Stat. 2098 (2003) (codified at 42 U.S.C. § 1396w-111(i)).

[217] Milt Freudenheim, *Clinton's Health Plan: Drug Companies Feeling Pressure of Clinton's Plan to Keep Their Prices Down*, N.Y. TIMES (Sept. 30, 1993), https://www.nytimes.com/1993/09/30/us/clinton-s-health-plan-drug-companies-feeling-pressure-clinton-s-plan-keep-their.html.

The Clinton plan ultimately failed,[218] and nearly thirty years later, Medicare still cannot negotiate for the prices of prescription drugs. However, we also still lack effective treatments for Alzheimer's, and the FDA's recent approval of Aduhelm, which may be weakly effective at best, threatens to bankrupt the Medicare program and impose significant financial burdens on all seniors. Paying for drugs based on the clinical value they provide, rather than enabling industry to treat Medicare as a price taker, could produce *high-quality* innovation that is more valuable for patients.

The asymmetry of these arguments creates an additional challenge. If stakeholders in industry and in Congress make innovation arguments only when prices and spending might go down, but never acknowledge the innovation consequences when pricing and spending rise, there is real potential for a one-way ratchet and continued asymmetric policymaking.[219] This is particularly the case where there is no existing constituent group presenting policymakers with an alternative vision of innovation policy. It is far easier politically for prices and utilization to rise perpetually rather than fall over time, if lobbying is successful both in defeating drug pricing reform efforts and in advancing coverage expansions.

This concern has implications not only for the policy of prescription drug pricing and spending, but also for the political economy behind the legislation. Even if legislators do not explicitly consider the innovation-related impacts of bills that would result in coverage expansions of various types, the pharmaceutical industry is surely aware of these consequences. In theory, industry may have an incentive to lobby for the passage of coverage-expanding bills on this basis. But in both the Part D and ACA debates, these issues were not at the forefront of the policy conversation, perhaps due to the strength of the political arguments about protecting patients, but also for fear of alerting policymakers to the asymmetry in their own positions.

To be sure, I do not mean to suggest that industry never raises innovation-related arguments. They do raise them in the context of coverage

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[218] However, experts often point to advertising campaigns waged against the bill by non-pharmaceutical stakeholders as ensuring that defeat. *See* HAYNES JOHNSON & DAVID S. BRODER, THE SYSTEM 198–99, 204–13 (1996); Dan Diamond, *"Harry and Louise" – and Hillary*, POLITICO (May 12, 2016), https://www.politico.com/story/2016/05/harry-louise-and-hillary-clinton-223139.

[219] To be sure, this phenomenon is not unique to prescription drug issues. As just one example, consider the adjacent field of copyright law. *See, e.g.*, Jessica Litman, *War Stories*, 20 CARDOZO ARTS & ENT. L.J. 337, 344 (2002) ("Recently, copyright legislation has seemed to be a one-way ratchet, increasing the subject matter, scope, and duration of copyright with every amendment."); Rebecca Tushnet, *Copy This Essay: How Fair Use Doctrine Harms Free Speech and How Copying Serves It*, 114 YALE L.J. 535, 543 (2004) ("Legally, then, copyright has been a one-way ratchet, covering more works and granting more rights for a longer time.").

expansion efforts—but only on the "downside." Industry stakeholders argued against the inclusion of drug pricing reform measures in the ACA on the grounds that they would threaten innovation,[220] even though they would simultaneously benefit financially from the coverage expansions. Accounts of the passage of the ACA suggest that this dynamic helps explain why the Obama Administration struck a deal with industry in the way that they did.[221] And they do raise them on the upside in the context of bills that are purposefully designed to promote innovation, such as by making it easier to bring new drugs to market.[222] But they do not raise them on the upside in the context of coverage expansion efforts.

Legislators on the receiving end of these arguments from industry ought to be aware of and consider their asymmetrical nature. If industry only makes innovation claims when prices will fall, but makes no mention of the issue when prices or utilization will rise, their claims ought to be understood as having a bias with the potential to skew policymaking. It is also not an answer to make concessions to industry with an eye toward tackling additional issues later. As Representative Waxman has written, "In all my years as a legislator, I can't recall a single example of a law where, when drug companies were granted excessive government concessions, we ever managed to scale them back later."[223]

C. Explaining Disparate Legislative Dynamics

Legislative stakeholders working to enact the Orphan Drug Act or Hatch-Waxman Act understood themselves quite explicitly to be making innovation policy, but the very same actors did not clearly discuss doing so in the context of Medicare Part D or the ACA. Understanding why legislators behaved differently in the different contexts can help point the way toward potential legislative reform options.

At least two possibilities ought to be considered. The first possibility, relating to committee jurisdiction, is only partially helpful. Specifically, some committees—such as the House and Senate Judiciary Committees, with their jurisdiction over patent law[224]—only have the opportunity to review some of

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[220] COHN, *supra* note 100, at 143.

[221] *See supra* text accompanying notes 100–106.

[222] *See, e.g.*, PhRMA, *PhRMA Statement on 21st Century Cures Act House Passage* (Nov. 30, 2016), https://phrma.org/resource-center/Topics/Research-and-Development/PhRMA-Statement-on-21st-Century-Cures-Act-House-Passage.

[223] WAXMAN, *supra* note 142, at 73.

[224] U.S. House Comm. on the Judiciary, *Subcommittees: Courts, Intellectual Property, and the Internet* (2021), https://judiciary.house.gov/subcommittees/courts-intellectual-property-and-internet-116th-congress/; Senate Comm. on the Judiciary, *Jurisdiction* (2021), https://www.judiciary.senate.gov/about/jurisdiction.

these pieces of legislation and may genuinely lack information about the role health law and pricing plays in incentivizing innovation.[225] But all four of the pieces of legislation discussed in Parts I and II had to pass through important health-related committees. Those Committees have developed greater expertise in this area over time.

A second possibility is simply that important legislative stakeholders genuinely did not perceive changes to health law that had the goal of increasing access as having innovation impacts or as being about innovation, unless they were specifically informed about them. When faced with innovation-related problems, policymakers turned to familiar solutions—intellectual property and intellectual property-like exclusivity periods—to address those issues. But when trying to solve access-related problems, policymakers did not think about the ways in which those familiar solutions, sounding in health law, would have implications for innovation as well.

A 1983 House Energy & Commerce Health Subcommittee hearing on the generic drug aspects of the Hatch-Waxman Act supports this argument. The hearing featured testimony by two FDA officials, the Deputy Commissioner (Dr. Mark Novitch) and the Chief Counsel (Tom Scarlett). In response to a statement by Dr. Novitch that, in his view, "as a public health agency, we want to be certain that our regulations and our enforcement of the laws entrusted to us are not inhibiting incentives to innovate," Representative Waxman asked pointed questions about whether this was an appropriate role for the FDA. He asked specifically: "if there is a concern regarding inadequate incentives to innovate, shouldn't that problem be addressed in the patent laws and not in the Federal Food, Drug, and Cosmetic Act?"[226] Scarlett subsequently stated that, in his view, the FDA has authority "implicit in the [FD&C] Act" to take innovation incentives into consideration, and that "we simply want to avoid diminishing incentives to innovate to the extent we can."[227] Representative Waxman was concerned about these responses, referring to them as "activist" and stating that Scarlett's "determination of what is diminishing incentives is taking upon yourselves a responsibility that Congress has and that the patent laws are set forth to address."[228]

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[225] Another example might be the House Committee on Ways & Means, which has overlapping jurisdiction over Medicare but does not have authority over FDA-related or intellectual property legislation. U.S. House Comm. on Ways & Means, *Jurisdiction & Rules* (2021), https://waysandmeans.house.gov/about/jurisdiction-and-rules.

[226] House Comm. on Energy & Commerce, *supra* note 175, at 19; *see also id*. ("Is that the job of the FDA?").

[227] *Id*. at 20-21.

[228] *Id*. at 21. Subsequently, the FDA would formally support the patent term restoration aspects of the bill, with then-Acting Commissioner Novitch expressing the agency's support in the 1984 Hearing before the Senate Committee on Labor and Human

The issue of accidental innovation policymaking has implications for both innovation policy and innovation politics, and particularly for drug pricing reform. But it is also not necessary for stakeholders to continue making innovation policy accidentally. Going forward, reforms might be made to the policymaking process that would seek to inform key stakeholders, including legislators, about the innovation-related consequences of their proposals.

IV. POTENTIAL POLICYMAKING REFORMS

This Part proposes reforms to the legislative process with the goal of ensuring that healthcare policymakers act with an awareness of the foreseeable consequences of their actions, including innovation-related consequences. The aim of these reforms would be to provide legislators and staffers both with additional information about the likely effects of legislative proposals and with ongoing analysis of those programs' implementation, post-enactment. In some (though certainly not all[229]) cases, policymakers might react to this additional information by changing their behavior, in ways that address concerns about both accidental and asymmetric policymaking.

Informing policymakers about bills' potential innovation impacts would be most likely to impact the types of concerns presented in Part III.A, in which policymakers may be creating innovation biases that could be somewhat easily avoided. But over time, providing this type of information should also begin to address the concerns present in both Parts III.B and III.C. Policymakers may develop a greater understanding of the role health law plays to shape innovation incentives, enabling them to more critically evaluate stakeholders' one-sided claims. This Part explores three potential entities or types of entities that might provide this type of information: CBO, a nonpartisan legislative agency with health expertise, or an entity like the former Office of Technology Assessment (OTA). Siting this responsibility within each of these three entities would have its strengths and its weaknesses.

Resources. *See* Sen. Comm. on Labor & Human Res., *supra* note 171, at 5, 7. In doing so, he did not face the type of criticism he had faced in the Energy & Commerce hearing about the proper role of the agency.

[229] Policymakers might not choose to change their behavior or might be unable to do so. The innovation-related consequences of a bill might well be smaller than other important consequences the drafters sought to achieve, as was certainly likely with the ACA. In another context, an administrative agency (a policymaking actor not the focus of this paper) may know that a particular regulatory action has innovation-related consequences but may be jurisdictionally constrained in considering those consequences as part of their decision-making process.

A. The Congressional Budget Office

One natural locus of innovation-related analysis would be CBO. Established by the Congressional Budget and Impoundment Control Act of 1974,[230] CBO is directed to provide Congressional committees with information about the budgetary consequences of legislative proposals.[231] CBO produces "several hundred" formal cost estimates annually, in addition to "thousands" of more informal estimates earlier in the legislative process.[232]

CBO might seek to consider innovation-related consequences as part of its legislative analyses, even if those consequences do not necessarily have direct budgetary implications of the type CBO typically analyzes. One example of this type of approach would be CBO's analysis of H.R. 3, the Democratic drug pricing bill, in late 2019. CBO's determination that the enactment of H.R. 3 would be likely to lead to fewer drugs coming to market is not budgetary in the way that typically matters to the agency,[233] and the Office specifically framed its analysis as one focused on H.R. 3's "Effect on Pharmaceutical Research and Development."[234] CBO might include similar sections in considering the implications of bills that would expand access to health insurance generally, or pharmaceutical coverage specifically (as with the ACA and Part D, respectively). CBO's subsequent formalization and revision of this model in August 2021 suggests that the agency is thinking deeply about how to measure these innovation effects, though to date the agency has continued to do so asymmetrically.[235]

Comparing two CBO reports in the prescription drug area is instructive in considering how the agency's thinking on this question has evolved over time. In 1998, before the creation of Medicare Part D, a CBO report focused on the Hatch-Waxman Act considered the ways in which increased competition from generic drugs had affected returns to pharmaceutical companies.[236] The report concluded that on balance, the Act's two reforms—the innovation-focused patent term extension and exclusivity

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[230] Pub. L. No. 93-344, 88 Stat. 297 (1974).
[231] *Id*. at § 202 (codified at 2. U.S.C. § 602).
[232] Cong. Budget Office, *Frequently Asked Questions About CBO Cost Estimates* (2021), https://www.cbo.gov/about/products/ce-faq.
[233] It is not obvious that fewer drugs coming to market would alter federal spending in a way that *more* drugs coming to market (as in the case of Medicare Part D) would not, and yet CBO's reports about Part D do not consider this issue explicitly. *See supra* Part I.A. If anything, *more* drugs coming to market would seem to have a clearer impact on federal spending, as the federal government would serve as a significant payer for these products under Medicare and Medicaid.
[234] Swagel, *supra* note 31, at 6.
[235] CONG. BUDGET OFFICE, *supra* note 34.
[236] CONG. BUDGET OFFICE, *supra* note 78.

provisions, and the access-focused creation of a simpler path to market for generic drugs—reduced returns from marketing a new drug somewhat (12%) but in a way that only had a small impact on the number of new drugs coming to market.[237] More interestingly, the report also devoted an entire chapter to the ways in which managed care insurance, which grew in prominence in the 1990s, has impacted returns for pharmaceuticals.[238] The report acknowledged that these demand-side factors may impact returns for pharmaceutical companies, but ultimately did not take them into account in its analysis.[239]

CBO's April 2021 report on *Research and Development in the Pharmaceutical Industry* now considers the role of insurance and demand-side factors much more prominently. Although CBO's reports surrounding the passage of Part D had not considered its impact on innovation incentives, CBO now explicitly acknowledges the literature identifying Part D's impact on innovation incentives.[240] More generally, CBO notes that "federal health care programs and subsidies increase demand for health care services and products, including prescription drugs," and that this type of increased demand "indirectly stimulate[s] spending on drug R&D."[241] The report references CBO's analysis of H.R. 3 as demonstrating a contrasting example of reduced innovation incentives.[242] This recognition that changes to insurance reimbursement policy could either increase or decrease incentives suggests that future CBO reports may take both of these issues into account going forward, though CBO has yet to do so.

Existing CBO analyses suggest that the office might be equipped to analyze not only whether a particular bill might be expected to lead to more or fewer new drugs, but how much value those drugs might provide for patients. Although CBO specifically disclaimed this type of analysis in evaluating the impact of H.R. 3,[243] they have previously published analyses which involve assessments of drugs' clinical value. In a 2012 report, CBO considered the relationship between prescription drug utilization and hospitalizations: if

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[237] *See id*. at 47 ("On average, therefore, the returns from marketing a new drug would probably still fully cover the capitalized costs of R&D despite the increase in generic sales since 1984. On the margin, however, a few drugs that were barely profitable to develop would no longer be profitable.").

[238] *Id*. at 5. The report notes both that managed care plans exert "downward pressure on prices" but also that those efforts "may be offset by the more frequent use of prescription drugs." *Id.*

[239] *Id*. at 37.

[240] CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY, at 17–18 (April 2021), https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf.

[241] *Id.* at 17.

[242] *Id*. at 12.

[243] CONG. BUDGET OFFICE, *supra* note 34, at 24.

patients' prescription drug costs go up or down and they respond by changing their utilization, what is the impact on overall Medicare spending on hospitalizations? CBO found that increases in patients' adherence to their medication caused Medicare spending on hospitalizations to decrease.[244] The clinical value of these drugs drives the relationship between adherence and spending, and is therefore implicit in CBO's analysis.

CBO's typically nonpartisan nature[245] combined with its technical expertise may make the office a strong candidate for this responsibility. The timing of its reviews may also prove to be useful: CBO completes pre-enactment analyses of proposed legislation as well as post-enactment reports.[246] The Office's pre-enactment innovation analyses could therefore be used by policymakers as they consider whether and how to move forward a particular piece of legislation. Further, innovation-related analyses may be useful for members of Congress to consider outside the healthcare context.[247]

At the same time, though, other aspects of CBO's structure may suggest reasons for siting this responsibility within a different policy actor. First, CBO "does not make policy recommendations,"[248] and so to the extent that such policy recommendations would be a desired part of this innovation analysis process,[249] other actors might be needed to provide such guidance. Second, a significant portion of CBO's resources focus on producing reports relating to proposed or just-enacted legislation, considering the potential future impacts of that legislation.[250] As a result, CBO may be less suited to

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[244] CONG. BUDGET OFFICE, OFFSETTING EFFECTS OF PRESCRIPTION DRUG USE ON MEDICARE'S SPENDING FOR MEDICAL SERVICES 1, 4–6 (2012).

[245] Cong. Budget Office, *Introduction to CBO* (2021), https://www.cbo.gov/about/overview ("CBO is strictly nonpartisan"). *But see* Zachary Karabell, *A Dynamic World Demands Dynamic Scoring*, POLITICO (Jan. 14, 2015), https://www.politico.com/magazine/story/2015/01/dynamic-scoring-114237/ (explaining how the debate over the use of dynamic scoring at the CBO has played out in partisan ways).

[246] *See supra* text accompanying notes 74-81 (analyzing both pre-enactment cost estimates of Medicare Part D as well as a full post-enactment analysis).

[247] As one example, the military's expertise in the use of procurement contracts to drive innovation may create similar incentive dynamics.

[248] Cong. Budget Office, *Introduction to CBO* (2021), https://www.cbo.gov/about/overview.

[249] To be sure, it would be one thing for CBO to recommend that Congress move a bill forward or not on the basis of its impacts, including those in the innovation context. But given the types of dynamics I describe *supra*, particularly in Part III.A, policymakers might want an independent assessment not only of the potential innovation impacts of their access-related proposals but also recommendations as to how potential conflicts between those two policy goals might be addressed, not simply the budgetary aspects thereof.

[250] Cong. Budget Office, *Frequently Asked Questions About CBO Cost Estimates* (2021), https://www.cbo.gov/about/products/ce-faq.

engage in ongoing evaluations of already enacted legislation, though the agency certainly does produce annual reports analyzing important areas of federal policy.[251] Finally, CBO has a large and very experienced health policy analysis group,[252] but there might be reasons to prefer to delegate this responsibility to an actor focused primarily on health care policy.

B. An Expert Health-Focused Agency

Given the complexities involved in analyzing health care policy issues, another logical home for this type of analysis would be one of the independent, nonpartisan legislative agencies specifically created to provide Congress with policy advice in the health care area. The Medicare Payment Advisory Commission (MedPAC) was established to advise members of Congress on issues affecting Medicare,[253] and its counterpart, the Medicaid and CHIP Payment and Access Commission (MACPAC), provides policy advice relating to Medicaid and the State Children's Health Insurance Program.[254] Each Commission is statutorily instructed to provide annual reports to Congress analyzing issues affecting its respective program,[255] and to "make recommendations to Congress" regarding program policy.[256]

Empowering MedPAC, MACPAC, or both to consider the innovation-related impacts of proposals that would alter prescription drug access, spending, or pricing would be in keeping with both Commissions' existing missions to make such recommendations. In recent years, both Commissions have taken on topics in the drug pricing and spending area that have innovation implications, and these types of analyses and recommendations could become a more regular fixture of each Commission's functions. As one example, MedPAC's June 2019 Report to the Congress includes a chapter focusing on "Medicare payment strategies to improve price competition and value for Part B drugs."[257] The report points out that, currently, Medicare "lacks tools to arrive at payment rates for new drugs that

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[251] Cong. Budget Office, *Products: Analytic Reports* (2021), https://www.cbo.gov/about/products.

[252] *See* Cong. Budget Office, *Organization and Staffing: Health Analysis Division* (2021), https://www.cbo.gov/about/organization-and-staffing.

[253] The Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4022, 111 Stat. 350 (1997) (codified at 42 U.S.C. § 1395b-6).

[254] The Children's Health Insurance Program Reauthorization Act of 2009, Pub. L. No. 111-3, § 506, 123 Stat. 91 (2009) (codified at 42 U.S.C. § 1396).

[255] 42 U.S.C. § 1395b-6(b)(1)(D); 42 U.S.C. § 1396(b)(1)(D).

[256] 42 U.S.C. § 1395b-6(b)(1)(B); 42 U.S.C. § 1396(b)(1)(B).

[257] MEDPAC, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 55 (June 2019), http://medpac.gov/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf.

balance an appropriate reward for innovation with value and affordability for beneficiaries and taxpayers."[258] The Commission goes on to recommend particular drug pricing reform policies that could "incorporate value, affordability, and an appropriate reward for innovation" into Medicare's pricing process.[259] In this report, MedPAC lays out and applies the relationship between drug pricing, innovation, and access that would enable them to analyze the innovation impacts of proposed policy options.[260]

The deep substantive expertise of the MedPAC and MACPAC Commissioners (not to mention the expert staff supporting their efforts) makes these entities a natural fit for this type of analysis. The membership of the Commissions is even specified by law:

> The membership of the Commission shall include (but not be limited to) physicians and other health professionals, experts in the area of pharmaco-economics or prescription drug benefit programs, employers, third-party payers, individuals skilled in the conduct and interpretation of biomedical, health services, and health economics research and expertise in outcomes and effectiveness research and technology assessment. Such membership shall also include representatives of consumers and the elderly.[261]

Because the Commissioners are identified as having broad expertise within health care policy, including but not limited to prescription drug issues, they may be particularly well-suited to analyze the impacts of a range of health care policy changes on prescription drug innovation. Congress recently provided both Commissions with access to otherwise confidential information about drug prices,[262] enabling them to conduct analyses that other actors cannot currently complete with as much accuracy.[263] Further, because both Commissions are explicitly instructed to make policy recommendations about

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[258] *Id*. at 56.
[259] *Id*. at 63.
[260] *Id*. at 63-64.
[261] 42 U.S.C. § 1395b-6(c)(2)(B); *see also* 42 U.S.C. § 1396(c)(2)(B) (spelling out similar requirements for MACPAC).
[262] Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, § 112 (2021) ("Providing the Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission with Access to Certain Drug Payment Information, Including Certain Rebate Information").
[263] Scholars and policymakers certainly try to estimate the net prices of drugs in the work that they do, *see, e.g.*, William B. Feldman et al., *Estimating Rebates and Other Discounts Received by Medicare Part D*, 2 JAMA HEALTH FORUM e210626 (2021), but because the pharmaceutical industry argues that these net prices are trade secrets, see Robin Feldman & Charles Tait Graves, *Naked Price and Pharmaceutical Trade Secret Overreach*, 22 YALE J.L. & TECH. 61, 63–64 (2020), it is difficult to obtain access to this information publicly.

their programs,[264] Commissioners and their staff might have the opportunity to consider innovation issues more proactively. For instance, they might note whether there is a particular clinical area which is underserved by existing pharmaceutical treatments, and that increasing reimbursement rates in that area might be helpful to encourage new innovation.[265]

There may also be drawbacks to siting this responsibility within MedPAC or MACPAC, though. Structurally, these agencies are not set up or staffed with the goal of providing pre-enactment analyses of ideas that members of Congress might be interested in proposing. To be sure, the Commissions' annual reports and additional projects provide detailed analyses of many policy options the Commissions recommend to Congress. Their work is ideally suited to ongoing reviews and analysis of existing laws, as well. But where members of Congress propose novel ideas for consideration or seek to respond quickly to emerging events, the annual cycle of Commission reviews may not be set up for that type of pre-enactment analysis. More substantively, the Commissions' focus on their individual programs—as central as they are to the functioning of the American healthcare system—may leave out the impacts of proposed policies on the majority of Americans who are not eligible for Medicare or Medicaid.[266]

C. The Office of Technology Assessment

A third, more general, model might involve an entity resembling the Office of Technology Assessment (OTA). In establishing the Office in 1972, Congress found that "the present mechanisms of the Congress do not and are not designed to provide the legislative branch" with information "relating to the potential impact of technological applications."[267] Congress therefore created the OTA to provide "competent, unbiased information concerning the physical, biological, economic, social, and political effects" of scientific and

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[264] 42 U.S.C. § 1395b-6(b)(1)(B); 42 U.S.C. § 1396(b)(1)(B).

[265] Sachs, *supra* note **Error! Bookmark not defined.**.

[266] To be sure, this is also a potential concern with delegating this responsibility to CBO, as well, as CBO is typically focused on *government* revenues and spending, *see* Cong. Budget Office, *Products* (2021), https://www.cbo.gov/about/products, rather than those of patients or on private actors within the insurance system. CBO does sometimes project what the impacts of policy proposals might be for patients and their out-of-pocket costs, though. *See, e.g.*, Cong. Budget Office, *Sections 121 and 128 (the Part D "Redesign" and "Inflation-Rebate" Provisions) of the Prescription Drugs Pricing Reduction Act* (July 24, 2019), https://www.cbo.gov/system/files/2019-07/Expected_Effects.pdf.

[267] Technology Assessment Act of 1972, Pub. L. No. 92-484, § 2, 86 Stat. 797 (1972) ("Findings and Declaration of Purpose").

technological issues.[268] For more than twenty years, the nonpartisan[269] OTA provided Congress with more than 750 technological assessments[270] in a wide range of areas, including the environment, healthcare, and national security.[271] But in 1995, Republican Speaker of the House Newt Gingrich led the effort to eliminate the Office, a move some have framed as an effort to "centralize power in the speaker's office,"[272] but which also had the effect of enabling the Republican House majority to identify its own experts and lobbyists, unencumbered by OTA's scientific analysis.[273]

The idea of OTA assembling a report focusing on the drivers of pharmaceutical innovation and access is not merely hypothetical. The Office published a report examining these themes in 1993.[274] The report did identify the link between health insurance and innovation incentives, noting as follows:

> The rapid increase in revenues for new drugs throughout the 1980s sent signals that more investment would be rewarded handsomely. The pharmaceutical industry responded as expected, by increasing its investment in R&D… The rapid increase in new drug revenues was made possible in part by expanding health insurance coverage for prescription drugs in the United States through most of the 1980s.[275]

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[268] *Id*.

[269] *See, e.g.*, Barton Reppert, *OTA Emerges as Nonpartisan Player: Surviving a Rocky Start, Science Agency Wins Over Most Skeptics*, WASH. POST (Jan. 5, 1988), https://www.princeton.edu/~ota/ns20/ota88_f.html.

[270] Studies "normally take 18 months to 2 years to complete and can be hundreds of pages long." Warren E. Leary, *Congress's Science Agency Prepares to Close Its Doors*, N.Y. TIMES (Sept. 24, 1995), https://www.nytimes.com/1995/09/24/us/congress-s-science-agency-prepares-to-close-its-doors.html.

[271] Jathan Sadowski, *The Much-Needed and Sane Congressional Office That Gingrich Killed Off and We Need Back*, THE ATLANTIC (Oct. 26, 2012), https://www.theatlantic.com/technology/archive/2012/10/the-much-needed-and-sane-congressional-office-that-gingrich-killed-off-and-we-need-back/264160/.

[272] Bruce Bartlett, *Gingrich and the Destruction of Congressional Expertise*, N.Y. TIMES (Nov. 29, 2011), https://economix.blogs.nytimes.com/2011/11/29/gingrich-and-the-destruction-of-congressional-expertise/.

[273] Sadowski, *supra* note 271. Gingrich did not stop with the OTA. In 2011, he argued that the CBO is "a reactionary socialist institution which does not believe in economic growth." Charles Riley, *Gingrich: CBO a "Reactionary Socialist Institution*," CNN MONEY (Nov. 22, 2011), https://money.cnn.com/2011/11/21/news/economy/gingrich_cbo_socialism/index.htm. A former Republican CBO director responded simply that "I think if you parse that phrase carefully, he got one out of three right," noting that "I do agree it is an institution." *Id*.

[274] OFFICE OF TECH. ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS AND REWARDS, OTA-H-522 (Washington, DC: U.S. Government Printing Office, Feb. 1993).

[275] *Id*. at 2; *see also id*. at 24-25; 26-27.

The report also went on to note the converse, concluding that "[a] decline in expected revenues would reduce a drug's expected returns and would certainly cause R&D on some new drug products to be discontinued or reduced."[276] The report did not present recommendations for how to alter reimbursement rules in the United States to encourage more socially valuable information, but it did spend a full chapter on "trends in payment for prescription drugs," noting the ways in which other countries "reward 'breakthrough' drugs at a higher rate than 'me-too' drugs."[277].

To be sure, the type of OTA-like report envisioned here would be different than the type of analysis provided today by CBO or a MedPAC or MACPAC. OTA reports took considerable time to complete, and the Office did not always complete a requested analysis in time to provide pre-enactment information to legislators.[278] As a result, rather than providing Congress with pre-enactment analysis of any individual healthcare bill or proposal, OTA or an OTA-like entity could reprise its pharmaceutical report, thirty years later: analyzing the drug development process and exploring the ways in which different areas of law impact that process. A report that explicitly considered the ways in which health law and policy impact not just access but also innovation would provide important context for policymakers to apply to a broad range of bills that might be proposed, with the benefit of considering Part D, the ACA, and other developments. OTA reports were organized to provide policymakers with several possible policy options, and to discuss the pros and cons of each one.[279] This type of transparency and discussion of difficult tradeoffs within health policy would be important to the types of innovation and access discussions policymakers must have.

Of course, the most significant challenge to this argument is that the OTA was eliminated as part of a partisan anti-expertise campaign, and no longer exists. Many scholars and other experts have called for the Office to be reconstituted in some form, given the need for members of Congress to gather information about a wide range of technological areas essential to our modern economy.[280] But it is difficult to imagine this occurring any time soon, given

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[276] *Id*. at 31.
[277] *Id*. at 263.
[278] Leary, *supra* note 270.
[279] *Id*.; *see also* M. Granger Morgan, *Death By Congressional Ignorance: How the Congressional Office of Technology Assessment – Small and Excellent – was Killed in the Frenzy of Government Downsizing*, PITTSBURGH POST-GAZETTE (Aug. 2, 1995), https://www.princeton.edu/~ota/ns20/ota95_f.html.
[280] *See, e.g.*, Darrell M. West, *It Is Time to Restore the US Office of Technology Assessment*, BROOKINGS (Feb. 10, 2021), https://www.brookings.edu/research/it-is-time-to-restore-the-us-office-of-technology-assessment/; Celia Wexler, *Bring Back the Office of Technology Assessment*, N.Y. TIMES (May 28, 2015), https://www.nytimes.com/roomfordebate/2015/05/28/scientists-curbing-the-ethical-

the continued partisan dynamics over the role of experts in policymaking. As a result, an OTA-like report would need to be commissioned from another existing actor. One option would be to involve the Congressional Research Service (CRS), which provides policy and legal analysis to Congress.[281] But experts have argued that the CRS lacks the focus on technological issues that previously existed within the OTA.[282] A more promising possibility might be the Government Accountability Office (GAO), which in 2019 established a Science, Technology Assessment, and Analytics team to provide technology assessment services to Congress.[283] Though GAO's technology assessment experience is still nascent, it might be an option for policymakers wishing to obtain an OTA-like report about the pharmaceutical innovation process.

V. CONCLUSION

This Article identifies and explores important examples of laws where Congress appears to have made key innovation policy decisions "by accident," without knowledge of their potential implications. The analysis presented here has implications not only for existing debates over drug pricing reform, but also for the process of legislation going forward. Particularly where interest groups may be motivated to maintain incentives for asymmetric policymaking, it will be important for policymakers to take account of these dynamics over time. Future research ought to consider the ways in which additional stakeholders, such as administrative agencies, may be subject to similar constraints on their information-gathering abilities.

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use-of-science/bring-back-the-office-of-technology-assessment. *See also generally* Zach Graves & Daniel Schuman, *Science, Technology and Democracy: Building a Modern Congressional Technology Assessment Office*, ASH CENTER (Jan. 2020) (arguing for a system that would split technology assessment responsibilities between a revived OTA and the Government Accountability Office).

[281] See Cong. Res. Serv., About CRS (2021), https://www.loc.gov/crsinfo/about/.

[282] West, *supra* note 280.

[283] *See* Gov't Accountability Office, *Our New Science, Technology Assessment, and Analytics Team* (Jan. 29, 2019), https://blog.gao.gov/2019/01/29/our-new-science-technology-assessment-and-analytics-team/.