

INTEGRATING HEALTH INNOVATION POLICY

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I. INTRODUCTION

In the last few years, scientists have brought to market a series of incredible new pharmaceutical products for once-untreatable illnesses. These new gene therapies have the ability to alter a patient’s own genetic material to help treat their disease in a single session, rather than through a drug that a patient may take for the rest of their life. Already, patients with rare inherited blindness or children with spinal muscular atrophy are eligible to receive these newly approved pharmaceuticals.¹ One-time treatments for devastating conditions like hemophilia, sickle-cell disease, and other inherited conditions are expected to be approved in the next few years.²

Although these new products represent genuine scientific breakthroughs, they come with a price tag to match. The first such one-time product to come to market, Luxturna, treats a small number of patients with a particular genetic form of blindness for \$850,000.³ The second approved product, Zolgensma, a one-time treatment for children with spinal muscular atrophy, is the most expensive drug ever marketed, with a list price of \$2.1 million.⁴ These prices represent floors, not ceilings — companies are already publicly suggesting that future gene therapy products will launch at even higher prices.⁵

Several features of these new treatments give insurers pause as they decide whether and under what circumstances to provide coverage for these pharmaceuticals. First, the unpredictability of these expenditures, given the rarity of some of these conditions, means that some insurers will have patients who are eligible to receive these

1. Katie Thomas, *This New Treatment Could Save the Lives of Babies. But It Costs \$2.1 Million.*, N.Y. TIMES (May 24, 2019), <https://nyti.ms/2HSwDM3> [<https://perma.cc/3MBX-FCTN>].

2. Carl O’Donnell & Tamara Mathias, *Pfizer, Novartis Lead Pharma Spending Spree on Gene Therapy Products*, REUTERS (Nov. 27, 2019, 7:10 AM), <https://www.reuters.com/article/us-genetherapy-novartis/pfizer-novartis-lead-pharma-spending-spre-on-gene-therapy-production-idUSKBN1Y11DP> [<https://perma.cc/E8J3-B95H>].

3. Thomas, *supra* note 1.

4. *Id.*

5. See Jared S. Hopkins, *BioMarin Explores Pricing Experimental Gene Therapy at \$2 Million to \$3 Million*, WALL ST. J. (Jan. 16, 2020, 10:58 AM), <https://www.wsj.com/articles/biomarin-explores-pricing-experimental-gene-therapy-at-2-million-to-3-million-11579190318> [<https://perma.cc/H4YV-SC37>].

treatments, but others will not.⁶ As a result, insurers face actuarial risk problems in planning their expenditures. Second, the new treatments' high price tags can have a material impact on insurer spending, affecting budgeting as well as increasing patients' costs in the future. Third, particularly for state Medicaid programs, money spent on these pharmaceuticals is money that must be found elsewhere in the budget — money that cannot be spent on treatments for other patients, or on education or infrastructure.⁷

But another, more uniquely American dynamic also threatens patient access to these new treatments. In the United States, patients rotate on and off of different insurance plans frequently, a phenomenon referred to in the literature as “churn.”⁸ As a result, an insurer knows that in a few months' or years' time, their patients with costly rare diseases may enroll in another insurer's plan or may lose their coverage entirely. As a result, the insurer does not want to pay millions of dollars even for a highly cost-effective one-time treatment today, if the health benefits of that treatment will accrue to a future insurer.⁹ Insurers therefore have incentives to make it difficult for patients to access these new medications.

This fragmentation of health insurance, in which patients may move in and out of private insurance, Medicaid eligibility, and uninsurance before becoming eligible for Medicare, is just one example of the ways in which our health care system is fragmented. Patients may be treated by a range of specialists who coordinate poorly, if at all, meaning that patients may be subject to duplicative,

6. Insurers also do not know when these products will be approved by the Food and Drug Administration or what their prices will be, meaning that they cannot easily plan for the coverage of these products in any given plan year.

7. *See, e.g.*, PETER R. ORSZAG & THOMAS J. KANE, HIGHER EDUCATION SPENDING: THE ROLE OF MEDICAID AND THE BUSINESS CYCLE, BROOKINGS 3 (2003), <https://www.brookings.edu/research/higher-education-spending-the-role-of-medicaid-and-the-business-cycle/> [https://perma.cc/EN92-UDF4].

8. *See* PAMELA FARLEY SHORT ET AL., CHURN, CHURN, CHURN: HOW INSTABILITY OF HEALTH INSURANCE SHAPES AMERICA'S UNINSURED PROBLEM, COMMONWEALTH FUND (2003), https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2003_nov_churn_churn_churn_how_instability_of_health_insurance_shapes_americas_uninsured_problem_short_churn_688_pdf.pdf [https://perma.cc/HSV7-2Y8E].

9. In practice, these prices often outweigh the healthcare value provided by these treatments. *See* VORETIGENE NEPARVOVEC FOR BIALLELIC RPE65-MEDIATED RETINAL DISEASE: EFFECTIVENESS AND VALUE, INST. FOR CLINICAL & ECON. REV. 56, 60 (2018), http://icer.org/wpengine.com/wp-content/uploads/2020/10/MWCEPAC_VORETIGENE_FINAL_EVIDENCE_REPORT_02142018.pdf [https://perma.cc/YW2C-XYKP]. However, in some cases (such as with potential hemophilia gene therapies), a price in the millions of dollars may actually be cost-saving, given the extremely high rates of hospitalizations and complications for such patients. *See* VALOCTOCOGENE ROXAPARVOVEC AND EMICIZUMAB FOR HEMOPHILIA A WITHOUT INHIBITORS: EFFECTIVENESS AND VALUE, INST. FOR CLINICAL & ECON. REV. 70 (2020), https://icer.org/wp-content/uploads/2020/10/ICER_Hemophilia-A_Final-Report_112020.pdf [https://perma.cc/BQL4-CPXM].

wasteful tests. Health care delivery is fragmented between hospitals, ambulatory clinics, physicians' offices, and other settings, creating concerns about the financial motives of providers to offer care in particular types of settings. Electronic health record ("EHR") systems often cannot communicate with each other, potentially leading to adverse events for patients whose providers are not aware of all of their relevant health information.¹⁰

The existing health policy and legal literature has identified these problems of health care fragmentation and argued that they drive up costs, lower health care quality, and may harm patients.¹¹ Some of these forms of fragmentation may be justified by other benefits (such as physician specialization), and in those cases scholars and policymakers have proposed reforms that attempt to mitigate the potential harms of fragmentation but not to eliminate the fragmentation itself.¹² In other cases, scholars have argued that fragmentation has few if any redeeming qualities (such as for EHRs that cannot share information) and have proposed reforms that would eliminate the fragmentation entirely.¹³

Yet scholars have not recognized the impact of health care fragmentation on incentives for innovation into new health care technologies. This Article therefore makes two primary contributions. First, it identifies and describes two new forms of health care fragmentation that have not been articulated in the literature: *fragmentation by benefit structure* and *fragmentation by policymaker*. For instance, patients do not only move in and out of different insurance plans over time. Even within those plans, insurance is often fragmented by type of product and is delivered separately for medical services and for pharmaceuticals.

Second, this Article applies the overarching framework of fragmentation both to questions of health care cost and quality and also to questions of innovation policy. The above-described *fragmentation over time*, as patients move in and out of different insurance plans, certainly does impact patients' access to care. But in so doing, it also impacts pharmaceutical companies' incentives to bring new drugs to market. In practice, insurance reimbursement

10. See *infra* text accompanying Section II.A for a more detailed explanation of these phenomena.

11. See, e.g., Einer Elhauge, *Why We Should Care About Health Care Fragmentation and How to Fix It*, in *THE FRAGMENTATION OF HEALTH CARE: CAUSES AND SOLUTIONS* 1, 2 (Einer Elhauge ed., Oxford Univ. Press 2009).

12. See, e.g., Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3022, 124 Stat. 119, 395-99 (2010).

13. See, e.g., Title XIII (Health Information Technology for Economic and Clinical Health Act, "HITECH") of the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115, 226-79 (codified in scattered sections of 42 U.S.C.); Karen Davis et al., *Medicare Essential: An Option to Promote Better Care and Curb Spending Growth*, 32 HEALTH AFFS. 900, 901 (2013).

functions to reward innovator firms for their discoveries. As a result, insurer decisions to provide reimbursement for a class of technologies expand the potential returns for companies in that area and drive research and development investment. By contrast, when an insurer aims to avoid covering a new class of products, that decision decreases potential returns and incentives to innovate in that class. When combined with fragmentation, this dynamic introduces a problematic incentive into our health care system, in which private market signals may distort innovative activity away from a class of therapies that would be highly socially valuable. Similarly, fragmentation by benefit structure and by policymaker have impacts on companies' innovation-related decisions.

Although these three forms of fragmentation — over time, by benefit structure, and by policymaker — all play out in different practical ways, their impacts on innovation incentives share a core deficiency. In each case, a particular actor (typically an insurer) would bear all the costs of making a particular coverage decision, but would reap few if any of the benefits. Those externalities would redound to other actors, including future insurers. As such, because these actors cannot internalize both the full costs and benefits of providing access to certain types of therapies, they will provide less access to those therapies relative to what might be socially advantageous, discouraging companies from investing in those kinds of products.

This Article proceeds in five Parts. Part II defines the concept of fragmentation and provides examples of the ways in which the concept has been deployed to describe a range of circumstances throughout our health care system. Many of these examples of fragmentation are explicit creatures of law, but others are driven more by economic incentives that arise under our existing legal and policy structures. Part II also details the impacts that the literature has previously identified as resulting from fragmentation, in terms of health care costs, quality, and patient outcomes.

Parts III, IV, and V examine particular forms of fragmentation in detail and articulate the impacts they are likely to have on pharmaceutical innovation. Part III begins with the above-described fragmentation over time, in which patients cycle on and off of different insurance programs (and may even lose insurance entirely), in a way that discourages insurers from providing coverage for certain products or services. Although the existing literature has previously identified the phenomenon of fragmentation over time, scholars have not considered the ways in which this form of fragmentation may create challenges for innovation policy. Because fragmentation over time encourages insurers to delay providing one-time treatments or preventive care, in hopes that an insured patient may soon become

another insurer's financial responsibility, it may discourage the development of those types of products.

Parts IV and V consider forms of fragmentation that have not been articulated in the literature, but that come into view when fragmentation is examined through an innovation policy lens. Part IV considers fragmentation by benefit structure, in which an insurer separates out the different benefits they offer (most commonly separating medical services from pharmaceuticals), in a way that alters insurers' incentives for coverage and consumption across the different benefits. Examples of this type of benefit structure fragmentation may be found in Medicare, Medicaid, and private insurance. Part IV then explains why this fragmentation is problematic for innovation policy, as it discourages or even prevents insurers from considering the relative benefits of pharmaceutical versus non-pharmaceutical treatment.

Part V presents the case of fragmentation in health care policymaking, which occurs when the relevant policymakers (both in Congress and at the federal agency level) each have only partial jurisdiction over a particular issue or have overlapping jurisdiction. In either case, the relevant policy actors may not internalize the costs and benefits of various courses of action, given their particular view of a problem, and high transaction costs functionally prohibit joint policymaking. Understanding this form of fragmentation reveals not only how our health care system came to take its current form but also why policy change is so difficult in this area. Fragmentation in policymaking also has impacts on innovation policy, as the dispersion of responsibility between different policymakers makes it difficult for any one actor to consider and address problems holistically.

Part VI identifies potential reforms to address these innovation-related biases caused by fragmentation. First, it argues that these biases represent a problem to be solved, given the costs of fragmentation and lack of offsetting benefits. Second, it articulates potential solutions at different levels of generality. Importantly, many of these proposals have the potential to address not only innovation policy concerns but also the more traditional cost and quality concerns expressed by scholars regarding health care fragmentation more generally. Using an innovation framework also helps explain why scholars' existing proposals for legal reforms to already-discussed problems of fragmentation are unlikely to fully address these problems of innovation incentives.

II. CONCEPTUALIZING FRAGMENTATION IN HEALTH LAW

The concept of fragmentation has been discussed throughout the literature in both health law and health policy.¹⁴ Legal scholars have considered the ways in which laws and policies both create and perpetuate fragmentation in health care,¹⁵ and public policy scholars have also attempted to quantify the effects of fragmentation on a range of dimensions, particularly including health care costs, quality, and patient outcomes.¹⁶ This Part aims to define the scope of fragmentation and articulate its role in the literature. First, this Part presents a common definition of fragmentation and illustrates the range of contexts within the health care system in which that definition has been both discussed and largely ignored. Second, this Part explains the impacts that fragmentation can have on health care costs, quality, and outcomes, as it has been studied so far.

A. Defining the Scope of Fragmentation

Scholars and policymakers often bemoan the highly fragmented nature of our health care system, by which they typically mean that our situation involves “multiple decision makers mak[ing] a set of health care decisions that would be made better through unified decision making.”¹⁷ When defined and used in this way, fragmentation is generally a pejorative term with a negative connotation. Fragmentation is not a desirable arrangement, in other words, and it has harmful consequences for our health care system. As a corollary, it would be “better” in certain ways to achieve a higher

14. The literature here is extensive, particularly in the health policy space. Important works in the legal literature include THE FRAGMENTATION OF HEALTH CARE: CAUSES AND SOLUTIONS (Einer Elhauge ed., Oxford Univ. Press 2009), Abbe R. Gluck & Nicole Huberfeld, *What Is Federalism in Healthcare For?*, 70 STAN. L. REV. 1689 (2018), and Ani B. Satz, *Fragmentation After Health Care Reform*, 15 HOUS. J. HEALTH L. & POL’Y 173 (2015). Key works in the policy literature include STEPHEN M. SHORTELL, ROBIN R. GILLIES, DAVID A. ANDERSON, KAREN M. ERICKSON & JOHN B. MITCHELL, REMAKING HEALTH CARE IN AMERICA: BUILDING ORGANIZED DELIVERY SYSTEMS (1996), and Benjamin D. Sommers & Sara Rosenbaum, *Issues in Health Reform: How Changes in Eligibility May Move Millions Back and Forth Between Medicaid and Insurance Exchanges*, 30 HEALTH AFFS. 228 (2011).

15. See generally Satz, *supra* note 14; Gluck & Huberfeld, *supra* note 14.

16. See, e.g., David U. Himmelstein et al., *Health Care Administrative Costs in the United States and Canada, 2017*, ANNALS OF INTERNAL MED. 134, 134 (2020); Justin J.J. Watson et al., *A Statewide Teleradiology System Reduces Radiation Exposure and Charges in Transferred Trauma Patients*, 211 AM. J. SURGERY 908, 908 (2016).

17. Elhauge, *supra* note 11, at 1. This definition has been cited by other legal scholars writing in this field. See, e.g., Ani B. Satz, *Overcoming Fragmentation in Disability and Health Law*, 60 EMORY L.J. 277, 300 (2010); Nicole Huberfeld, *The Universality of Medicaid at Fifty*, 15 YALE J. HEALTH POL’Y L. & ETHICS 67, 67 (2015).

level of integration overall.¹⁸ Importantly, though, some (but not all) forms of fragmentation have offsetting benefits. Identifying these forms of fragmentation and differentiating them from less salutary instances is one of the challenges faced in the literature.

This general, broad definition can be applied to a range of different circumstances within our health care system, from the smallest to the largest setting. Articulating a few of these examples helps illustrate the breadth of the fragmentation issue, as well as the potential challenges in resolving the resulting patient care problems. For instance, fragmentation at the level of a particular *patient* may occur when a patient sees different specialists for different illnesses. The average Medicare beneficiary sees two primary care physicians and five specialists in any given year, and many patients see far more.¹⁹ This type of specialization may increase the quality of patients' care if physicians develop deeper understandings of particular conditions, but it may also impose harms on patients, if these different providers fail to coordinate amongst themselves. A patient may be misdiagnosed, may suffer an adverse event that could have been avoided if a provider had been able to take full account of information possessed by other specialists,²⁰ or may simply face additional time and administrative burdens as they need to provide their health history anew with each additional physician they encounter.²¹

Abstracting up from the level of the patient, fragmentation at the level of *organizational structure* may create different incentives for various types of health care delivery organizations to provide care to patients.²² Physician groups, hospitals, ambulatory surgical centers, retail clinics, pharmacies, and other types of provider organizations may process these incentives quite differently. For instance,

18. Importantly, scholars do not typically advance an optimal theory of integration directing policymakers to the point at which integration may cease to be beneficial. Cf. Elhauge, *supra* note 11, at 3. However, when scholars consider the real-world costs and harms to patients of fragmentation, and the legal and economic structures that lead to these harms, it is difficult to believe that our system as it exists today is optimal. As such, most scholars argue that it would be a positive development to encourage more integration in our system, even if they have different views about how far to go along that spectrum. I return to this question *infra*, in Part VI.

19. Hoangmai H. Pham et al., *Care Patterns in Medicare and Their Implications for Pay for Performance*, 356 NEW ENG. J. MED. 1130, 1130 (2007).

20. See, e.g., INST. OF MED., *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* 4 (National Academies Press 2001); Alain Enthoven, *Curing Fragmentation with Integrated Delivery Systems*, in *THE FRAGMENTATION OF HEALTH CARE: CAUSES AND SOLUTIONS*, *supra* note 11 at 61, 62.

21. See Mark A. Hall & Kevin A. Schulman, *Property, Privacy, and the Pursuit of Integrated Electronic Medical Records*, in *THE FRAGMENTATION OF HEALTH CARE: CAUSES AND SOLUTIONS*, *supra* note 11 at 165, 165.

22. See Kristin Madison, *Defragmenting Health Care Delivery Through Quality Reporting*, in *THE FRAGMENTATION OF HEALTH CARE: CAUSES AND SOLUTIONS*, *supra* note 11 at 87, 87–88.

physicians may prefer to perform common surgical procedures such as colonoscopies or cataract removals at ambulatory surgical centers,²³ because these centers may provide a cheaper option than a hospital for non-emergency procedures.²⁴ However, they may also come with a conflict of interest, as these centers are often owned by the physicians themselves, who then profit from performing additional procedures there rather than in a hospital.²⁵

Even more abstractly, fragmentation over *time* as patients move in and out of different insurance plans may encourage insurers to delay or avoid providing preventive care if the benefits of that care would accrue to other payers in the future.²⁶ People may move into and out of public insurance programs as they become eligible for Medicaid and Medicare throughout their life, and they may move between private insurers if they change jobs or if their employer changes their insurance offerings.²⁷ Because insurers know that their beneficiaries may soon be the responsibility of other insurers, their incentives to pay for preventive care now are limited, when future insurers would recoup any savings from that care. Such care may be highly socially valuable, however, and may even have positive societal externalities.²⁸

Other, related forms of fragmentation may occur alongside forms like these and exacerbate their potential negative consequences. For instance, fragmentation in EHR platforms across physician practices, institutions, or payers may make communication across those groups difficult or even impossible. As a result, it may be more challenging for physicians to deliver medically appropriate care, and patients may experience negative health consequences. Even if care is delivered appropriately, patients may endure needless administrative hassles, including not only the above-mentioned need to repeatedly provide their health history to new providers but also the need to transfer their records between providers, including using technologies that are not commonly accessible (such as a fax machine).²⁹

23. See MEDICARE PAYMENT ADVISORY COMM'N REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 137 (Mar. 2019), http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch5_sec.pdf?sfvrsn=0 [https://perma.cc/M54B-W7MF] [hereinafter MEDPAC].

24. See *id.* at 130; Brent K. Hollenbeck et al., *Ambulatory Surgery Centers and Their Intended Effects on Outpatient Surgery*, 50 HEALTH SERVS. RSCH. 1491, 1491–92 (2015).

25. See MEDPAC, *supra* note 23, at 129; Hollenbeck et al., *supra* note 24, at 1492.

26. See Elhauge, *supra* note 11, at 1. I take up the question of fragmentation over time in more detail in Part III.

27. See generally Sommers & Rosenbaum, *supra* note 14.

28. See, e.g., Michael Kremer & Christopher M. Snyder, *Preventives Versus Treatments*, 130 Q.J. ECON. 1167, 1172 (2015).

29. Sarah Kliff, *The Fax of Life: Why American Medicine Still Runs on Fax Machines*, VOX (Jan. 12, 2018, 3:53 PM), <https://www.vox.com/health-care/2017/10/30/16228054/american-medical-system-fax-machines-why> [https://perma.cc/JV6Z-WHN9].

Scholars and policymakers have also considered how law might help solve each of these problems individually. In particular, the Affordable Care Act (“ACA”) and related legislation took steps to address many of the above forms of fragmentation. Most importantly, the ACA aimed to achieve near-universal coverage by expanding Medicaid and private insurance to prevent Americans from churning into uninsurance.³⁰ The ACA also encouraged the development of Accountable Care Organizations³¹ in an effort to promote care coordination among the many physicians who may treat a single patient.³² The ACA not only required that insurers cover certain preventive services, but also required that they do so with no cost-sharing to the patient.³³ And the 2009 Health Information Technology for Economic and Clinical Health (“HITECH”) Act aimed to promote the meaningful use of interoperable EHRs,³⁴ although much progress remains to be made in this area.³⁵

Although the existing literature has considered several different types of fragmentation, the framing of the definition means that the literature has also left other types of fragmentation out of the discussion. In the following Parts, this Article takes up two forms of fragmentation that have not been discussed in the legal literature — fragmentation by benefit structure, and fragmentation by policymaker. It is not obvious why these structural forms have been absent from the fragmentation discussion, but one possibility is that they have been considered to be parts of other strands of legal scholarship — perhaps

30. Allison K. Hoffman, *Three Models of Health Insurance: The Conceptual Pluralism of the Patient Protection and Affordable Care Act*, 159 U. PA. L. REV. 1873, 1886, 1920 (2011).

31. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3022, 124 Stat. 119, 395 (2010).

32. See Nicholas Bagley, *Bedside Bureaucrats: Why Medicare Reform Hasn't Worked*, 101 GEO. L.J. 519, 574–77 (2013).

33. See, e.g., Tom Baker, *Health Insurance, Risk, and Responsibility After the Patient Protection and Affordable Care Act*, 159 U. PA. L. REV. 1577, 1602–03 (2011); PREVENTIVE SERVICES COVERED BY PRIVATE HEALTH PLANS UNDER THE AFFORDABLE CARE ACT, KAISER FAM. FOUND. (2015), <https://kff.org/health-reform/fact-sheet/preventive-services-covered-by-private-health-plans/> [https://perma.cc/PLW4-UHD3].

34. Nicolas P. Terry, *Certification and Meaningful Use: Reframing Adoption of Electronic Health Records as a Quality Imperative*, 8 IND. HEALTH L. REV. 43, 46–48 (2011); Rebecca S. Eisenberg & W. Nicholson Price, II, *Promoting Healthcare Innovation on the Demand Side*, 4 J.L. & BIOSCIENCES 3, 39–41 (2017); David Blumenthal, *Launching HITECH*, 362 NEW ENG. J. MED. 382, 382 (2010).

35. See, e.g., Michael F. Furukawa et al., *Despite Substantial Progress in EHR Adoption, Health Information Exchange and Patient Engagement Remain Low in Office Settings*, 33 HEALTH AFFS. 1672, 1672 (2014).

federalism for the former,³⁶ and administrative law and legislation for the latter³⁷ — rather than the fragmentation discussion.

B. Assessing the Impacts of Fragmentation

The existing literature has examined the effects of different types of fragmentation on health care costs, quality, and patient outcomes. This Part briefly summarizes some of this voluminous literature, explaining how fragmentation can often drive up costs, lower quality, and negatively impact patient outcomes. Because there are so many different types of fragmentation, each of these results may occur to different degrees and in different ways, depending on the type of fragmentation at issue.

For instance, different types of fragmentation may drive up costs in different ways. Fragmentation at the level of the patient or in EHRs may lead physicians to perform repeated diagnostic tests, if they cannot communicate with other physicians to see if the tests have already been done or cannot obtain the results of previous tests that have been done.³⁸ The fragmentation of insurance plans drives up administrative costs in our health care system, as provider networks must retain the infrastructure to communicate with and bill many different insurers, all with different reimbursement structures.³⁹ These costs are far higher than the costs borne by other developed nations, even those with mixed public and private insurance systems.⁴⁰

Fragmentation also impacts health care quality. Primarily because of the dynamics around fragmentation over time, as articulated above, insurers' incentives to provide not only preventive care but also maintenance care for many chronic conditions may be decreased if resulting complications would be borne by a future insurer. In part

36. See, e.g., Abbe R. Gluck, *Intrastatutory Federalism and Statutory Interpretation: State Implementation of Federal Law in Health Reform and Beyond*, 121 YALE L.J. 534, 583 (2011); Theodore W. Ruger, *Of Icebergs and Glaciers: The Submerged Constitution of American Healthcare*, 75 L. & CONTEMP. PROBS. 215, 216 (2012).

37. See, e.g., Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131, 1134 (2012); Jennifer Nou, *Intra-Agency Coordination*, 129 HARV. L. REV. 421, 422 (2015); Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1, 21 (2008).

38. See, e.g., Bridget A. Stewart et al., *A Preliminary Look at Duplicate Testing Associated with Lack of Electronic Health Record Interoperability for Transferred Patients*, 17 J. AM. MED. INFORMATICS ASS'N 341, 342 (2010); David A. Hyman, *Health Care Fragmentation: We Get What We Pay For*, in THE FRAGMENTATION OF HEALTH CARE: CAUSES AND SOLUTIONS, *supra* note 11, at 21, 23.

39. See, e.g., Himmelstein et al., *supra* note 16, at 134; Steffie Woolhandler et al., *Costs of Health Care Administration in the United States and Canada*, 349 NEW ENG. J. MED. 768, 768 (2003); KAREN DAVIS ET AL., SLOWING THE GROWTH OF U.S. HEALTH CARE EXPENDITURES: WHAT ARE THE OPTIONS?, COMMONWEALTH FUND 4 (Jan. 2007).

40. DAVIS ET AL., *supra* note 39, at 4–5; see also Himmelstein et al., *supra* note 16, at 134; Woolhandler et al., *supra* note 39, at 768.

reflecting these incentives, adults with chronic illnesses (such as diabetes, heart disease, and high blood pressure) receive just half of the chronic care recommended by clinical guidelines.⁴¹ By contrast, Medicare beneficiaries enrolled in insurance plans that have special financial incentives to provide higher quality care are more likely to receive appropriate chronic care or preventive services (such as breast cancer screening and cholesterol testing) than are beneficiaries enrolled in plans without such incentives.⁴²

Fragmentation may also negatively impact patient outcomes. The more physicians treating a Medicare patient after a heart attack, the less likely the patient is to be alive at one year after the event, and the more expensive the care episode (even after controlling for factors including case severity).⁴³ Another study found that veterans who receive care through both the Department of Veterans Affairs and Medicare are at higher risk of death from prescription opioid overdose than veterans who receive care through either system exclusively.⁴⁴

There are also complex interactions between these different metrics. In some cases, fragmentation may *lower* costs — but may simultaneously impose at least some negative impacts on quality. For instance, at least some insurance plans manage mental health benefits separately from other health care services.⁴⁵ The resulting incentive is for plans to minimize provision of mental health services.⁴⁶ Although this may drive down mental health service costs temporarily, it may also externalize costs onto other health care services⁴⁷ (such as if patients become more likely to visit the emergency room), and the negative health impact on patients who are unable to receive the mental health care they need may be substantial.

The existing literature on forms of fragmentation and the effects thereof has considered a broad range of circumstances. However, it still leaves out many different forms of fragmentation, two of which are taken up in Parts IV and V of this Article. Further, even for the types of fragmentation where their effects have been carefully

41. See, e.g., Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 *NEW ENG. J. MED.* 2635, 2641 (2003).

42. John Z. Ayanian et al., *Medicare Beneficiaries More Likely to Receive Appropriate Ambulatory Services in HMOs than in Traditional Medicare*, 32 *HEALTH AFFS.* 1228, 1234 (2013).

43. Jonathan S. Skinner et al., *Is Technological Change in Medicine Always Worth It? The Case of Acute Myocardial Infarction*, 25 *HEALTH AFFS.* 34, 42–43 (2006).

44. See Patience Moyo et al., *Dual Receipt of Prescription Opioids from the Department of Veterans Affairs and Medicare Part D and Prescription Opioid Overdose Death Among Veterans: A Nested Case-Control Study*, 170 *ANNALS OF INTERNAL MED.* 433, 433 (2019).

45. Barak Richman et al., *Fragmentation in Mental Health Benefits and Services: A Preliminary Examination into Consumption and Outcomes*, in *THE FRAGMENTATION OF HEALTH CARE: CAUSES AND SOLUTIONS*, *supra* note 11, at 279, 280.

46. See *id.*

47. See *id.*

examined (as with fragmentation over time, for instance), scholars have largely considered the impact of fragmentation on patient care (in terms of quality and outcomes) and systemwide costs. Scholars have not considered the impact of fragmentation on pharmaceutical innovation, and the kinds of therapies that different forms of fragmentation encourage and discourage scientists from pursuing. This Article takes up that question as it applies to both new and already-considered forms of fragmentation.

III. FRAGMENTATION OVER TIME

Fragmentation over time has already received significant attention in the policy literature. This form of fragmentation occurs as people churn on and off of different insurance programs (or even insurance at all) over time, in a way that discourages many insurers from providing coverage for certain products or services. Churn often affects patients' ability to obtain care,⁴⁸ particularly when it is driven by changes in income or eligibility for certain programs (such as a new mother who loses her Medicaid coverage just sixty days after the birth of her child⁴⁹ but who may have difficulty affording private insurance). The frequency of churn encourages insurers to attempt to delay paying for an expensive product or procedure until the patient becomes a beneficiary of a different insurer, creating challenges for patient access especially in particular therapeutic areas.

This Part considers two examples of fragmentation over time: the general fragmentation of our health insurance structures, in which patients transition into and out of Medicare, Medicaid, and employer-sponsored coverage on the basis of age, income, and status, as well as specific illustrations of the challenges posed by this fragmentation for access to new pharmaceuticals. This Part then explains how fragmentation over time creates challenges for innovation incentives. Because fragmentation encourages insurers to delay providing care particularly for certain kinds of products in the hopes that an insured patient will be someone else's financial responsibility in the near future, it may discourage the development of those types of products.

48. See, e.g., Sommers & Rosenbaum, *supra* note 14, at 228; Nicole Huberfeld & Jessica L. Roberts, *Health Care and the Myth of Self-Reliance*, 57 B.C. L. REV. 1, 42–43 (2016).

49. 42 U.S.C. § 1396a(e)(5); Kathy Gifford et al., *Medicaid Coverage of Pregnancy and Perinatal Benefits: Results from a State Survey*, KAISER FAM. FOUND. (Apr. 2017), <https://www.kff.org/report-section/medicaid-coverage-of-pregnancy-and-perinatal-benefits-introduction/> [<https://perma.cc/59DE-TV23>].

A. Examples of Time-Based Fragmentation

The two examples of fragmentation considered in this Part illustrate the general structure of fragmentation over time as well as a particular example of how this fragmentation can impede access to care. These two examples help demonstrate the interaction between legal doctrine and economic incentives. Fragmentation over time is generally created by law — statutes and regulations govern who is eligible to access different forms of insurance at different times in their lives. The churn resulting from this fragmentation, though, then creates economic incentives for insurers, particularly to discourage patients' access to care. Changing these legal and policy levers can be expected to alter these economic incentives.

1. Fragmentation in Insurance Structure

Fragmentation in the structure of the insurance market is a long-standing feature of the U.S. health insurance system. Most Americans receive their insurance through one of three primary insurance programs: Medicare, intended to provide a universal coverage program for Americans over the age of 65;⁵⁰ Medicaid, providing safety net coverage to a broad coalition of patients;⁵¹ and private insurance, largely delivered through employer-sponsored plans.⁵² Yet

50. PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 368–70 (1982). Medicare does cover additional populations today. For instance, it has been expanded to cover certain categories of younger Americans with long-term disabilities. Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1329, 1371. Unlike Medicaid, Medicare is entirely federally run. See Ruger, *supra* note 36, at 220.

51. Although Medicaid was enacted simultaneously with Medicare in 1965, see STARR, *supra* note 50, at 369–70, the program has a different organizational structure and a different focus. Medicaid is organized as a classic cooperative federalism program, with joint administration between the federal government and the states. Gluck, *supra* note 36, at 562. Unlike Medicare, whose eligibility requirements and benefits provided remain consistent across the country, each state's Medicaid program differs in its implementation. See *id.* at 563; see also Public Welfare Amendments of 1962, Pub. L. No. 87-543, tit. I, sec. 122, tit. XI, § 1115, 76 Stat. 172, 192 (1962) (codified as amended at 42 U.S.C. §§ 1301–1314 (1988)) (providing for section 1115 waivers). Medicaid also covers a more diffuse group of Americans, unlike Medicare's universal coverage program for seniors. Medicaid was initially designed to provide health care for the “deserving poor,” David Orentlicher, *Medicaid at 50: No Longer Limited to the “Deserving” Poor?*, 15 *YALE J. HEALTH POL'Y L. & ETHICS* 185, 185–86 (2015), including children, pregnant women, parents of minor children, and elderly and disabled individuals, Nicole Huberfeld, *The Universality of Medicaid at Fifty*, 15 *YALE J. HEALTH POL'Y L. & ETHICS* 67, 70 (2015). The Affordable Care Act (ACA) attempted to expand Medicaid to all Americans below 138% of the poverty line, see *id.* at 69 n.9, 70 n.14, but the Supreme Court rendered this expansion optional for states, Gillian E. Metzger, *To Tax, To Spend, To Regulate*, 126 *HARV. L. REV.* 83, 108 (2012).

52. See, e.g., *Health Insurance Coverage of the Total Population*, KAISER FAM. FOUND. (2018), <https://www.kff.org/other/state-indicator/total-population/> [<https://perma.cc/NMZ7->

millions of patients each year transition in and out of these programs, or even in and out of plans within one of these programs. Twelve percent of the roughly 150 million people with employer-sponsored insurance (or nearly twenty million people) change coverage each year, a figure that rises to 43% of the 65 million people enrolled in Medicaid as of 2019.⁵³

Transitions out of Medicaid are not only common, but are likely to be particularly disruptive from an access-to-care perspective. Consider the fact that Medicaid covers roughly half of all births in the United States,⁵⁴ but pregnant women lose guaranteed Medicaid coverage at just sixty days postpartum.⁵⁵ After sixty days, if a woman cannot requalify for Medicaid or obtain private insurance, she may become uninsured. Particularly in states that have not expanded Medicaid under the ACA, an income of as little as a few thousand dollars a year may disqualify someone from Medicaid, but is clearly insufficient to support the purchase of private insurance.⁵⁶ It is no wonder that, prior to the passage of the ACA, 55% of pregnant women with Medicaid coverage became uninsured within six months after delivery⁵⁷ — a figure which remains high today in non-expansion states.⁵⁸ This churn may have severe health consequences, as women continue to suffer and even die from pregnancy-related complications for many months after delivery.⁵⁹

2V49] (noting that 49% of Americans receive insurance from their employers, 20% are insured through Medicaid, and 14% through Medicare).

53. See *id.*; Benjamin D. Sommers et al., *Insurance Churning Rates for Low-Income Adults Under Health Reform: Lower Than Expected But Still Harmful for Many*, 35 HEALTH AFFS. 1816, 1817 (2016).

54. Joyce A. Martin et al., *Births in the United States, 2017*, NAT'L CTR. FOR HEALTH STAT. (Aug. 2018), <https://www.cdc.gov/nchs/data/databriefs/db318.pdf> [<https://perma.cc/UG88-PDKC>]; Alison Kodjak, *From Birth to Death, Medicaid Affects the Lives of Millions*, NPR (June 27, 2017, 5:01 AM), <https://www.npr.org/sections/health-shots/2017/06/27/534436521/from-birth-to-death-medicaid-affects-the-lives-of-millions> [<https://perma.cc/2UBL-UJZ2>].

55. 42 U.S.C. § 1396a(e)(5); Jamie R. Daw et al., *Women in the United States Experience High Rates of Coverage “Churn” in Months Before and After Childbirth*, 36 HEALTH AFFS. 598, 598 (2017).

56. In Texas, an eligibility limit at 17% of \$21,720, the federal poverty level, for a family would disqualify a family with an income of \$3,692. See Tricia Brooks et al., *Medicaid and CHIP Eligibility, Enrollment, and Cost Sharing Policies as of January 2020: Findings from a 50-State Survey*, KAISER FAM. FOUND., at 2, 10 (Mar. 26, 2020) <https://www.kff.org/medicaid/fact-sheet/where-are-states-today-medicaid-and-chip> [<https://perma.cc/L7V7-CJQ6>].

57. Daw et al., *supra* note 55, at 601.

58. Jamie R. Daw et al., *High Rates of Perinatal Insurance Churn Persist After the ACA*, HEALTH AFFS. BLOG (Sept. 16, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190913.387157/full/> [<https://perma.cc/LS2K-AYXJ>].

59. Emily E. Petersen et al., *Vital Signs: Pregnancy-Related Deaths, United States, 2011–2015, and Strategies for Prevention, 13 States, 2013–2017*, 68 MORBIDITY & MORTALITY WKLY. REP. 423, 425 (May 2019) (noting that 11.7% of deaths occurred more than 42 days postpartum).

Transitions out of Medicaid can also occur for a variety of other reasons. Children may age out of their Medicaid coverage at eighteen or twenty-one,⁶⁰ even if they have not secured replacement insurance. Beneficiaries, particularly those with unstable incomes, may find themselves moving in and out of Medicaid's income eligibility limits over a year.⁶¹ Most challengingly, patients who lose their Medicaid eligibility often do not obtain other forms of insurance,⁶² and as such, patients losing their Medicaid coverage are likely to lose their access to care in general.

Transitions in and out of employer-sponsored plans are perhaps the most frequent transition observed, but their ability to disrupt patient care varies significantly by the type of transition observed.⁶³ Patients who transition between employers may experience an insurance disruption that is logistically complex, and they may need to select different care providers, but they are more likely to retain roughly equivalent access to care.⁶⁴ However, people who lose their jobs and the insurance that comes with it may find it challenging to obtain replacement insurance coverage, as with people who transition out of Medicaid.

Finally, age-based transitions into Medicare may be the least disruptive in terms of patient access, and in fact are likely to *promote* access to care. Patients who become eligible for Medicare coverage find it easier to afford their medications than patients who have not yet turned sixty-five.⁶⁵ Other studies show that patients may undergo particular procedures or access particular services (including preventive services like mammograms⁶⁶ as well as procedures which are unlikely to be emergencies, such as hip and knee replacements⁶⁷) more frequently after turning 65, suggesting that access to Medicare

60. The age at which this transition occurs depends on the state. *See, e.g.*, Short, *supra* note 8, at 6; *What Is the Medicaid Program?*, U.S. DEP'T OF HEALTH AND HUMAN SERVS. (Feb. 12, 2014), <https://www.hhs.gov/answers/medicare-and-medicaid/what-is-the-medicaid-program/index.html> [<https://perma.cc/4S8N-WRND>].

61. Short, *supra* note 8, at 7.

62. *Id.* at 2 (“[T]wo-thirds of those leaving Medicaid or other public insurance programs became uninsured.”).

63. *See* Sommers et al., *supra* note 53, at 1817, 1820.

64. *Id.*

65. *See* Robin A. Cohen & Maria A. Villarroel, *Strategies Used by Adults to Reduce Their Prescription Drug Costs: United States, 2013*, NCHS DATA BRIEF NO. 184, at 1 (Jan. 2015), <https://www.cdc.gov/nchs/data/databriefs/db184.pdf> [<https://perma.cc/YD48-2NXX>]. Of course, Medicare is itself internally fragmented between drug and non-drug coverage, as discussed *infra* in Part IV.

66. Sandra Decker & Carol Rapaport, *Medicare and Disparities in Women's Health 1*, (Nat'l Bureau of Econ. Rsch., Working Paper No. 8761, 2002) (“[T]urning 65 significantly increases the chance that a black woman, especially a less educated black woman, has had a mammogram.”).

67. *See* David Card, Carlos Dobkin & Nicole Maestas, *The Impact of Nearly Universal Insurance Coverage on Health Care Utilization: Evidence from Medicare*, 98 AM. ECON. REV. 2242, 2243, 2252 (2008).

has enabled them to do so. The fact that Medicare provides coverage to many who may otherwise be uninsured or underinsured also creates incentives for *patients* to avoid or postpone care until they obtain access to Medicare. In other words, because patients can only transition *into* Medicare (and not out of it), they do not experience the same kind of coverage disruptions as patients receiving other forms of insurance. Patients may still move between Medicare plans over the course of their Medicare eligibility, but they cannot lose their insurance entirely.

Patient churn — between different forms of insurance and between insurance and the lack thereof — affects not only patients' access to care, but also their insurers' incentives to provide that care. If the average patient is only on a particular insurance plan for a few years, an insurer may attempt to ration care by discouraging a patient from obtaining a particularly costly procedure or product until the patient becomes a beneficiary of another plan.⁶⁸ If the insurer can delay the patient's access for long enough, the insurer may indeed save money, as they did not have to provide reimbursement for the expensive service or product. This rationing may have harmful consequences for patient care, particularly if a patient's condition worsens while they fight for access to the service in question.⁶⁹

2. Time-Based Fragmentation's Impact on Access to Treatments

An insurer's incentives to delay care may be particularly acute in the context of costly, one-time treatments or cures. Consider the new generation of cures for Hepatitis C, of which Gilead's Sovaldi has likely received the most public attention.⁷⁰ These cures were a true advance over the standard of care: rather than the previous treatment regimen, which required nearly a year of intravenous treatment, had serious side effects, and even then often failed to work, patients could now take a pill for a much shorter time and have a far greater chance

68. See generally Bradley Herring, *Suboptimal Provision of Preventive Healthcare Due to Expected Enrollee Turnover Among Private Insurers*, 19 HEALTH ECON. 438 (2010).

69. For instance, studies suggest that patients who are uninsured or who have Medicaid are diagnosed with cancer at later stages than are privately insured patients. See generally Michael T. Halpern et al., *Association of Insurance Status and Ethnicity with Cancer Stage at Diagnosis for 12 Cancer Sites: A Retrospective Analysis*, 9 LANCET ONCOLOGY 222 (2008).

70. The anger over the high price of Sovaldi was so great that the Senate Finance Committee conducted an investigation into its pricing. See generally U.S. SENATE COMM. ON FIN., *THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM* (2015), [https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20\(Full%20Report\).pdf](https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf) [https://perma.cc/CA76-8W7J].

of being cured.⁷¹ The health care community and the public in general could have responded by praising Gilead for developing a drug that not only improved on existing treatments, but that cured a chronic disease that is particularly prevalent among low-income and marginalized Americans.⁷²

However, Sovaldi's price resulted in a different outcome. Sovaldi came with a list price of \$84,000 per treatment course.⁷³ The sheer number of patients with Hepatitis C rendered the overall budgetary impact of paying for Sovaldi unsustainable.⁷⁴ As a result, access to this class of drugs was rationed. State Medicaid programs in particular rationed access by explicitly restricting treatment to patients with the most advanced disease, a restriction which was not medically indicated.⁷⁵

This rationing was encouraged not only by state Medicaid programs' inability to absorb the cost of Sovaldi in the near term,⁷⁶ but also by the existence of fragmentation over time. Sovaldi may be cost-effective, and it likely helps the health care system avoid some of the costliest complications of Hepatitis C.⁷⁷ However, due to the relative frequency of churn within the Medicaid program,⁷⁸ these benefits would likely accrue to future payers, rather than to Medicaid. In other words, state Medicaid programs would bear the full cost of providing Sovaldi to their beneficiaries, but likely would not reap the

71. See generally THE COMPARATIVE CLINICAL EFFECTIVENESS AND VALUE OF SIMEPREVRIN AND SOFOSBUVIR IN THE TREATMENT OF CHRONIC HEPATITIS C INFECTION ES2–ES6, INST. FOR CLINICAL & ECON. REV. (Apr. 2014), <https://collections.nlm.nih.gov/master/borndig/101642256/Comparative%20Clinical%20Effectiveness%20and%20Value%20of%20Simeprevir%20and%20Sofosbuvir.pdf> [https://perma.cc/EN54-W9YP].

72. Maxine M. Denniston et al., *Chronic Hepatitis C Virus Infection in the United States, National Health and Nutrition Examination Survey 2003 to 2010*, 160 ANNALS OF INTERNAL MED. 293, 293 (2014).

73. Carolyn Y. Johnson & Brady Dennis, *How an \$84,000 Drug Got Its Price: "Let's Hold Our Position . . . Whatever the Headlines,"* WASH. POST (Dec. 1, 2015, 2:27 PM), <https://www.washingtonpost.com/news/wonk/wp/2015/12/01/how-an-84000-drug-got-its-price-lets-hold-our-position-whatever-the-headlines/> [https://perma.cc/Q2VU-CEWJ]. However, Sovaldi was not the only new cure for Hepatitis C, and other companies soon entered and competed with Gilead to offer rebates in exchange for preferred coverage. See U.S. SENATE COMM. ON FIN., *supra* note 70, at 109 (discussing AbbVie's "aggressive" rebate program).

74. See, e.g., INST. FOR CLINICAL & ECON. REV., *supra* note 71, at 84.

75. Soumitri Barua et al., *Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infection in the United States*, 163 ANNALS OF INTERNAL MED. 215, 215 (2015). See generally *Hepatitis C: The State of Medicaid Access: National Summary Report*, CTR. FOR HEALTH L. & POL'Y INNOVATION, HARV. L. SCH. (Oct. 23, 2017), https://hepcstage.wpengine.com/wp-content/uploads/2017/10/State-of-HepC_2017_FINAL.pdf [https://perma.cc/S263-U5P4].

76. States typically must balance their budgets each year, while the federal government is not so bound. See David Gamage, *Preventing State Budget Crises: Managing the Fiscal Volatility Problem*, 98 CALIF. L. REV. 749, 753, 755 (2010).

77. See, e.g., INST. FOR CLINICAL & ECON. REV., *supra* note 71, at 83–85.

78. See, e.g., Sommers, *supra* note 53, at 1817; Daw et al., *supra* note 55, at 601.

future benefits of doing so. As such, Medicaid programs faced strong incentives to limit Sovaldi's availability.

Another example of the ways in which new technologies are revealing the problems of fragmentation over time comes in the area of gene therapies. Many pharmaceutical companies are developing gene therapy products designed to be administered once rather than taken over time, particularly for the treatment of rare genetic diseases. These gene therapies have only begun entering the market, but they are already commanding eye-popping prices in the range of millions of dollars.⁷⁹ At these prices, some of these products may not be cost-effective, but others that reduce the need for other expensive drugs or hospital stays in the longer term may be cost-effective or even cost-saving.⁸⁰ However, the same short-term dynamics facing Sovaldi arise in the context of these gene therapies. In addition to potential financing and budgeting challenges, an insurer covering these products now will be responsible for their full cost, but they will likely reap only a portion of the benefits, much of which would redound to future insurers.

Observers recognizing these dynamics have proposed a variety of innovative approaches to attempt to alter these incentives. In the context of Sovaldi, scholars have even proposed that the government should buy Gilead, as “[b]uying the company rather than purchasing its products just works out to be a far cheaper route” to providing patients with access to the drug.⁸¹ In the gene therapy context, some scholars have argued that the million-dollar-plus cost of these therapies could be financed over time, like a mortgage, rather than having insurers pay the full cost up front.⁸² A mortgage-like structure would ease the one-time financial burden of these cures, converting their financing to more like that of maintenance therapies and mitigating the above incentives. However, a mortgage arrangement could encourage pharmaceutical companies to set even higher prices

79. Thomas, *supra* note 1.

80. Joshua T. Cohen et al., *Putting the Costs and Benefits of New Gene Therapies Into Perspective*, HEALTH AFFS. BLOG (Sept. 4, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190827.553404/full/> [<https://perma.cc/7KGQ-XMCE>].

81. Peter B. Bach & Mark Trusheim, *The U.S. Government Should Buy Gilead for \$156 Billion to Save Money on Hepatitis C*, FORBES (Jan. 17, 2017, 6:00 AM), <https://www.forbes.com/sites/sciencebiz/2017/01/17/the-u-s-government-should-buy-gilead-for-156-billion-to-save-money-on-hepatitis-c/#73c5ad4e71a2> [<https://perma.cc/UH9B-NWNF>].

82. *See, e.g.*, Vahid Montazerhodjat et al., *Buying Cures Versus Renting Health: Financing Health Care with Consumer Loans*, 8 SCI. TRANSLATIONAL MED. 1, 1 (2016). Dr. Scott Gottlieb, who would go on to serve as FDA Administrator in the Trump Administration, advanced this argument as well. *See generally* Scott Gottlieb & Tanisha Carino, *Establishing New Payment Provisions for the High Cost of Curing Disease*, AEI RSCH. 4 (July 2014), https://www.aei.org/wp-content/uploads/2014/07/-establishing-new-payment-provisions-for-the-high-cost-of-curing-disease_154058134931.pdf [<https://perma.cc/QGT7-ET3Z>].

in the first instance. Furthermore, legal questions about the mortgage, to whom it attaches, and its transferability⁸³ would need to be resolved before such structures could be implemented.

B. Time-Based Fragmentation's Effects on Innovation Policy

Fragmentation over time impacts patients' access to care and the resulting quality of care they receive. Because a patient's current insurer will bear the full cost of any care they provide reimbursement for, but will not reap the full benefits of that care due to patient churn, insurers' incentives to provide preventive care or costly one-time therapies are lower than would be socially optimal.⁸⁴ However, the literature has largely not considered the impact of these dynamics on innovation into future health care technologies. Essentially, fragmentation over time discourages innovation into such technologies, even where they would be highly socially valuable, because it discourages insurers from paying for these one-time products.

In practice, insurance reimbursement functions similarly to a prize system rewarding innovator firms, with the power to redirect innovation incentives accordingly.⁸⁵ When an insurer provides or increases reimbursement for a new class of patients or products, that reimbursement expands the potential returns on investment companies can expect for products with consumer demand in that particular area.⁸⁶ Empirical research into different legal and regulatory developments that require the Centers for Medicare and Medicaid Services ("CMS") to cover particular technologies has shown that innovator firms respond to those developments by increasing their investments in that area, as would be expected if they foresaw

83. Rachel Sachs, Nicholas Bagley & Darius Lakdawalla, *Innovative Contracting for Pharmaceuticals and Medicaid's Best-Price Rule*, 43 J. HEALTH POL. POL'Y & L. 5, 13–14 (2018).

84. This generalized statement about the skewed incentives facing insurers in this context is broadly applicable to different types of insurers. Other, more practical concerns, like those about financing and predictability faced by state Medicaid programs in the context of the Hepatitis C drugs, vary by insurer. These concerns can in principle be dealt with separately and do not necessarily pose challenges from an innovation perspective.

85. This link between reimbursement and innovation is an increasing area of focus for both scholars and policymakers. *See, e.g.*, Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999, 1013 (2014); Kevin Outterson, *The Legal Ecology of Resistance: The Role of Antibiotic Resistance in Pharmaceutical Innovation*, 31 CARDOZO L. REV. 613, 645–55 (2010); Arti K. Rai, *The Ends of Intellectual Property: Health as a Case Study*, 70 L. & CONTEMP. PROBS. 125, 128–29 (2007); Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J.L. & TECH. 153, 193, 201–08 (2016).

86. *See* Sachs, *supra* note 85, at 179.

increased revenues associated with those insurance expansions.⁸⁷ For example, pharmaceutical companies expected Medicare's 1993 decision to provide reimbursement for the flu vaccine to lead to large increases in vaccination rates among seniors,⁸⁸ and an associated increase in profitability for the vaccine. As a result, the 1993 decision was followed by a substantial increase in the number of new flu vaccine clinical trials.⁸⁹

By contrast, when an insurer endeavors not to provide reimbursement for a new class of products, or even just tightly controls access to the class, that decision decreases the potential return on investment companies can expect in the class. They can be expected to respond accordingly, by decreasing new investments into the type of product involved. In this case, because insurers are aiming to discourage patients from obtaining costly one-time therapies, pharmaceutical firms may prefer to invest in the development of less expensive maintenance treatments that patients must take over time, perhaps for the rest of their lives. A recent analyst report from Goldman Sachs put the question bluntly, asking "is curing patients a sustainable business model?"⁹⁰

This dynamic introduces an unfortunate innovation disincentive into our system. From a social welfare perspective, preventive interventions and cures may be far more valuable than maintenance therapies. This is particularly likely to be the case for communicable diseases, where vaccination campaigns have positive externalities on non-vaccinated members of society, or where cures like Sovaldi have the potential to eliminate a disease with a high burden of illness among a marginalized population. Fragmentation over time discourages investment into cures or preventive interventions, causing signals to the private market to align poorly with the social value of these health care technologies.

87. See, e.g., Margaret E. Blume-Kohout & Neeraj Sood, *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*, 97 J. PUB. ECON. 327, 327 (2013); see also 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) (qualifying the findings of Blume-Kohout and Sood by noting that truly innovative activity takes longer to emerge); Amy Finkelstein, *Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry*, 119 Q.J. ECON. 527, 556–57 (2004) (discussing increased investment in vaccine trials, but not in other trials, e.g., preclinical trials); Daron Acemoglu & Joshua Linn, *Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry*, 119 Q.J. ECON. 1049, 1084 (2004).

88. Finkelstein, *supra* note 87, at 559–60. Although this increase occurred, it was less dramatic than may have been expected. See *id.*

89. *Id.* at 537.

90. Tae Kim, *Goldman Sachs Asks in Biotech Research Report: "Is Curing Patients a Sustainable Business Model?"*, CNBC (Apr. 11, 2018, 7:20 PM), <https://www.cnbc.com/2018/04/11/goldman-asks-is-curing-patients-a-sustainable-business-model.html> [<https://perma.cc/Z8WS-ECGA>]. Their report suggests that in some cases it might be, but in other cases it might not be. *Id.*

IV. FRAGMENTATION BY BENEFIT STRUCTURE

A second form of fragmentation that has not been discussed in the legal literature is *fragmentation by benefit structure*. This form of fragmentation occurs when a particular insurance program separates out the different benefits it covers, in a way that alters incentives for coverage and consumption across the different benefits. This separation can occur in different ways and impact different actors, as described below, but in each situation the effect of fragmentation is the same. Insurers, providers, and/or patients under this form of fragmentation will trade off different benefits in ways that are not justified either therapeutically or from a cost-effectiveness perspective, but rather are encouraged by the fragmented benefit structure.

This Part briefly considers two examples of fragmentation by benefit structure: the design of the federal Medicare program and private insurers' construction of pharmaceutical coverage. In both examples, the relevant insurance programs have separated out the coverage of or payment for pharmaceuticals from the coverage of standard health care services and other health care technologies. This Part then explains why that separation is problematic for innovation policy. The separation of drug and non-drug coverage discourages or even prevents insurers from considering the relative benefits of pharmaceutical versus non-pharmaceutical coverage, in a way that likely discourages the development of certain types of pharmaceuticals.

A. Examples of Benefit Structure Fragmentation

The two examples of fragmentation by benefit structure considered in this Part demonstrate the different ways in which fragmentation can occur, and the different actors involved in each type of decision. Fragmentation can be a creature of law (as in the Medicare context) or be encouraged for cost-based reasons (as in the private insurance example). Fragmentation can also be chosen by policymakers in a way that primarily implicates the decisions of insurers and physicians (as in the Medicare context), or in a way that also involves patient decision-making (in the private insurance example). These different permutations of fragmentation by benefit structure allow for different strategies to encourage integration, as considered *infra* in Part VI.

1. Fragmentation in Medicare Design

At the time of its enactment in 1965,⁹¹ Medicare contained two separate insurance benefits. Medicare Part A provided coverage for inpatient hospital admissions,⁹² while Part B provided coverage for physician services in an outpatient setting.⁹³ Each benefit has its own internal structure and payment system. For instance, most beneficiaries do not pay premiums for their Part A benefits, although the program does require a significant deductible and coinsurance for lengthy hospital stays.⁹⁴ Beneficiaries do owe monthly premiums in Part B, though, with a smaller deductible followed by 20% coinsurance.⁹⁵ In other words, benefit fragmentation was baked into the program from the beginning.

For nearly forty years, Medicare did not contain a standard pharmacy benefit for seniors. Medicare Part D, the program's pharmacy benefit, was created by the Medicare Modernization Act of 2003.⁹⁶ Although many newly eligible beneficiaries previously had access to separate pharmacy coverage, 27% of seniors had no prescription drug coverage prior to Part D's implementation.⁹⁷ The Part D payment system is also distinct from the Part A and B systems, with separate income-adjusted monthly premiums⁹⁸ and an infamously complex internal deductible and coinsurance structure.⁹⁹

91. *Key Milestones in Medicare and Medicaid History, Selected Years: 1965–2003*, 27 HEALTH CARE FIN. REV. 1 (2005), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/05-06Winpg1.pdf> [<https://perma.cc/VXL3-J6TT>].

92. 42 U.S.C. § 1395c.

93. 42 U.S.C. § 1395k(a)(2).

94. See CTRS. FOR MEDICARE & MEDICAID SERVS., *Medicare Costs at a Glance* (2020), <https://www.medicare.gov/your-medicare-costs/medicare-costs-at-a-glance> [<https://perma.cc/52W2-JEAX>].

95. See CTRS. FOR MEDICARE & MEDICAID SERVS., *Part B Costs* (2020), <https://www.medicare.gov/your-medicare-costs/part-b-costs> [<https://perma.cc/UUA3-B5Z9>].

96. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections of 26 and 42 U.S.C.).

97. *Prescription Drug Trends*, KAISER FAM. FOUND. 5 (May 2010); see also Dana Gelb Safran et al., *Prescription Drug Coverage and Seniors: Findings from a 2003 National Survey*, HEALTH AFFS., W5-160 (Apr. 19, 2005).

98. See CTRS. FOR MEDICARE & MEDICAID SERVS., *Medicare Costs at a Glance* (2020), <https://www.medicare.gov/your-medicare-costs/medicare-costs-at-a-glance> [<https://perma.cc/CDK3-U356>].

99. In 2010, Part D beneficiaries first had an initial deductible of \$310, then paid 25% of the cost of their drugs until the total plan spend on their drugs reached \$2,830. Beneficiaries were then 100% responsible for the next \$3,610 of medications in the “donut hole” phase of the benefit, at which point they would enter the catastrophic phase of their benefits and pay just 5% of drug costs. Christopher Weaver, *Closing Medicare Drug Gap Helps Democrats Sell Reform*, KAISER HEALTH NEWS (Mar. 29, 2010), <https://khn.org/news/health-reform-doughnut-hole/> [<https://perma.cc/RU7V-7GAR>]. The Affordable Care Act included provisions to close the donut hole gradually by 2020, and a 2018 budget agreement in Congress accelerated the closing to 2019. See Dena Bunis, *Medicare ‘Doughnut Hole’ Will*

Today, different prescription drugs are often available through both Part D and Part B. Part D is understood as the standard pharmacy benefit — if a physician prescribes a drug for a patient to pick up at their local pharmacy and take at home, that drug is typically covered under Part D.¹⁰⁰ However, an increasingly important set of drugs are administered in outpatient settings. These are typically injectable or infused biologics, prescribed for the treatment of complex diseases like autoimmune conditions or for cancer. Because of their site of administration, these drugs are typically covered under Part B.¹⁰¹

Today, most seniors enrolling in traditional Medicare obtain coverage through each of these programs, combining coverage under the highly fragmented Parts A, B, and D to access a comprehensive set of benefits.¹⁰²

2. Fragmentation in Financing by Private Insurers

Private insurance plans are beginning to display these same fragmentation dynamics. Many people enrolled in private insurance plans are required to spend larger amounts than they had previously in the deductible phase of their plans, where they are financially responsible for the full amount of their care until it reaches a certain dollar amount.¹⁰³ At that point, their insurance assumes at least partial financial responsibility. A rapidly increasing number of patients are enrolled in high-deductible health plans, which by definition require deductibles of at least \$1,400 per person or \$2,800 per family.¹⁰⁴ Although just 4% of privately insured patients were enrolled in such

Close in 2019, AARP (Feb. 9, 2018), <https://www.aarp.org/health/medicare-insurance/info-2018/part-d-donut-hole-closes-fd.html> [<https://perma.cc/XQ9D-LNWK>]. After an initial deductible, patients now pay 25% of the costs of their medicines until they reach the catastrophic phase. *Id.*

100. See MEDPAC, *Improving Medicare Part D*, in REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 157, 186 (June 2016), <http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0> [<https://perma.cc/Z6NS-ERKS>].

101. See *Medicare Part B drug and oncology payment policy issues*, in REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM, *supra* note 100, at 115, 121.

102. For a discussion of Medicare Advantage, which has the potential to integrate some of these benefits but nevertheless faces structural shortcomings in doing so, see *infra* Section VI.B.2.

103. See Gary Claxton et al., *Increases in Cost-Sharing Payments Continue to Outpace Wage Growth*, PETERSON-KAISER FAM. FOUND. HEALTH SYS. TRACKER (June 15, 2018), <https://www.healthsystemtracker.org/brief/increases-in-cost-sharing-payments-have-far-outpaced-wage-growth/> [<https://perma.cc/RBT3-JNYH>] (noting that deductible spending rose from \$151 in 2006 to \$417 in 2016).

104. Rev. Proc. 2019-25 § 2, I.R.B. 2019-22.

plans in 2006, a full 30% were in 2016.¹⁰⁵ Employers are increasingly offering these plans — sometimes *only* these plans¹⁰⁶ — as a way to lower their own health care costs. The idea is to impose increasing financial burdens on their employees, which both reduces the employer’s costs directly and may discourage the employees from receiving care, reducing overall utilization and spending.

Increasing numbers of patients now have not only general deductibles, but also separate annual prescription drug deductibles. In other words, no matter how much patients have already spent on health care services, they must spend an additional amount out of pocket for prescription drugs before their insurance assumes responsibility there as well. Nearly 15% of beneficiaries now have separate prescription drug deductibles,¹⁰⁷ a number that is far greater for enrollees in high-deductible plans (33% of whom have separate drug deductibles) than those in other types of plan arrangements.¹⁰⁸ As with the rationale behind high-deductible plans in general, separate pharmacy deductibles may discourage patients from taking medications regularly,¹⁰⁹ reducing pharmacy costs by reducing utilization.

B. Benefit Structure Fragmentation’s Effects on Innovation Policy

Fragmentation by benefit structure creates problematic incentives from an innovation policy perspective.¹¹⁰ Ideally, a patient and her physician should be able to choose a particular method of treatment based on factors including the treatment’s efficacy and its safety.¹¹¹

105. KAISER FAM. FOUND. ET AL., EMPLOYER HEALTH BENEFITS 2019 ANNUAL SURVEY 142 (2019), <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2019> [https://perma.cc/CSC7-84UD].

106. *See id.* at 75.

107. *See id.* at 166.

108. Adam J. Fein, *Shopping for Prescriptions: How Deductibles Will Reshape the Pharmacy Industry*, DRUG CHANNELS (Nov. 9, 2017), <https://www.drugchannels.net/2017/11/shopping-for-prescriptions-how.html> [https://perma.cc/E28G-CDGL]. These additional deductibles can run into the thousands of dollars, *Medical and Prescription Drug Deductibles for Plans Offered in Federally Facilitated and Partnership Marketplaces for 2015*, slide 16, KAISER FAM. FOUND. (Nov. 18, 2014), <https://www.kff.org/health-reform/fact-sheet/medical-and-prescription-drug-deductibles-for-plans-offered-in-federally-facilitated-and-partnership-marketplaces-for-2015/> [https://perma.cc/MEC9-QNJC], although the average for workers in employer-sponsored plans is \$194. KAISER FAM. FOUND., *supra* note 105, at 166–67.

109. *See* IMS INST. FOR HEALTHCARE INFORMATICS, EMERGENCE & IMPACT OF PHARMACY DEDUCTIBLES 17–19 (Sept. 2015), <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/emergence-and-impact-of-pharmacy-deductibles.pdf> [https://perma.cc/2UPH-TDSA].

110. Fragmentation by benefit structure may also have impacts on the quality of patient care, for reasons that are similar to those articulated in Part II.

111. More generally, the patient and her physician should be able to choose a method of treatment that best aligns with the patient’s wishes. (For some patients, this may well mean

Whether the treatment is a drug or non-drug intervention should not on its own matter to the patient.¹¹² However, in a fragmented benefit structure, whether the treatment is a drug or something else will matter financially to the insurer and to the patient as well.

Fragmentation by benefit structure discourages insurers from considering the relative costs and benefits of pharmaceutical treatment versus non-pharmaceutical treatment for a given condition as part of its coverage decisions. Consider certain mental health conditions, where a patient's symptoms may improve either with continued therapy sessions with trained providers or with the use of pharmaceutical treatments (although many patients may need both).¹¹³ In theory, patients and their providers would have evidence about the relative costs and benefits of each approach and choose the model that works best for them.

In practice, fragmentation by benefit structure creates competing incentives between these two treatment modalities. A patient's prescription drug insurer has an incentive to attempt to avoid covering the drug in question, knowing that alternative treatment options are available for the patient — and knowing that those options are the financial responsibility of a different insurer. Even if the pharmaceutical treatment is the best choice for that patient, the insurer providing the patient's pharmacy benefit coverage will have the financial incentive to encourage the patient to access the non-drug treatment instead. On the other hand, the patient's medical insurer has an incentive to encourage reimbursement for the prescription drug coverage, knowing that those options will not be its financial responsibility. In essence, the insurer responsible for each part of the patient's care faces incentives to minimize its own expenditures, separate from the insurer responsible for the patient's other medical services. These incentives exist separate and apart from the scientific evidence about which of these therapies might be better for the patient.

The result of these financial pressures for innovation incentives is likely to depend on both the type of possible interventions involved

no method at all, and simply watchful waiting.) But the treatment's safety and efficacy are likely two factors that will be important to most patients.

112. Whether the treatment is a drug or not may matter for the patient's ability to remain adherent to the treatment regimen. A once-daily pill may be more "effective" than a weekly appointment with a treatment provider (as in the case of mental health counseling or physical therapy) if the patient can more easily take the pill. However, a once-daily pill may be less "effective" than an implanted medical device, as in the case of birth control, if the patient forgets to take the pill on occasion, while the implanted device continues to work.

113. See, e.g., Charles B. Nemeroff et al., *Differential Responses to Psychotherapy Versus Pharmacotherapy in Patients with Chronic Forms of Major Depression and Childhood Trauma*, 100 PNAS 14293 (2003); see also Richard A. Friedman, *To Treat Depression, Drugs or Therapy?*, N.Y. TIMES (Jan. 8, 2015, 8:00 AM), <https://nyti.ms/2jZAQmh> [<https://perma.cc/PH5W-3T45>].

and the strength of the insurers' financial incentives in each case. When there is a pharmaceutical and a non-pharmaceutical intervention available for the same condition, as in this mental health situation, these competing incentives between insurers responsible for different aspects of a patient's care may end up encouraging (or discouraging) innovation in either direction — but the key point is that the insurers' motivations depend on the cost of the product to them, not its clinical value. In other cases, though, there may be a tradeoff between a pharmaceutical intervention and a non-medical intervention. In the case of cardiovascular disease, for instance, exercise and dietary modifications have demonstrated benefits for patients, in addition to the benefits they might receive from standard pharmaceutical therapy with statins.¹¹⁴ In those cases, the incentive for the pharmaceutical insurer to avoid paying for the drug in question will not be balanced by a countervailing incentive from the patient's medical insurer, and if the costs of the drug are sufficiently high,¹¹⁵ the insurer may attempt to avoid providing reimbursement for the product. In general, these incentives encourage insurers to make coverage determinations based on cost to that insurer, rather than the quality of the comparative evidence and the potential benefits to the patient.¹¹⁶

Patients with fragmented deductibles or other cost-sharing obligations may face similar pressures, discouraging them from obtaining access to high-cost prescription drugs. Where the patient's out-of-pocket costs are divided between pharmaceutical and non-pharmaceutical services (as in both the Medicare Part D case and the case for many private insurers), the patient may find it difficult to

114. See Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 *YALE L. J.* 1900, 1928–30 (2013); U.S. DEP'T OF HEALTH & HUMAN SERVS., *PHYSICAL ACTIVITY AND HEALTH: A REPORT OF THE SURGEON GENERAL 7* (1996), <https://www.cdc.gov/nccdphp/sgr/pdf/sgrfull.pdf> [<https://perma.cc/2JSE-ZP8T>].

115. This is not the case for statins, which are quite inexpensive. For instance, the generic version of the brand-name blockbuster statin Crestor cost Medicare an average of \$195 per beneficiary in 2018. *Medicare Part D Drug Spending Dashboard*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD> [<https://perma.cc/28BD-JK8V>] (last updated Dec. 17, 2019); see also Andrew Pollack, *Generic Crestor Wins Approval, Dealing a Blow to AstraZeneca*, *N.Y. TIMES* (July 20, 2016), <https://nyti.ms/2a963y3> [<https://perma.cc/34CD-KER6>].

116. In some ways, this disincentive may counterbalance other, existing incentives. Kapczynski and Syed have argued that the existence of patent rights encourages firms to invest in the development of new pharmaceuticals rather than the development of information about non-medical interventions like exercise and diet, because patent rights function to “predictably and systematically distort private investment decisions . . . by overstating the value of highly excludable information goods and understating the value of highly nonexcludable ones.” Kapczynski & Syed, *supra* note 114 at 1907. Innovator firms will prefer to invest in the development of highly excludable information about new pharmaceuticals, as compared to highly nonexcludable information about the relationship between exercise and disease. See *id.* at 1935–36.

afford the increased financial burden associated with prescription drugs and may avoid or delay filling their prescriptions.¹¹⁷ Because these financial pressures discourage patients from filling their prescriptions, they likely diminish pharmaceutical company revenues, potentially decreasing innovation incentives for drugs with high patient out-of-pocket costs.

V. FRAGMENTATION IN POLICYMAKING

Another form of fragmentation that has largely been absent from the health law literature is fragmentation in health care policymaking. Essentially, fragmentation in policymaking occurs when the relevant policymakers each have only partial jurisdiction over a particular issue or have overlapping jurisdiction. In the first case, the effect of fragmentation is to narrow the focus of a particular policymaker as to the real causes and the potential solutions of a particular problem. This may lead policymakers to fail to act entirely, or instead to use the particular policy tools within their jurisdiction to address an issue, regardless of whether those tools are the best ones for the job. In the latter case, overlapping responsibilities may lead to similar outcomes, where competing policymakers may both decline to act or may both try to act and in so doing block each other's actions. In both cases, the relevant policymakers may not appropriately consider the costs and benefits of various courses of action, given their particular view of a problem. Although these questions have not been taken up in a focused way by health law scholars, administrative law scholars have taken up more general questions about the jurisdiction of administrative agencies and agency collaboration.¹¹⁸ Their analyses help enumerate the ways in which these partial or overlapping jurisdictional assignments hinder policymaking, although work still

117. See Rabah Kamal et al., *What Are the Recent and Forecasted Trends in Prescription Drug Spending?*, PETERSON-KAISER FAM. FOUND. HEALTH SYS. TRACKER (Feb. 20, 2019), <https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/> [<https://perma.cc/4L6V-F45F>] (noting that one in four people taking prescription drugs have difficulty affording their prescriptions); Dana P. Goldman et al., *Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health*, 298 J. AM. MED. ASS'N 61, 63 (2007); Stacie B. Dusetzina et al., *Cost Sharing and Adherence to Tyrosine Kinase Inhibitors for Patients with Chronic Myeloid Leukemia*, 32 J. CLINICAL ONCOLOGY 306, 306 (2014). These problems are worse for patients in the United States than for patients in other countries. See, e.g., Steven G. Morgan & Augustine Lee, *Cost-Related Non-Adherence to Prescribed Medicines Among Older Adults: A Cross-Sectional Analysis of a Survey in 11 Developed Countries*, 7 BMJ. OPEN e014287, 1 (2017). Medicare Part D's particular benefit design quirks also encourage beneficiaries to engage in strategic behavior regarding the donut hole. See Liran Einav et al., *The Response of Drug Expenditure to Nonlinear Contract Design: Evidence from Medicare Part D*, 130 Q. J. ECON. 841, 841 (2015).

118. See, e.g., Freeman & Rossi, *supra* note 37, at 1133; Nou, *supra* note 37, at 422.

must be done in both applying their analysis both to the health law framework and to non-administrative contexts.

This Part will first consider two main examples of fragmentation in health care policymaking: fragmentation in administrative agencies and fragmentation in Congressional committees. Describing how jurisdiction over health care policy issues is divided between agencies and between committees is helpful for understanding not only how our health care system came to take its current form but also why policy change is difficult in this area. This Part will then explain how this form of fragmentation is problematic for innovation policy. In particular, issues regarding drug innovation and access are dispersed between policymakers in a way that makes it difficult for any one actor to consider and address these problems.

A. Examples of Policymaking Fragmentation

The two examples of fragmentation in health care policymaking considered in this Part illustrate not only the fact of this fragmentation, but also a number of useful dimensions along which fragmentation can be considered. For instance, fragmentation in administrative agencies is typically explicitly compelled by legislation and regulation. The United States Food & Drug Administration (“FDA”) is primarily responsible for administering the Federal Food, Drug, and Cosmetic Act, while the Centers for Medicare and Medicaid Services (“CMS”) is responsible for overseeing the operation of the Medicare and Medicaid programs. On the other hand, fragmentation in Congressional committees is largely traceable to jurisdictional norms and rules of procedure. While these norms can be extremely strong, they do not have the same force of law. As a result, they can be circumvented when necessary (as discussed below).

A second important consideration is that policymaking fragmentation is both an example and a cause of fragmentation, unlike the forms of fragmentation considered in the previous two Parts. Although fragmentation in policymaking suffers from many of the same challenges from a policy perspective as fragmentation in benefit structure and fragmentation over time, fragmentation in policymaking also has the ability to cause or exacerbate fragmentation elsewhere in the innovation policy ecosystem. For instance, if CMS is interested in addressing a particular issue in innovation policy, they may only have the legal authority to do so within Medicare and Medicaid, meaning that the greater number of Americans with private employer-sponsored coverage¹¹⁹ would not benefit from CMS’s intervention.

119. See *Health Insurance Coverage of the Total Population*, KAISER FAM. FOUND. (2019), <https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> [https://

The result is to create or exacerbate fragmentation in benefit design between employer-sponsored and publicly run insurance coverage systems.

1. Fragmentation in Administrative Agencies

Administrative agency jurisdiction over health-related issues is highly fragmented between multiple policymakers.¹²⁰ Within the realm of health innovation policy, jurisdiction is primarily fragmented among four key agencies: the National Institutes of Health (“NIH”), the United States Patent & Trademark Office (“USPTO”), the FDA, and CMS.¹²¹ Together, these agencies oversee the key aspects of innovation and access for healthcare technologies — how those technologies are developed, protected, approved, and paid for. Yet each agency oversees a different aspect of this process, and accordingly each agency has particular interests and expertise in that area.

The NIH finances an enormous amount of biomedical research across all areas of interest. Disbursing nearly \$40 billion in research funding each year,¹²² the NIH funds both basic research, to elucidate our scientific understanding of particular diseases and bodily processes, and also applied research, to translate those basic research

perma.cc/6VHA-WCE8] (noting that 49% of Americans have employer-sponsored coverage, while 21% are enrolled in Medicaid and 14% in Medicare).

120. See Satz, *supra* note 14, at 212–13. Many of the most extreme examples come from the division of responsibility between the FDA and the United States Department of Agriculture (USDA), which have finely divided responsibility over the safety of many food products. U.S. FOOD & DRUG ADMIN., INVESTIGATIONS OPERATIONS MANUAL 3-24 to -25 (2020), <https://www.fda.gov/media/113432/download> [<https://perma.cc/M8RB-4QVJ>]. The USDA regulates open-faced sandwiches, while the FDA regulates closed-face sandwiches. *Id.* The USDA regulates pepperoni pizza, while the FDA regulates cheese pizza. *Id.* Perhaps most challengingly, the FDA has jurisdiction over nearly all types of fish and seafood except catfish, which is under the USDA’s jurisdiction. U.S. GOV’T ACCOUNTABILITY OFF., RESPONSIBILITY FOR INSPECTING CATFISH SHOULD NOT BE ASSIGNED TO USDA 1–2 (May 2012), <https://www.gao.gov/assets/600/590777.pdf> [<https://perma.cc/KL33-4CL2>]; *FDA Transfers Siluriformes Fish Inspection to USDA*, U.S. FOOD & DRUG ADMIN. (last updated May 2, 2016), <https://www.fda.gov/food/cfsan-constituent-updates/fda-transfers-siluriformes-fish-inspection-usda> [<https://perma.cc/CGC2-ZPT3>].

121. Additional agencies may play a role in the health innovation and access process, but they often do so only in particular situations. For instance, controlled substances approved by the FDA must undergo additional scheduling with the Drug Enforcement Administration. Rebecca S. Eisenberg & Deborah B. Leiderman, *Cannabis for Medical Use: FDA and DEA Regulation in the Hall of Mirrors*, 74 FOOD & DRUG L.J. 246, 256–57 (2019). As another example, some mosquito-related products are regulated by the FDA (including those intended to prevent disease) while others are regulated by the Environmental Protection Agency. Clarification of the Food and Drug Administration and Environmental Protection Agency Jurisdiction Over Mosquito-Related Products, 82 Fed. Reg. 46,500, 46,500 (Oct. 5, 2017).

122. *What We Do: Budget*, NAT’L INST. HEALTH, <https://www.nih.gov/about-nih/what-we-do/budget> [<https://perma.cc/2PB8-RNAC>] (last updated June 29, 2020).

findings into new healthcare technologies or medical practices.¹²³ The NIH's influence reaches beyond this direct funding, however, as the agency also uses its agenda-setting ability to encourage non-governmental actors to invest in research in particular fields, recently including neuroscience¹²⁴ and precision medicine.¹²⁵

The NIH has spent decades using its authority to make and administer grants to foster innovation in health care technologies and services. Although there are certainly open policy questions about how the NIH uses its authority in this space,¹²⁶ it is surely fair to say that the agency has developed deep expertise in biomedical research funding. However, the NIH's work is largely confined to this area. The NIH's specialty is research, and its focus is on ensuring that basic research is performed and that the process of translating that research into clinical discoveries has begun.

Once the initial research into a particular technology has been performed, researchers typically turn to the USPTO in an effort to obtain patents on their discovery. The process of bringing a new health care technology to market is often lengthy (due to the need to obtain FDA approval or clearance in addition to the research involved),¹²⁷ expensive,¹²⁸ and risky.¹²⁹ In such cases, companies

123. See Mike Lauer, *NIH's Commitment to Basic Science*, NAT'L INSTS. HEALTH: OPEN MIKE (Mar. 25, 2016), <https://nexus.od.nih.gov/all/2016/03/25/nihs-commitment-to-basic-science> [https://perma.cc/EX4M-77YM].

124. Non-governmental entities have contributed over \$240 million toward the goals set forth by the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative. OFF. OF SCI. & TECH. POL'Y, EXEC. OFF. OF THE PRESIDENT, OBAMA ADMINISTRATION PROPOSES OVER \$300 MILLION IN FUNDING FOR THE BRAIN INITIATIVE 1 (Feb. 2015), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/brain_initiative_fy16_fact_sheet_ostp.pdf [https://perma.cc/TAK3-Y6AU].

125. Non-governmental entities, including hospitals, universities, and technology companies, have made contributions to the Precision Medicine Initiative. Press Release, WHITE HOUSE OFF. OF THE PRESS SEC'Y, *FACT SHEET: Obama Administration Announces Key Actions to Accelerate Precision Medicine Initiative* (Feb. 25, 2016), <https://obamawhitehouse.archives.gov/the-press-office/2016/02/25/fact-sheet-obama-administration-announces-key-actions-accelerate> [https://perma.cc/SQJ3-WM3L].

126. For instance, researchers have asked questions about how the NIH chooses to allocate its scarce resources. Michael S. Lauer, David Gordon & Michelle Olive, *Matching Taxpayer Funding to Population Health Needs: Not So Simple*, 116 CIRCULATION RES. 1301, 1301 (2015); see also *Funding: Report on NIH Funding vs. Global Burden of Disease*, NAT'L INSTS. HEALTH, https://report.nih.gov/info_disease_burden.aspx [https://perma.cc/MYM8-Y7T2] (last updated June 30, 2018); Thomas Insel, *Post by Former NIMH Director Thomas Insel: Transparency*, NAT'L INST. MENTAL HEALTH (Mar. 13, 2015), <http://www.nimh.nih.gov/about/director/2015/transparency.shtml> [https://perma.cc/M8MQ-7TXV] (considering existing investments within NIMH based on public health need and whether other criteria ought to matter).

127. On average, the process of drug development can take twelve to sixteen years before FDA approval. Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. REV. 672, 719 (2014).

128. Most estimates put the cost of developing a new drug at well over \$1 billion, although the typical cost is hotly debated. *Compare, e.g.*, Joseph A. DiMasi et al.,

argue that patents are critical protections enabling them to invest the needed resources years before a product can be brought to market.¹³⁰ The USPTO therefore functions to grant patents, preventing competing firms from copying the technology at issue for twenty years from the patent's filing date.¹³¹ Companies typically obtain more than one patent per technology, although numbers vary widely: small-molecule drugs are commonly protected by a handful of patents, while some biologic drugs are protected by more than 100.¹³²

The USPTO has deep expertise in the administration of the patent system, and it deploys examiners with technological training as it decides whether or not an applicant has met the legal standards for obtaining a patent. However, the patent statute is facially neutral, applying a one-size-fits-all framework to highly disparate technologies,¹³³ which may in practice require very different levels of incentives for scientists in the field.¹³⁴ The USPTO further lacks substantive rulemaking authority¹³⁵ and cannot officially tailor the law by area of technology.¹³⁶ As a result, even though the USPTO plays a key role in the health innovation process, the agency has limited ability to consider whether and how the patent system could work

Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. HEALTH ECON. 20, 20 (2016) (estimating pre-approval costs to be \$2.558 billion), with Cynthia M. Ho, *Drugged Out: How Cognitive Bias Hurts Drug Innovation*, 51 SAN DIEGO L. REV. 419, 426, 448–57 (2014) (estimating development costs to be a “fraction” of \$1 billion). The costs to develop new medical devices vary depending primarily on the FDA pathway required. See JOSH MAKOWER ET AL., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION: A SURVEY OF OVER 200 MEDICAL TECHNOLOGY COMPANIES 28 (Nov. 2010), https://www.advamed.org/sites/default/files/resource/30_10_11_10_2010_Study_CAgenda_makowerreportfinal.pdf [<https://perma.cc/QP9Y-6PFL>] (estimating the average total cost for a high-risk device at \$94 million and for a moderate-risk device at \$31 million).

129. Michael Hay et al., *Clinical Development Success Rates for Investigational Drugs*, 32 NATURE BIOTECH. 40 (2014).

130. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1617 (2003); see also Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1286 (2009).

131. 35 U.S.C. § 154(a)(2).

132. Lisa Larrimore Ouellette, *How Many Patents Does It Take to Make a Drug? Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMMS. TECH. L. REV. 299, 321 (2010); W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 527 (2014).

133. For a more general treatment of this issue, see Michael W. Carroll, *One for All: The Problem of Uniformity Cost in Intellectual Property Law*, 55 AM. U. L. REV. 845 (2006), Michael W. Carroll, *One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights*, 70 OHIO ST. L.J. 1361 (2009), and Tejas N. Narechania, *Patent Conflicts*, 103 GEO. L.J. 1483, 1488 (2015).

134. See, e.g., Burk & Lemley, *supra* note 130, at 1622–23; Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CALIF. L. REV. 1, 39, 46 (2001).

135. Michael J. Burstein, *Rules for Patents*, 52 WM. & MARY L. REV. 1747, 1755 (2011).

136. The Federal Circuit has in some cases helped tailor patent law by technological field, although its efforts to do so are limited by statutes' facial technological neutrality. See generally Burk & Lemley, *supra* note 130.

more effectively to promote health innovation and access, let alone how other legal tools could do so.

Unlike in other technological fields, manufacturers of pharmaceutical innovations must typically obtain approval or clearance from the FDA before marketing their products. These requirements do add time and expense to the product development process, but particularly in the case of new pharmaceuticals, the FDA is also a powerful innovation-promoting agency. The FDA both forces pharmaceutical companies to develop information about their own products through its role as market gatekeeper¹³⁷ and encourages the development of particular types of socially valuable pharmaceuticals in its role as administrator of particular innovation incentives. Most notably, the FDA administers a number of exclusivity periods, which resemble the patent system in their function.¹³⁸ The FDA also administers four expedited approval pathways to speed the review process for new pharmaceuticals that are intended to treat serious conditions and represent advances over existing treatments.¹³⁹

The FDA's expertise in evaluating the safety and efficacy of new health care technologies must be understood in the context of the traditional view that emphasizes the agency's consumer protection function.¹⁴⁰ The agency certainly cares deeply about the science involved in approving these new products and about the process of innovation. But it also recognizes that its reputation is the source of the public's trust in its authority — that when the FDA approves a new product, it is critical for patients to trust that the product is safe and effective for its intended use.¹⁴¹ The FDA's risk/benefit decision-

137. Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMMS. & TECH. L. REV. 345, 370 (2007); Kapczynski & Syed, *supra* note 114, at 1956; cf. Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193, 198–99 (2005) (explaining why companies will be less likely to develop this information if it is not appropriable).

138. See generally Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals — Do We Really Need Both?*, 18 MICH. TELECOMMS. & TECH. L. REV. 419 (2012). Several statutes instruct the FDA to award manufacturers of newly approved drugs periods of exclusivity, which prevent the FDA from approving follow-on generics or biosimilar products for statutorily specified periods of time. See, e.g., 21 U.S.C. § 355(j)(5)(F)(ii) (providing that the FDA may not accept for filing an application for a small-molecule generic product that uses an innovator company's clinical trial data for five years); 42 U.S.C. § 262(k)(7)(A) (providing innovator biologic companies with twelve years of data exclusivity from the innovator product's approval to the biosimilar's approval); 21 U.S.C. § 360cc(a) (conferring seven years of market exclusivity for orphan drug products).

139. For an overview and comparison of these four programs, see FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., OMB CONTROL NO. 0910-0765, GUIDANCE FOR INDUSTRY: EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS — DRUGS AND BIOLOGICS 7–8 (May 2014), <https://www.fda.gov/media/86377/download> [<https://perma.cc/6V7M-BGHU>].

140. Eisenberg, *supra* note 137, at 367, 387.

141. DANIEL CARPENTER, REPUTATION AND POWER 10–11 (2010).

making as it decides whether or not to approve new products must be understood against this primacy of the agency's consumer protection function, not only against its innovation promoting function.¹⁴²

Once a new health care technology is approved, manufacturers focus on ensuring that they receive insurance reimbursement for their product, so that they may recoup their investment. In this capacity, CMS's decisions about which health care services and products to purchase for the more than 100 million Americans receiving health insurance through the federal government¹⁴³ strongly influence manufacturers' decisions about the kinds of technologies they will choose to develop.¹⁴⁴

Yet CMS's legal authority is primarily designed to promote access to health care technologies, rather than to encourage innovation into new products. To that end, Medicare and Medicaid are often legally required to cover most (and in some cases all) FDA-approved drugs,¹⁴⁵ to ensure that vulnerable populations are not discriminated against and do not experience interruptions in their drug coverage.¹⁴⁶ Even the most innovation-focused policy lever belonging to CMS, its implementation of the Medicare new technology add-on payment program,¹⁴⁷ is designed to promote access to particularly costly new technologies whose use is not adequately reflected within the traditional Medicare reimbursement system,¹⁴⁸ not to promote innovation into new, paradigm-shifting healthcare technologies.

The fragmentation of health innovation policymaking between these agencies is constructed by law, but it is not necessarily

142. For instance, the FDA must consider how to balance Type I and Type II errors in innovation policy — whether it is more concerning for the agency to approve a potentially unsafe, ineffective drug or to fail to approve a drug which later turns out to be safe and effective. See Rachel E. Sachs, *Delinking Reimbursement*, 102 MINN. L. REV. 2307, 2323–24 (2018).

143. See CTRS. FOR MEDICARE & MEDICAID SERVS., FISCAL YEAR 2016: JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES 109 (2015), <https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2016-CJ-Final.pdf> [<https://perma.cc/MN75-LB9J>].

144. See *supra* text accompanying notes 85–89.

145. By law, Medicare Part D plans must cover at least two FDA-approved drugs per therapeutic class, 42 C.F.R. § 423.120(b)(2)(i) (2015), and for six classes of drugs, Medicare must cover essentially all products, 42 U.S.C. § 1395w-104(b)(3)(G)(iv). State Medicaid programs choosing to cover prescription drugs must cover all FDA-approved drugs, with limited exceptions. 42 U.S.C. § 1396r-8(d)(2).

146. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL § 30.2.5 (rev. 18, Jan. 15, 2016), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf> [<https://perma.cc/M3EJ-6Z3F>]; see also Douglas B. Jacobs & Benjamin D. Sommers, *Using Drugs to Discriminate — Adverse Selection in the Insurance Marketplace*, 372 NEW ENG. J. MED. 399, 399 (2015).

147. See 42 U.S.C. § 1395ww(d)(5)(K).

148. Alexandra T. Clyde et al., *Experience with Medicare's New Technology Add-on Payment Program*, 27 HEALTH AFFS. 1632, 1633 (2008).

intractable even under current policy. For instance, the NIH, FDA, and CMS share a parent agency — the Department of Health and Human Services — who can create space for cooperative policymaking.¹⁴⁹ Congress has even made explicit its preference for such cooperation, requiring the NIH specifically to report on its interagency activities, in an effort “to increase interagency collaboration and coordination.”¹⁵⁰ The FDA has entered into formal memoranda of understanding with many other federal agencies, including both the NIH and CMS.¹⁵¹ In practice, though, these instances of cooperation tend to be the exception rather than the norm. Both legal and practical barriers limit the ability of agencies to interact collaboratively, particularly in resource-constrained agencies with limited personnel.¹⁵²

2. Fragmentation in Congressional Committees

Legislative jurisdiction in Congress as it relates to health care is also highly fragmented across committees. Two examples are illustrative here. First, imagine that Congressional leadership wants to pass a broad legislative reform package regarding innovation policy, implicating all four of the policy areas described above: research funding, intellectual property, drug approval, and insurance reimbursement. The law will need to pass through at least three main committees in each legislative chamber. In the Senate, the Health, Education, Labor and Pensions (“HELP”) Committee has jurisdiction over the NIH and the FDA,¹⁵³ and so would have control over those policy areas. The Senate Judiciary Committee has responsibility for reforms to the patent system.¹⁵⁴ And the insurance reimbursement piece would primarily be controlled by the Senate Finance Committee, with its jurisdiction over Medicare, Medicaid, and health-related issues,¹⁵⁵ but may also go through the HELP Committee.¹⁵⁶ Other committees may come in as needed. For instance, to the extent

149. Rachel E. Sachs, *Administering Health Innovation*, 39 CARDOZO L. REV. 1991, 2015 (2018).

150. 42 U.S.C. § 283a(a).

151. *Domestic MOUs*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/fda-memoranda-understanding/domestic-mous> [<https://perma.cc/AY8R-FW45>] (last updated Aug. 31, 2020).

152. Sachs, *supra* note 149, at 2041–43.

153. U.S. SENATE COMM. ON HEALTH, EDUC., LABOR & PENSIONS, *Issues*, <https://www.help.senate.gov/about/issues/> [<https://perma.cc/XE4X-A28T>]; see also U.S. Senate Rules, Rule 25(m), <https://www.rules.senate.gov/rules-of-the-senate> [<https://perma.cc/8BNJ-AEEX>].

154. U.S. Senate Rules, *supra* note 153, at 25(l).

155. *Id.* at 25(i) (noting that the Finance Committee has jurisdiction over “Health programs under the Social Security Act”).

156. *Id.* at 25(m)(1).

that the law involves funding in addition to policy changes, the Appropriations Committee may also be involved.¹⁵⁷

In the House, the structure is similar. The Energy and Commerce Committee has jurisdiction over the NIH and the FDA,¹⁵⁸ and the Judiciary Committee would control the patent-related portion of the bill.¹⁵⁹ The insurance reimbursement piece would again be split, primarily between the Energy and Commerce Committee (with jurisdiction over Medicaid and shared oversight of Medicare)¹⁶⁰ and the Ways and Means Committee (with shared oversight of Medicare).¹⁶¹ Depending on the breadth of the insurance reimbursement piece, the Committee on Education and the Workforce and the Committee on Oversight and Government Reform may also be involved, with their respective responsibilities for ERISA plans and federal government insurance.¹⁶² And as with the Senate, the Appropriations Committee may become involved with funding decisions made by the package.¹⁶³

A second example helps demonstrate how even a much narrower bill would still need to pass through multiple committees with fragmented oversight. Consider a bill that would reform coverage for a population of patients known as the “dual eligibles” — the roughly twelve million Americans enrolled in both Medicare and Medicaid.¹⁶⁴ In caring for these patients, Medicare and Medicaid interact in complex ways, with Medicare covering some benefits and Medicaid covering others.¹⁶⁵ If Congress wanted simply to tweak some small feature of these patients’ benefits, such a bill would still need to pass

157. See *id.* at 25(b); ADA S. CORNELL, CONG. RSCH. SERV., R43889, *Health Policy: Resources for Congressional Staff* 7 (June 12, 2018), <https://fas.org/sgp/crs/misc/R43889.pdf> [<https://perma.cc/3RHX-GJ42>].

158. See U.S. HOUSE COMM. ON ENERGY & COMMERCE, *Jurisdiction*, <https://energycommerce.house.gov/about-ec/jurisdiction> [<https://perma.cc/5WVY-C4WE>]; CORNELL, *supra* note 157, at 4–5.

159. U.S. HOUSE COMM. ON THE JUDICIARY, *Subcommittees: Courts, Intellectual Property, and the Internet*, <https://judiciary.house.gov/subcommittees/courts-intellectual-property-and-internet-116th-congress> [<https://perma.cc/X69Q-N6S2>] (last visited Sept. 20, 2020).

160. U.S. HOUSE COMM. ON ENERGY & COMMERCE, *supra* note 158; see also CORNELL, *supra* note 158, at 4–5.

161. U.S. HOUSE COMM. ON WAYS & MEANS, *Jurisdiction & Rules*, <https://waysandmeans.house.gov/about/jurisdiction-and-rules> [<https://perma.cc/X69Z-P79N>]; see also CORNELL, *supra* note 157, at 6–7.

162. See CORNELL, *supra* note 157, at 4, 5–6.

163. *Id.* at 3–4.

164. CTRS. FOR MEDICARE & MEDICAID SERVS., PEOPLE DUALY ELIGIBLE FOR MEDICARE AND MEDICAID (2020), https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MMCO_Factsheet.pdf [<https://perma.cc/NZ7U-JZGS>].

165. Medicaid also serves as the secondary payer for Medicare benefits. *Id.*; MACPAC, *How Medicaid Interacts with Other Payers*, <https://www.macpac.gov/subtopic/how-medicare-interacts-with-other-payers/> [<https://perma.cc/NGX2-ZW56>] (last visited Sept. 20, 2020).

through multiple committees in the House. The Energy and Commerce Committee has jurisdiction over the Medicaid portion of their benefits,¹⁶⁶ while Energy and Commerce and Ways and Means would jointly exercise jurisdiction over the Medicare portion.¹⁶⁷ In the Senate, only the Finance Committee would need to approve the changes,¹⁶⁸ but internal staff allocations of responsibility over Medicare and Medicaid may complicate matters.

B. Policymaking Fragmentation's Effects on Innovation Policy

Fragmentation in health care policymaking has at least three impacts for health innovation policy. First and most obviously, it delays and may derail the creation of new regulation and the passage of new legislation. The attempt (and failure) by the Clinton Administration to pass a comprehensive healthcare reform bill provides a clear example.¹⁶⁹ The bill would have implicated the jurisdictions of at least five committees in the House and Senate in major ways, and an additional eight or nine in more minor ways.¹⁷⁰ Further, committee chairs on the major House committees (particularly Ways and Means, Energy and Commerce, and Education and Labor) struggled to “stake out the widest possible jurisdictions for themselves to maintain *future* control” of the program.¹⁷¹ While jurisdictional disputes were of course not the only factor in the Clinton plan’s failure to pass,¹⁷² the time and political capital spent in these negotiations surely did not help the bill’s prospects.¹⁷³

Second, fragmentation forces health care policymaking into particular channels and forms. A legislator or agency official focusing on an innovation-related problem will be limited to her committee’s jurisdiction or her agency’s organic statute in identifying and implementing solutions to that problem. In order to use additional legal tools, she may try to convince actors on other committees or in

166. U.S. HOUSE COMM. ON ENERGY & COMMERCE, *supra* note 158.

167. *See id.*; U.S. HOUSE COMM. ON WAYS & MEANS, *supra* note 161.

168. *See* U.S. Senate Rules, *supra* note 153, at 25(i).

169. For a comprehensive history of this effort, see HAYNES JOHNSON & DAVID S. BRODER, *THE SYSTEM* (1st ed. 1996).

170. *Id.* at 621.

171. *Id.* at 455.

172. One factor commonly pointed to was the advertising campaign against the bill run primarily through the Health Insurance Association of America, the trade organization representing insurance companies. *Id.* at 198–99, 204–13; *see also* Dan Diamond, ‘Harry and Louise’ — and Hillary, POLITICO (May 12, 2016, 5:28 PM), <https://www.politico.com/story/2016/05/harry-louise-and-hillary-clinton-223139> [<https://perma.cc/KP6D-KXMR>].

173. In theory, passage through each committee was not required. There was discussion in the House of Representatives of creating an ad hoc “supercommittee” composed of representatives of each of the relevant committees, which would streamline the legislative process. However, the relevant committee chairs opposed the move. JOHNSON & BRODER, *supra* note 169, at 305, 621.

related agencies to work with her, but that collaboration is difficult, costly for resource-constrained agencies, and may delay or disrupt potential legislation.

Some examples of this may be found in the lengthy, distinguished government service of Representative Henry Waxman. Under Representative Waxman's fifteen-year chairmanship of the Health and Environment Subcommittee of the Energy and Commerce Committee,¹⁷⁴ some of the laws that are most important to our health innovation ecosystem were passed. Representative Waxman's leadership in developing legislation like the (subsequently named) Hatch-Waxman Act and the Orphan Drug Act¹⁷⁵ intersects in important ways with the Energy and Commerce Committee's jurisdiction.

The Hatch-Waxman Act was a legislative compromise,¹⁷⁶ creating an abbreviated path to market for generic versions of branded drugs¹⁷⁷ but also providing a period of patent term extension for time that branded drugs lose traversing the FDA approval process.¹⁷⁸ The aim of the generic drug portion of the bill was to make lower-priced versions of drugs available to American patients, and Representative Waxman was able to do so through the FDA, over which his committee had jurisdiction. However, the patent term restoration portion of the law ran through the Judiciary Committee, which subsequently approved the bill.¹⁷⁹

Similarly, Representative Waxman led the creation and passage of the Orphan Drug Act, designed to incentivize the development of drugs for the treatment of rare diseases. The Act provides both patent-like exclusivity periods to companies obtaining FDA approval for

174. HENRY WAXMAN, *THE WAXMAN REPORT* 30, 34, 131 (1st ed. 2009) (noting that he assumed the Chairmanship in 1979 and relinquished it when control of the House transferred to Republicans in 1994).

175. Representative Waxman also played a key role in the creation and passage of the Affordable Care Act and the Children's Health Insurance Program. Jonathan Weisman, *Henry Waxman, Key Democrat and Force for Health Care Law, Is to Retire*, N.Y. TIMES (Jan. 30, 2014), <https://nyti.ms/1eiQSYi> [<https://perma.cc/UU68-9L9K>]. But those laws were more leadership-driven and involved more committees than did the Hatch-Waxman Act and the Orphan Drug Act, which Waxman developed and promoted himself. Cf. Robert A. Katzmann, *Making Sense of Congressional Intent: Statutory Interpretation and Welfare Policy*, 104 YALE L.J. 2345, 2361 (1995) (noting that congressional organization reforms increased fragmentation but provided more opportunities for legislative entrepreneurship); GREGORY WAWRO, *LEGISLATIVE ENTREPRENEURSHIP IN THE U.S. HOUSE OF REPRESENTATIVES 2* (2001) (defining legislative entrepreneurship and noting its importance in the drafting and passage of legislation).

176. See, e.g., Rebecca S. Eisenberg & Daniel A. Crane, *Patent Punting: How FDA and Antitrust Courts Undermine the Hatch-Waxman Act to Avoid Dealing with Patents*, 21 MICH. TELECOMMS. & TECH. L. REV. 197, 244 (2015); Dan L. Burk, *Means and Meaning in Patent Remedies*, 92 TEX. L. REV. SEE ALSO 13, 22 (2013).

177. See 21 U.S.C. § 355(j).

178. See 35 U.S.C. § 156(c).

179. *Generic Drug Legislation Cleared by Congress*, CQ ALMANAC (1984).

these products, as well as research and development tax credits.¹⁸⁰ Representative Waxman was easily able to shepherd the FDA exclusivity periods through the Energy and Commerce Committee, but the addition of the tax credits meant that the bill also implicated the jurisdiction of the Ways and Means Committee in the House, and the Finance Committee in the Senate.¹⁸¹ The involvement of these different committees, particularly in the Senate, jeopardized the bill's passage, but public pressure ultimately prevailed to drive it through Congress.¹⁸²

Representative Waxman's creative solutions to these policy problems undoubtedly worked — but they were possible only because he controlled the relevant subcommittee of key jurisdiction. If he had hoped to solve them either in whole or in part with different policy tools, he would have had to rely more heavily on the leaders of other committees. In some ways, the committee and agency structure puts blinders on our policymakers: They only “see” or have access to certain types of policy levers, and they must rely on other committees or agencies to use other tools. Many of these problems can be addressed using a range of policy levers, but each has their pros and cons,¹⁸³ and it may be that an ideal solution to the problem of less-expensive prescription drugs would have involved health laws within the jurisdiction of the Ways and Means Committee, for instance.

Third, the fragmentation of authority and functions between different agencies and committees prevents any particular agency or committee from internalizing the full costs and benefits of an innovation-related action it might take. As a result, an agency may make a policy decision that redounds to its benefit, but that imposes other costs on the system as a whole — perhaps costs that outweigh the initial benefits. Two examples of ways in which NIH and FDA decisions may benefit those agencies but cause problems for CMS more generally are instructive. As one example, when NIH researchers make an important scientific discovery, the agency may seek to license that discovery to the private sector for further development and eventual commercialization.¹⁸⁴ In general, this is a

180. Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303, 378–79 (2013); Orphan Drug Act, Pub. L. No. 97-414, § 2, § 4, 96 Stat. 2049, 2050–51, 2053–56 (1983). The 2017 tax reform in Congress reduced this tax credit from 50% to 25%. Act of Dec. 22, 2017, Pub. L. No. 115-97, § 13401, 131 Stat. 2054, 2133–34 (entitled “Modification of Orphan Drug Credit”).

181. WAXMAN, *supra* note 174, at 65–67.

182. *Id.* at 58–60, 67–68.

183. See Heled, *supra* note 138, at 430–32.

184. Zachary Brennan, *NIH's Exclusive Licenses to Biotech, Pharma Start-Ups: Lots of Secrecy, Few Successes*, REGUL. AFFS. PROFS. SOC'Y (May 10, 2016), <https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2016/5/nih%E2%80%99s-exclusive-licenses-to-biotech,-pharma-start-ups-lots-of-secrecy,-few-successes> [<https://perma.cc/A5KR-PPUX>].

positive occurrence, not only for the NIH (which benefits financially through the royalties it receives) but also for society, if these promising new therapies do come to market. However, the NIH is able to grant exclusive licenses, such that one company will control the resulting product and its intellectual property.¹⁸⁵ In such a case, the company may possess great bargaining power in its negotiations with subsequent insurers, including CMS, in its administration of the Medicare and Medicaid programs. To put it more succinctly, the NIH may earn money from the grant of an exclusive license — and CMS must then pay monopoly prices for the resulting technology.

As another example, the FDA administers a number of programs designed to expedite new drugs for unmet needs to market, as noted above.¹⁸⁶ Each program shares this goal of faster approval, even as they all have slightly different requirements before a manufacturer may qualify for these programs (though companies often qualify for more than one of the programs) and entitle manufacturers to slightly different sets of FDA benefits upon qualification. Perhaps most substantively, the Accelerated Approval program enables manufacturers to obtain FDA approval for a product intended to treat a “serious or life-threatening disease or condition” if the manufacturer demonstrates improvement in a surrogate endpoint “that is reasonably likely to predict clinical benefit.”¹⁸⁷ A surrogate endpoint “is a laboratory measurement or a physical sign used as a substitute for a clinically meaningful endpoint that measures directly how a patient feels, functions, or survives.”¹⁸⁸ A classic example is cholesterol; a drug intended to decrease a patient’s risk of death from heart attack may do so by lowering their cholesterol. The clinical trials for the product in question may measure only the cholesterol level rather than the rate of heart attacks among the trial population, allowing the trial to be completed more speedily and cheaply.¹⁸⁹ The Accelerated Approval program requires manufacturers to complete post-approval clinical trials to verify the drug’s effectiveness on the true clinical endpoint at issue.¹⁹⁰ However, these trials are often not completed.¹⁹¹

185. *Id.*

186. *Guidance for Industry: Expedited Programs for Serious Conditions — Drugs and Biologics*, CTR. FOR DRUG EVALUATION & RES. 1, 7–8 (2014), <https://www.fda.gov/media/86377/download> [https://perma.cc/6V7M-BGHU] (comparing FDA programs for expediting drug approval).

187. 21 U.S.C. § 356(c)(1)(A).

188. Robert J. Temple, *A Regulatory Authority’s Opinion About Surrogate Endpoints*, in *CLINICAL MEASUREMENT IN DRUG EVALUATION* 3, 4 (Walter S. Nimmo & Geoffrey T. Tucker eds., 1995); *see also* 21 C.F.R. § 314.510 (2017).

189. Katalin Bognar et al., *The Role of Imperfect Surrogate Endpoint Information in Drug Approval and Reimbursement Decisions*, 51 *J. HEALTH ECON.* 1, 2 (2017); *see also* Thomas R. Fleming, *Surrogate Endpoints and FDA’s Accelerated Approval Process*, 24 *HEALTH AFFS.* 67, 67–68 (2004).

190. 21 U.S.C. § 356(c)(2)(A).

The FDA's approval of these drugs on the basis of surrogate endpoints creates problems for CMS and the health care system more generally. When the FDA approves these drugs, there is uncertainty about whether they actually provide clinical benefits for patients. If confirmatory trials are not completed, physicians may struggle in counseling their patients about their treatment options. When confirmatory trials are completed, at least some of these drugs turn out not to provide any clinical benefit.¹⁹² Yet under current law, Medicare and Medicaid must cover most and in many cases all of these drugs. That coverage requirement places the bargaining power in the hands of pharmaceutical companies, enabling them to charge high prices, often in the hundreds of thousands of dollars, for drugs with no demonstrated clinical efficacy.¹⁹³ The FDA may benefit from approving these drugs, as it mitigates criticism often levied against the agency for the length of its approval process.¹⁹⁴ But CMS incurs costs since it must pay for these products, and it has little ability to provide helpful information to providers about when they may seek to use one drug or another.

VI. IDENTIFYING OPPORTUNITIES FOR INTEGRATION

Parts III, IV, and V have described particular forms of health care fragmentation and articulated the ways in which they bias innovation incentives away from different types of socially valuable health care technologies and policies. In short, health law and health institutions create misaligned incentives in terms of both providing cost-effective, quality care and developing new health care technologies. This Part first contends that this bias is a problem to be solved, arguing that policymakers should pursue solutions aimed at promoting integration in our health care system. This Part then articulates several legal solutions at different levels of generality, arguing that many of these proposals have the potential to address not only this innovation-related concern but also the more traditional cost and quality concerns expressed by scholars regarding health care fragmentation generally.

191. Huseyin Naci et al., *Characteristics of Preapproval and Postapproval Studies for Drugs Granted Accelerated Approval by the US Food and Drug Administration*, 318 J. AM. MED. ASS'N 626, 634 (2017).

192. See, e.g., Elisabeth Mahase, *Preterm Births: US Panel Recommends Withdrawal of Prevention Drug in Controversial Vote*, 367 BMJ 1, 1 (2019).

193. See, e.g., Aaron S. Kesselheim & Jerry Avorn, *Approving a Problematic Muscular Dystrophy Drug: Implications for FDA Policy*, 316 J. AM. MED. ASS'N 2357, 2358 (2016).

194. In fact, the FDA typically reviews and approves new drug applications more quickly than do other pharmaceutical regulators. See Nicholas S. Downing et al., *Regulatory Review of Novel Therapeutics — Comparison of Three Regulatory Agencies*, 366 NEW ENG. J. MED. 2284, 2284 (2012).

This analysis adds to the existing scholarly discussion in at least two ways. First, the innovation biases created by health care fragmentation not only strengthen the existing case for integration-encouraging reforms, but also tell us about what kinds of reforms might be preferred. Particularly where scholars largely lack a theory of optimal health care fragmentation, bringing an innovation perspective into the analysis helps point the way toward metrics that can be brought to bear on this question. And second, using an innovation lens helps expose gaps in currently proposed solutions to health care fragmentation and demonstrates why other legal levers might be more or at least differently effective. Specifically, existing proposals that rely on legal tools including fraud and abuse laws or antitrust reform are unlikely to address the innovation incentive problem.

A. Framing the Approach to Integration

Fragmentation in health care is not, on its own, necessarily a problem to be solved. Some degree of fragmentation along different dimensions within our health care system is desirable. Physician specialization may increase fragmentation of care for a particular patient, but it may also increase care quality as physicians deepen their experience with particular conditions. The proliferation of and competition between providers, hospitals, or insurers may promote competition or drive down costs.

But scholars have objected to forms of fragmentation that impose harmful consequences on health care costs, quality, and patient care, arguing that they represent a problem to be solved. In many cases, the claim is that these harms are caused by fragmentation and can be resolved through integration-promoting reforms. The push to render EHRs interoperable falls into this category — there are few benefits but real harms where these records are designed to prevent communication with each other, and promoting interoperability pushes the system towards a single standard, if not a single type of EHR.¹⁹⁵

In other cases, scholars recognize the benefits of fragmentation but seek to reduce its harms. For instance, the promotion of care

195. In other words, all such records might operate through a single software platform or would use a common type of interface, but could still be customized and serviced by many different vendors. As an analogy, in the electronic industry, participants have often employed common standards for a particular technology. When a consumer purchases a compact disc (CD), that CD will work on a CD player made by any company; those companies have all agreed to pool any technology they own that is essential to practice that particular standard, and then to employ that standard going forward. *See, e.g.*, Jonathan M. Barnett, *The Anti-Commons Revisited*, 29 HARV. J.L. & TECH. 127, 184 (2015). One could imagine a similar practice in the EHR context.

coordination efforts does not seek to disrupt the model of physician specialization, but rather seeks to mitigate the patient care harms that may result from fragmented care. Care coordination may increase costs further in the process, if it involves additional health care professionals in a patient's care, or it may lower them, if it avoids wasteful or harmful care. But the promotion of care coordination itself is agnostic as to the financial result.

The existing literature convincingly makes the case that fragmentation imposes serious costs of various kinds, and that at least some integration-promoting reforms would be valuable to pursue.¹⁹⁶ However, the literature also lacks a theory of optimal integration of decision-making. Without such a theory, it is difficult to identify and evaluate potential solutions to fragmentation because there is no clear answer as to how far efforts to promote health care integration should go. Even if there is broad agreement that the system has currently gone too far in the direction of fragmentation along several dimensions, the concern is that potential solutions — particularly ones which are too prescriptive about the ultimate outcome to be achieved — may resolve the issue too far in the other direction, forgoing some of the benefits of fragmentation and creating new harms.

As a result, existing proposals often make space for or encourage health care integration but do not mandate a particular outcome, in an effort to decrease the harms associated with the current approach but also avoid the potential costs of bureaucratic error. The example of EHRs is again instructive. The HITECH Act offered tens of billions of dollars in subsidies for EHR systems — on the condition that providers achieve “meaningful use” of those platforms,¹⁹⁷ a standard which aims to promote interoperability.¹⁹⁸ However, the Act did not specify the form of the EHR system, identifying only a set of goals and leaving the implementation details to private actors. The hope is that actors on the ground will identify better solutions to these problems when financially incentivized to do so (and sometimes penalized when they do not) than will policymakers acting at some distance.¹⁹⁹

Incorporating into the discussion the above-described ways in which health care fragmentation biases innovation incentives away from new technologies that might be socially valuable helps

196. See *supra* text accompanying notes 17–34.

197. Terry, *supra* note 34, at 46–47.

198. *Promoting Interoperability*, CTRS. FOR MEDICARE & MEDICAID SERVS. (2019), <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index?redirect=/ehrincentiveprograms/> [<https://perma.cc/8CRU-JEYR>].

199. See Terry, *supra* note 34, at 56–57.

strengthen existing arguments in favor of promoting health care integration in at least two ways. First, these innovation-related biases only add to the more visible existing costs of fragmentation. On top of the increased health care costs and quality harms that result from different forms of fragmentation, we can add this more invisible harm — the creation of an incentive system that is biased against certain types of socially valuable health care technologies. As a result, the already articulated costs are greater than previously described. So too, therefore, is the case that our health care system is tilted too far towards fragmentation.

Second, the forms of fragmentation articulated in Parts III, IV, and V were not designed to have the described innovation-related effects. Rather, the innovation biases resulting from these forms of fragmentation are an unintended consequence of other policies. Some of those policies are supported by strong arguments. Dividing health care decision-making authority between a number of different executive branch agencies within the Department of Health and Human Services (“HHS”) has the feature of enabling each agency to specialize in a particular aspect of health care policymaking, even as it functions to disaggregate responsibility for pharmaceutical innovation. But other policies are simply accidents of history. For instance, there was little need for a standard pharmacy benefit at the time of Medicare’s passage in 1965. Part D’s creation four decades later has largely siloed prescription drugs from other Medicare benefits, which may not have happened if the entire package had been developed at the same time. If there is no particular policy advantage of or reason behind such fragmentation, it suggests that moving in the direction of health care integration may not be subject to costs in the same way.

This second argument helps point toward an optimal framework for health care fragmentation, if the system is viewed from an innovation perspective. Overall, our health care system should aim to debias innovation incentives, all things considered. More specifically, our system should not *accidentally* devalue the development of drugs that are primarily valuable among low-income Americans as compared with drugs that are primarily valuable among the elderly,²⁰⁰ or cures as compared to maintenance drugs,²⁰¹ or drugs for late-stage cancers as compared to early-stage cancers,²⁰² or non-drug interventions as compared to drugs.²⁰³ To be sure, we may choose to

200. See Sachs, *supra* note 85, at 199.

201. See Kim, *supra* note 90.

202. Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials*, 105 AM. ECON. REV. 2044, 2044 (2015).

203. See Kapczynski & Syed, *supra* note 114, at 1902–03.

do so purposefully. But by and large, the examples presented in Parts III, IV, and V seemingly did not intend to create the innovation biases that resulted.

In general, we should strive for a reimbursement system that aligns our prescription drug purchasing decisions with some measure of social value. HHS seemingly agrees with this goal, as it has been striving to increase the amount of its reimbursement that is based on quality or value, rather than volume (a development that, to date, has been limited to healthcare services rather than technologies).²⁰⁴ In the long run, this may mean designing a reimbursement system to avoid the types of biases articulated in the previous parts. In the short term, it may mean simply identifying different payment biases and their innovation impacts and taking steps to redress those specific biases. At the very least, though, it means being purposeful and intentional about changes to our health care system and the potential impacts they may have on both fragmentation and innovation. There is no single way to accomplish these goals, although different strategies at different levels of generality are articulated in the next subpart.

Although this Article has used terms like “debias” in arguing for this vision of a more ideal reimbursement system, it is important to be clear that no reimbursement system can be truly neutral. Adopting a reimbursement system to align drug purchasing with social value is itself a choice, one that promotes investment in certain types of projects over others. Policymakers may well choose to implement explicit tweaks to such a system, as seen through the statutory creation of special FDA-administered incentives to develop drugs for diseases affecting children,²⁰⁵ or incentives that encourage the development of drugs for rare diseases.²⁰⁶ But in practice, express societal preferences like these have typically been implemented through the NIH or FDA, not through health insurance. The

204. *Better, Smarter, Healthier: In Historic Announcement, HHS Sets Clear Goals and Timeline for Shifting Medicare Reimbursements from Volume to Value*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Jan. 26, 2015), <https://wayback.archive-it.org/3926/20170127185400/http://www.hhs.gov/about/news/2015/01/26/better-smarter-healthier-in-historic-announcement-hhs-sets-clear-goals-and-timeline-for-shifting-medicare-reimbursements-from-volume-to-value.html> [https://perma.cc/H52N-UGVY] (setting goals “of tying 85 percent of all traditional Medicare payments to quality or value by 2016 and 90 percent by 2018”); Sylvia M. Burwell, *Setting Value-Based Payment Goals — HHS Efforts to Improve U.S. Health Care*, 372 *NEW ENG. J. MED.* 897, 897 (2015).

205. See, e.g., Amy C. Madl, *Using Value-Agnostic Incentives to Promote Pharmaceutical Innovation*, 71 *STAN. L. REV.* 1305, 1338 (2019) (describing the pediatric priority review voucher system); Kurt R. Karst, *Pediatric Testing of Prescription Drugs: The Food and Drug Administration’s Carrot and Stick for the Pharmaceutical Industry*, 49 *AM. U. L. REV.* 739, 742–43 (2000) (discussing the six months of additional exclusivity provided to manufacturers who conduct pediatric studies on their drugs).

206. Michael Abramowicz, *Orphan Business Models: Toward a New Form of Intellectual Property*, 124 *HARV. L. REV.* 1362, 1384–88 (2011) (describing the Orphan Drug Act).

implication is that our reimbursement system is already neutral with respect to innovation,²⁰⁷ and incentives can best be administered from the outside, rather than disrupting our existing reimbursement structure. But because our reimbursement system largely represents a series of historical accidents, it is not meaningful to talk about the incentives it creates as representing a chosen, optimal set.

To be sure, this more ideal reimbursement system that aligns reimbursement with social value is also agnostic about the results to be achieved and does not prescribe a particular form of innovation. Innovation by its nature is unpredictable, and it is generally not possible to fully specify in advance the types of transformative treatments we hope to encourage scientists to discover and deliver to patients.²⁰⁸ Yet where systemic costs or innovation biases can be identified and are likely to discourage the development of socially valuable products, those biases should be addressed.

With this revised vision of a health care reimbursement system in mind, it is easy to see how some of the legal tools scholars have proposed to deal with previously articulated forms of fragmentation would not likely have an effect here. Scholars have argued that legal tools drawn from antitrust law, fraud and abuse law, and state regulations can limit the harmful effects of certain types of health care fragmentation.²⁰⁹ Legal tools like these may well help address systemic costs stemming from the kinds of fragmentation that have concerned those scholars, at the level of patient care and institutional structure. But they will do little to address the forms of fragmentation that skew innovation incentives. Solutions to these problems must be found elsewhere in the law.

B. Articulating Potential Solutions

This subpart aims to identify legal reforms with the ability to debias the above-described incentive skews by promoting integration in prescription drug reimbursement. These legal reforms exist at

207. To be sure, the system also contains explicit preferences for access in certain populations. Beyond Medicare's focus on elderly Americans or the broad-based Children's Health Insurance Program, Congress has created smaller programs to meet the health care needs of particular, often vulnerable patient populations, including the Ryan White HIV/AIDS Program, 42 U.S.C. § 300ee, and the Black Lung Benefits Act, 30 U.S.C. § 901.

208. To that end, we may recognize that there are particular diseases with a high societal burden of illness but that lack effective treatments (such as Alzheimer's disease), and we may create special incentives for these treatments, through the reimbursement system or otherwise (such as through grants). See W. Nicholson Price II, *Grants*, 34 *BERKELEY TECH. L.J.* 1, 3–4 (2019).

209. See, e.g., Tim Greaney, *Competition Policy and Organizational Fragmentation in Health Care*, 71 *U. PITT. L. REV.* 217, 225, 228–29 (2009); Timothy Stoltzfus Jost & Ezekiel J. Emanuel, *Legal Reforms Necessary to Promote Delivery System Innovation*, 299 *J. AM. MED. ASS'N* 2561, 2561–62 (2008).

different levels of generality, some achieving a broader incentive realignment and others solving more specific problems. These solutions also exist at different levels of feasibility, with more specific solutions possible (at least in part) under existing legal arrangements, and broader reforms requiring substantial legislative changes.

Before articulating the contours of potential solutions, however, it is useful to be clear about the ways in which they would or would not construct a system that aligns reimbursement with social value. Specifically, there is a distinction between *whether* our system provides reimbursement for a particular technology, and *how much* reimbursement it provides. We may well solve the problem of fragmentation over time’s disincentive to provide reimbursement at all (a “whether” problem), but we may do so in a way that bears no resemblance to the overriding question of social value. In other words, we may ensure that our system pays for the latest gene therapies — but if *how much* we pay for them bears no relation to the value they provide to society, our system will not achieve the goal of aligning reimbursement with social value. None of the below reforms inherently solve this problem. However, they could all be coupled — some more easily than others — with reforms that address this issue.²¹⁰

1. Systemic Integration-Encouraging Reforms

Policymakers may wish to identify a single solution that would address each of the above three fragmentation-induced disincentives. The most obvious such solution is universal health care, although there are nearly infinite ways to implement such a program. Nearly all Organization for Economic Corporation and Development (“OECD”) countries (except the United States) offer universal health care to their citizens,²¹¹ but these programs are implemented in different ways. The United Kingdom’s National Health Service (“NHS”) model, providing health care for all through a public, government-run system financed through taxes,²¹² differs starkly from Germany’s model, involving many highly regulated insurers (both public and private),

210. Although I nod to some of these reforms in the explanations of potential solutions for the different types of fragmentation, I and others have explored them in more detail elsewhere. *See generally, e.g.*, Mark Lemley, Lisa Larrimore Ouellette & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 N.Y.U. L. REV. 75 (2020); Steven D. Pearson, Len Nichols & Amitabh Chandra, *Policy Strategies for Aligning Price and Value for Brand-Name Pharmaceuticals*, HEALTH AFFS., Mar. 15, 2018.

211. *Universal Health Coverage*, OECD, <https://www.oecd.org/els/health-systems/universal-health-coverage.htm> [https://perma.cc/32YV-75SB].

212. The United Kingdom is typically observed to be a paradigm example of the Beveridge model of national health insurance. Timothy Stoltzfus Jost, *Why Can’t We Do What They Do? National Health Reform Abroad*, 32 J.L. MED. & ETHICS 433, 433–34 (2004).

hospitals, and physicians.²¹³ These different models illustrate that there are many different ways to design methods of paying for and delivering health care on a nationwide scale. Most importantly, though, each of these models works to provide affordable health care for all of the relevant country's residents.

Each of these models is also capable of solving the problems of fragmentation that contribute to distortions in innovation incentives, irrespective of the details of the program. This is most obviously true in the case of fragmentation over time. A national health insurance system where a person will be insured by the government throughout that person's lifetime has no incentive to delay effective care until the person becomes the responsibility of another insurer, as there is no other insurer. Even in a system of multiple insurers, required benefits packages may be set by a central governing body in a way that prevents insurers from denying such care.

Similarly, in practice even very different systems of social health insurance avoid the problem of fragmentation by benefit structure, both in terms of insurers' incentives and in terms of patients' incentives. With few exceptions internationally, insurers are responsible for all of a beneficiary's care, and it is not divided up between medical insurers and pharmacy insurers.²¹⁴ The issue of American patients' incentives to avoid needed pharmaceutical treatment due to high deductibles and out-of-pocket payments is largely avoided as these countries highly constrain patients' out-of-pocket costs to just a few dollars per prescription, if any payment is required at all.²¹⁵

213. Germany is often referred to as a core example of the social insurance or Bismarck model, where citizens must obtain insurance, but that insurance may be provided by a regulated private provider rather than the government. *Id.* For a more detailed history of this model, see Henry E. Sigerist, *From Bismarck to Beveridge: Developments and Trends in Social Security Legislation*, 20 J. PUB. HEALTH POL'Y 474 (1999).

214. See, e.g., Jaden Brandt et al., *Prescription Drug Coverage in Canada: A Review of the Economic, Policy, and Political Considerations for Universal Pharmacare*, 11 J. PHARM. POL'Y & PRAC. 1, 2 (2018).

215. NHS patients are often entitled to free drugs at the pharmacy but cannot be asked to pay more than £9.15 per prescription (approximately \$12 in U.S. dollars). See *Help with NHS Prescription Costs*, NAT'L HEALTH SERV., <https://www.nhs.uk/help-nhs-prescription-costs> [<https://perma.cc/BPV2-4XT2>] (last visited Nov. 13, 2020). Most drugs in the German system have co-pays of just a few euros. See James C. Robinson, Dimitra Panteli & Patricia Ex, *Reference Pricing in Germany: Implications for U.S. Pharmaceutical Purchasing*, COMMONWEALTH FUND, Feb. 2019, at 1, 4, https://www.commonwealthfund.org/sites/default/files/2019-02/Robinson_reference_pricing_germany_ib.pdf [<https://perma.cc/DRZ3-WACB>]. But Medicare beneficiaries can be required to pay thousands of dollars out of pocket, without limit, for their medications. See Juliette Cubanski et al., *No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending*, KAISER FAM. FOUND. (Nov. 7, 2017), <https://www.kff.org/medicare/issue-brief/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending/> [<https://perma.cc/S5GR-CXPR>].

In part because the above problems of fragmentation have been addressed by comprehensive health care provisions, any fragmentation in policymaking that does exist has less ability to create innovation distortions. As in the U.S., prescription drug regulators in other countries are typically separate from the agencies that administer health insurance programs,²¹⁶ an arrangement with the potential to cause the type of externality concerns that arise here as well. That is, if European pharmaceutical regulators choose to approve a drug on the basis of little evidence, there is the potential to externalize the costs of that approval onto insurance regulators. However, these countries in practice decouple the decisions made by these actors and do not impose the same coverage requirements on their insurance regulators that the United States does.²¹⁷ The NHS makes an independent decision whether or not to provide reimbursement for a newly approved drug, based on the evidence marshaled in support of that drug's approval and its price.²¹⁸ The NHS's ability to decline to provide reimbursement for a drug if the pharmaceutical company is aiming to charge a price out of proportion to the evidence of the drug's clinical benefits increases the agency's bargaining power over drug pricing and limits the pharmaceutical regulators' ability to impose the costs of speedier drug approval processes on national health care budgets.²¹⁹

A highly regulated system of universal health care coverage, whether implemented primarily through a public payer or through a network of private payers, can address each of these innovation distortions through a single set of reforms. However, if this system is unlikely to be adopted in the near term, additional innovation-related solutions may be found that are particular to each of the above-described forms of fragmentation.

2. Narrowly Tailored Integration-Encouraging Reforms

Rather than pursuing a broad-based health care overhaul, policymakers may instead choose more narrowly tailored reforms within each of the three described areas of fragmentation — over

216. That is, the European Medicines Agency (the analogue to our FDA) exists separate and apart from the national health insurers.

217. See Jeanne Whalen, *Why the U.S. Pays More Than Other Countries for Drugs*, WALL ST. J. (Dec. 1, 2015, 9:27 PM), <https://www.wsj.com/articles/why-the-u-s-pays-more-than-other-countries-for-drugs-1448939481> [<https://perma.cc/ELS6-PV7H>]; Lemley, Ouellette & Sachs, *supra* note 210, at 95–96.

218. NICE *Technology Appraisal Guidance*, NAT'L INST. FOR HEALTH & CARE EXCELLENCE, <https://www.nice.org.uk/About/What-we-do/Our-Programmes/NICE-guidance/NICE-technology-appraisal-guidance> [<https://perma.cc/5863-8STM>].

219. See Whalen, *supra* note 217 (“Of 40 branded drugs covered by Medicare Part B and also available in England in the third quarter [of 2015], 98% were more expensive in the U.S[.]”).

time, by benefit structure, and by policymaker. These reforms are largely integration-encouraging, rather than integration-forcing. They make it clear that increased integration is valuable and will be rewarded in some fashion, but they also allow Congress to leave the choice of how far to integrate mostly to subject matter experts, in both government and the private sector. At present, both governmental actors and private sector entities have tried to implement versions of some of the below reforms, but their actions are largely workarounds for the existing legal system or are otherwise limited by law and regulation. It would be better for Congress and the executive branch to expand these actors' ability to engage in reforms like these more generally, rather than force them to fit their proposals within existing regulatory authorities.

a. Fragmentation Over Time

Patient churn into and out of different insurance plans over time discourages insurers from covering costly one-time therapies, if that insurer will be responsible for all of the costs of that therapy but will receive few if any of its resulting health benefits.²²⁰ The unpredictability of these financial burdens can also pose problems for insurers. Particularly for state Medicaid programs, which operate with balanced-budget constraints (i.e., limits on their ability to incur deficits),²²¹ a newly approved product with a price in the millions of dollars may impose an unpredictable, unaffordable burden in the short term. Compounding the issue is that some of these treatments may be approved for very small patient populations, affecting just a few hundred or thousand people in the United States.²²² At those rates, it may be a matter of luck whether an insurer has such a patient in their risk pool. Scholars and policymakers have argued that a form of single payer insurance for these one-time treatments might be valuable,²²³ but in the absence of such a program, other creative solutions have been proposed.

220. See *supra* Section III.B.

221. See Gamage, *supra* note 76, at 755.

222. See, e.g., *FDA Approves Novel Gene Therapy to Treat Patients With a Rare Form of Inherited Vision Loss*, FOOD & DRUG ADMIN. (Dec. 18, 2017), <https://www.fda.gov/news-events/press-announcements/fda-approves-novel-gene-therapy-treat-patients-rare-form-inherited-vision-loss> [<https://perma.cc/9CPQ-HLKL>] (noting that the condition affects “approximately 1,000 to 2,000 patients in the U.S.”).

223. See Bill Cassidy, *How Will We Pay for the Coming Generation of Potentially Curative Gene Therapies?*, STAT NEWS FIRST OPINION (June 12, 2019), <https://www.statnews.com/2019/06/12/paying-for-coming-generation-gene-therapies/> [<https://perma.cc/24EH-24Y4>] (“Medicaid or some other government program could pay for gene therapies . . . Society as a whole pays, as opposed to just the insurance pool to which the patient belongs at the time the therapy is given.”). Bill Cassidy is a United States Senator from Louisiana.

Many of these solutions share the same features: they would allow for the cost of these single-dose therapies to be paid over time, rather than all at once. But they vary in their details. One potential reform strategy would enable employers or insurers (depending on the plan design) to pay a small monthly amount for each beneficiary in exchange for access to a pool of eligible gene therapies, whether or not they enroll any beneficiaries who need such treatments.²²⁴ Another reform strategy would create a quasi-mortgage, in which an insurer covering a patient would pay a portion of the cost of the received therapy each year that a patient remains on their insurance plan.²²⁵ In theory, this mortgage would transfer with a patient to a subsequent insurer, but such agreements would necessarily have to contemplate scenarios in which a patient lost their insurance but did not obtain subsequent insurance, or in which a patient passed away before the payments were completed.

From a practical perspective, strategies like these have pros and cons. They allow employers and insurers to smooth potential risks over time, which should encourage insurers to provide access to these new therapies, thereby increasing innovation incentives in that area. However, they may be administratively challenging to implement, and they will only work for one-time therapies with high prices. That is, these strategies might increase access to a million-dollar one-time treatment. But these strategies will not work for a drug that costs several hundred thousand dollars, but must be taken continuously, even if the aggregate price far outweighs that of the one-time therapy.²²⁶ Perhaps more fundamentally, these strategies are not necessarily coupled with reforms to an underlying drug pricing system and may even encourage higher list prices in the first instance.

Varying arrangements of intermediaries have already sprung up in an effort to implement some of the above strategies.²²⁷ However,

224. Jeremy Schafer, *Should Employers Take a Chance on Little-Known Embarc to Pay for Gene Therapy?*, STAT NEWS FIRST OPINION (Nov. 12, 2019), <https://www.statnews.com/2019/11/12/embarc-program-pay-gene-therapy/> [<https://perma.cc/6LQA-BT5J>]; see also *Cigna Health Services Business Pioneers an Innovative Solution to Affordably Bring Life-Changing Therapies to Patients*, CIGNA (Sept. 5, 2019), <https://www.cigna.com/newsroom/news-releases/2019/cigna-health-services-business-pioneers-an-innovative-solution-to-affordably-bring-life-changing-therapies-to-patients> [<https://perma.cc/93PB-3SPF>].

225. See Montazerhodjat et al., *supra* note 82, at 1; Cassidy, *supra* note 223.

226. For example, Spinraza, a drug that treats spinal muscular atrophy, costs \$750,000 in the first year of treatment and then about \$375,000 a year after that, resulting in a total cost of \$4 million over a decade. Thomas, *supra* note 1.

227. See, e.g., Shelby Livingston, *Cigna Aims To Expand Affordable Access to Gene Therapies*, MODERN HEALTHCARE (Sept. 6, 2019, 6:10 PM), <https://www.modernhealthcare.com/payment/cigna-aims-expand-affordable-access-gene-therapies> [<https://perma.cc/5B2K-A3FY>]; *AveXis Announces Innovative Zolgensma Gene Therapy Access Programs for US Payers and Families*, NOVARTIS (May 24, 2019),

existing legal arrangements prevent full experimentation with the above strategies. For instance, Novartis has announced that it will work with payers to make available Zolgensma, its \$2.1 million gene therapy for spinal muscular atrophy, through five-year pay-over-time options rather than only through a large up-front payment.²²⁸ Yet private insurers will find it difficult to enter into these arrangements when so many legal questions about their implementation remain unsettled (such as how these payments would transfer to a second insurer, if the beneficiary changes insurers in that time frame).²²⁹ And it may not be possible for most state Medicaid programs to enter into such arrangements, in the absence of such transferability — they likely cannot make these payments if the patient in question has died or become a beneficiary of another insurance plan.

Legal reforms could permit all payers to experiment with broader integration of these benefits over time, without resort to costly intermediaries. Statutory changes at the state and federal level could remove many of the problems state Medicaid programs might face in implementing these payment models. Alternatively, it is possible that CMS could use its existing waiver authority to greenlight broader experimentation than exists today, if not as fully as might be possible with legislation. Federal legislation might be needed to enable the transfer of a drug mortgage between insurers, although CMS might be able to implement a program between Medicare and Medicaid itself through regulation.²³⁰

b. Fragmentation by Benefit Structure

The separation of pharmacy benefits from medical benefits in a range of insurance programs discourages insurers from considering the relative costs and benefits of pharmaceutical and non-pharmaceutical therapy for a given condition.²³¹ As noted in Part IV, though, coverage is fragmented for different reasons. The siloing of pharmaceutical coverage into Medicare Part D is a creature of statute, but largely happened accidentally (from an innovation perspective). By contrast, there is no law requiring private insurers to maintain separate pharmacy deductibles, but doing so enables them to pass on a greater share of costs to the patient, lowering the insurer's own financial responsibility for the patient's care.

<https://www.novartis.com/news/media-releases/avexis-announces-innovative-zolgensma-gene-therapy-access-programs-us-payers-and-families> [<https://perma.cc/2UYZ-68KP>].

228. NOVARTIS, *supra* note 227.

229. See Sachs, Bagley & Lakdawalla, *supra* note 83, at 14.

230. See *id.* at 14–16.

231. See *supra* Section IV.B.

Because of this existing fragmentation in our health care system and the differences in drivers of this problem, solutions may need to be targeted at the level of particular health care programs. Within Medicare, where existing law *requires* fragmentation in patients' benefits, policy experts have proposed different versions of either permitting or requiring integration of the Medicare benefit structure.²³² These policy experts are largely concerned with patient out-of-pocket costs, inefficiency, and administrative expense,²³³ but many of their arguments resemble the innovation-related concerns presented here, as they consider the role integration would play in giving beneficiaries "incentive[s] to seek the highest-value care."²³⁴ By contrast, within private insurance, where existing law *permits* fragmentation in patients' benefits largely to financially advantage employers and insurers, state or federal legislation could be used to outlaw such fragmentation entirely.

As with potential reforms for the fragmentation over time issue, these potential reform strategies also have their pros and cons. They all have the ability to solve the core problem regarding incentives to trade off pharmaceutical and non-pharmaceutical treatments for a given condition. If patients are able to pursue the highest-value treatment for their needs, that should result in increased incentives for pharmaceutical companies to make high-value pharmaceuticals, especially where there are few effective non-pharmaceutical treatments. Particularly within the Medicare program, although there may be administrative costs incurred in the transition to a more unified benefit structure, there may be few unexpected costs to the existence of the unification itself, as the current fragmentation was less an affirmative policy choice than an exercise in path-dependent legislation. However, a core problem with these reforms is that they might not necessarily solve the trade-off problem between pharmaceutical and non-pharmaceutical care, if insurers are able to structure their plan designs to steer patients in one direction or another. In theory, their incentives to do so should be much smaller, under a unified benefits package. But they would not be zero, and it may not be desirable to ask regulators to police specific plan designs, in the absence of demonstrated discrimination or other egregious factors.

232. See, e.g., Karen Davis et al., *Medicare Essential: An Option to Promote Better Care and Curb Spending Growth*, 32 HEALTH AFFS. 900, 900 (2013). See generally Amanda Cassidy, *Restructuring Medicare*, HEALTH AFFS., June 2013, <https://www.healthaffairs.org/doi/10.1377/hpb20130620.136304/full/> [<https://perma.cc/7LT7-MQ2W>] (surveying a series of proposals).

233. See Davis et al., *supra* note 232, at 901.

234. See Cassidy, *supra* note 232, at 4.

In at least some cases, patients have the choice to pursue integrated plans today. For instance, many seniors may choose a more integrated health insurance plan through Medicare Part C,²³⁵ also known as Medicare Advantage. Medicare Advantage plans are offered by private insurers as an alternative to the traditional Medicare program. These plans provide both Part A and Part B benefits, and 90% of Medicare Advantage plans include prescription drug coverage as would otherwise be provided under Part D.²³⁶

However, these are not sufficient replacements for statutory and regulatory changes pushing towards more integrated plans. Although Medicare Advantage enables patients to integrate some of their benefits within the statutorily-fragmented Medicare, Medicare Advantage plans do not always include pharmacy benefits, may have networks that exclude a patient's preferred physicians, may require onerous administrative burdens before certain services and products are covered, and may simply exclude certain patient groups.²³⁷ Today, only a third of seniors are enrolled in Medicare Advantage plans.²³⁸ It is a very different program than traditional Medicare, and the choice between them is based on far more than simple integration. As such, legal reforms will be needed to ensure that integrated plans are available to patients, on terms that are not meaningfully worse than the terms of fragmented plans.

c. Fragmentation by Policymaker

Fragmentation of health care policymaking by decisionmaker both limits the tools available to relevant actors as they attempt to solve innovation-related issues and prevents those policymakers from internalizing the full costs and benefits of their actions. Particularly in the agency context, these limitations are often imposed by agencies' organic statutes, restricting an agency's jurisdiction to particular areas of law. The FDA has expressed concern about pharmaceutical companies' efforts to delay generic competitors from coming to market in a timely fashion, but the agency needs more tools to deal with this issue.²³⁹ At the same time, the law requiring the FDA to

235. See 42 U.S.C. § 1395w-21.

236. Gretchen Jacobson et al., *Medicare Advantage 2019 Spotlight: First Look*, KAISER FAM. FOUND., Oct. 2018, <http://files.kff.org/attachment/Data-Note-Medicare-Advantage-2019-Spotlight-First-Look> [https://perma.cc/SU9M-YG5P].

237. For instance, most patients with end-stage renal disease have been excluded from Medicare Advantage plans. 42 U.S.C. § 1395w-21(a)(3)(B); 42 C.F.R. § 422.50(a)(2) (2015).

238. Gretchen Jacobson et al., *A Dozen Facts About Medicare Advantage in 2019*, KAISER FAM. FOUND., June 2019, <https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage-in-2019/> [https://perma.cc/RU6R-2GFY].

239. See, e.g., *Statement from FDA Commissioner Scott Gottlieb, M.D., on New Agency Efforts to Shine Light on Situations Where Drug Makers May Be Pursuing Gaming Tactics*

approve certain drugs through the Accelerated Approval program more quickly and on the basis of less evidence than would have traditionally been tolerated imposes costs on CMS, which must then cover these products which have uncertain efficacy.²⁴⁰

Potential solutions to these two problems as they exist within the interagency context may take a number of forms. First, to make a broader range of policy tools available to agencies as they confront innovation-related problems, reforms that permit agencies to use those tools themselves or that encourage partnerships between agencies could be productive. For instance, to counter branded pharmaceutical companies who abuse the citizen petition process in an attempt to delay the FDA's approval of generic competitors,²⁴¹ the FDA could be given greater authority to levy penalties against these companies. Or, in pursuing bad actors,²⁴² the FDA could be given greater resources to partner with agencies like the Federal Trade Commission. Second, to enable agencies to consider the full costs and benefits of their actions, reforms could either permit or require interagency processes before certain actions are taken. For instance, procedures that enable communication between the FDA and CMS on the dynamics of the accelerated approval program and perhaps require changes in the FDA's behavior on that basis would serve this purpose. However, legal solutions are not likely to be as effective in solving issues involving jurisdiction within Congressional committees. The problem there is political, rather than legal in nature.

In general, although these solutions are targeted at two distinct problems of fragmentation by decisionmaker, they may have similar advantages and disadvantages. Expanding potential avenues of communication between agencies can enable agencies to address a

to *Delay Generic Competition*, FOOD & DRUG ADMIN. (May 17, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-agency-efforts-shine-light-situations-where-drug> [https://perma.cc/Y4FM-DFPR]; *Statement from FDA Commissioner Scott Gottlieb, M.D., on New Agency Actions to Further Deter 'Gaming' of the Generic Drug Approval Process by the Use of Citizen Petitions*, FOOD & DRUG ADMIN. (Oct. 2, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-agency-actions-further-deter-gaming-generic-drug> [https://perma.cc/CN8G-EE3L].

240. Both the FDA and CMS have taken this position. New Drug, Antibiotic, and Biological Drug Product Regulations, Accelerated Approval, 57 Fed. Reg. 58,942, 58,942 (Dec. 11, 1992) (codified at 21 C.F.R. pts. 314, 601 (2017)); *Medicaid Drug Rebate Program Notice: State Medicaid Coverage of Drugs Approved by the FDA Under Accelerated Approval Pathway*, CTRS. FOR MEDICARE & MEDICAID SERVS. (June 27, 2018), <https://www.medicare.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-185.pdf> [https://perma.cc/C72X-6Y5S].

241. Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305, 323 (2016).

242. Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 168 (2016); Jordan Paradise, *REMS as a Competitive Tactic: Is Big Pharma Hijacking Drug Access and Patient Safety?*, 15 HOUS. J. HEALTH L. & POL'Y 43, 47 (2015).

wider range of innovation-related problems and can provide agencies with a broader range of inputs into decisions they will be called upon to make. However, collaboration of this type surely has costs. Most obviously, it is costly in terms of scarce agency resources (both time and financial).²⁴³ But it may also create challenges for agencies by asking them to cede control over their core priorities, and even to make decisions against their core interests.²⁴⁴ It will therefore be difficult to craft reforms which rightly compel recalcitrant agency officials to comply with important, worthwhile collaborations while also respecting these key concerns.

At present, there is certainly some amount of interagency collaboration, or at least review. Some of it has been encouraged by Congress, which requires the NIH to report on its interagency activities in hopes of “increas[ing] interagency collaboration and coordination.”²⁴⁵ For proposed rules submitted to the Office of Management and Budget (“OMB”) for review, those rules must be circulated to other “affected agencies” who may weigh in on the desirability of the proposal.²⁴⁶ But these existing processes are incomplete. The NIH is not required to engage in much interagency collaboration at all,²⁴⁷ and its resources for doing so are limited. OMB interagency review may be helpful for proposed rules, but much of the conflicts between health-related agencies do not arise in the rulemaking context, and thus OMB’s process does not reach such tensions. It is in theory possible for a strong HHS Secretary or a particularly involved President and Office of Science and Technology Policy to mediate some of these conflicts, but it often does not happen.²⁴⁸ Particularly where agencies must use authority created by old statutes to confront new problems,²⁴⁹ legal reforms to enlarge the scope of interagency interaction will be needed.²⁵⁰ Congress might choose to do this at many different levels of generality, perhaps establishing a non-partisan organization to review the ways in which

243. Sachs, *supra* note 149, at 2042.

244. *Id.* at 2042–43.

245. 42 U.S.C. § 283a.

246. Executive Order 12866: Regulatory Planning and Review, 58 Fed. Reg. 51,735 (Oct. 4, 1993); *see also* Jim Tozzi, *OIRA’s Formative Years: The Historical Record of Centralized Regulatory Review Preceding OIRA’s Founding*, 63 ADMIN. L. REV. 37, 47–48 (2011).

247. In a few cases, Congress has mandated certain interagency efforts that involve the NIH, such as the Interagency Pain Research Coordinating Committee as created by the Affordable Care Act. 42 U.S.C. § 284q(b)(1); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 409J(b), 124 Stat. 119, 585–86 (2010). However, most of the interagency efforts in which the NIH is involved are not mandated by statute.

248. *See, e.g.*, Sachs, *supra* note 149, at 2025–27.

249. *See generally* Jody Freeman & David B. Spence, *Old Statutes, New Problems*, 163 U. PA. L. REV. 1 (2014).

250. *See* Freeman & Rossi, *supra* note 37, at 1136–37; Benjamin & Rai, *supra* note 37, at 21; JULIE E. COHEN, BETWEEN TRUTH AND POWER 199 (2019).

innovation-related agencies' policies create barriers to innovation and make policy recommendations,²⁵¹ or by creating an innovation regulator either within HHS or within the executive branch with the power to intervene and mediate innovation-related conflicts.²⁵²

VII. CONCLUSION

Fragmentation pervades nearly every aspect of the American health care system. Given fragmentation's documented impacts on costs, quality, and access to care, perhaps it is no surprise that it also has an impact on innovation incentives in the first instance. Viewing fragmentation through an innovation lens allows for consideration of new forms of fragmentation that have not yet been discussed in the legal literature, as well as new perspectives on already known forms of fragmentation. Although more research is needed to determine the magnitudes of the effects described in this Article, the identification of reform proposals can help policymakers begin to solve these innovation-related biases.

251. This is not purely hypothetical. A first draft of the 21st Century Cures Act would have created a national Medical Product Innovation Advisory Commission to “review the interaction of Federal agencies with respect to the discovery, development, and delivery of new medical products and how such interactions influence medical product innovation.” 114th Cong., 21st Century Cures Act § 229A(b)(2)(B) (discussion document 2015), <https://www.fdalawblog.net/wp-content/uploads/archives/docs/Cures-Discussion-Document.pdf> [<https://perma.cc/26SK-K3KV>].

252. Sachs, *supra* note 149, at 2043–46.