American Journal of Law & Medicine (2024), 50: 3-4, 161–167
doi:10.1017/amj.2025.2

American Society of Law, Medicine & Ethics
Where Multidisciplinary Education Improves Practice

ARTICLE

Just Fix the Damn Payment System!

Frances H. Miller*

Boston University School of Law, Boston, MA, USA and Boston University School of Public Health, Boston, MA, USA
Email: fmiller@bu.edu

Abstract

This piece takes as a given that we are stuck with our fragmented, inefficient, multi-payor health care system for at least the short run. It then analyzes the deficiencies of three payment mechanisms whereby regulators (including Congress) have invited private sector providers to help ameliorate perceived problems. The first concerns an inadequate supply of nursing home beds in the early '70s, the next focuses on Medicare Advantage as a supposedly superior cost containment alternative to traditional Medicare, and the final one involves the 'devil's bargain' struck with the pharmaceutical industry to get prescription drug coverage added to Medicare. All three teach the same lesson: the government needs to be more vigilant not to give away the store when it invites the private sector in.

Keywords: Medicare; Medicaid; Hatch-Waxman; health care expenditures; health insurance; health care payment system

Just fix the damn roads!"[1] That memorable slogan famously propelled Gretchen Whitmer to her first term as Michigan's governor.[2] Constituents latched on to the message, parroting the phrase at the then-gubernatorial candidate during a 2018 Fourth of July parade.[3] The slogan was simple, pragmatic, and addressed a problem state government could actually do something about. Indeed, the voters understood, approved the message, and elected her as that purple state's first Democratic governor in almost a decade – and by a nearly ten percent margin.[4] They re-elected her in 2022,[5] in no small part because she (mostly) lived up to that promise.[6] I have been deeply immersed in analyzing, teaching and writing about the health sector for more than half a century, and, inspired by Governor Whitmer's adopted platform, offer my prescription for mending our broken health system, I now say: "Just fix the damn payment system!"

It's that simple, and it's damned hard. Worse, I have no easy solution to offer, not least because fixing it requires federal government action, a far more unwieldly beast than addressing the problems of a single

* My thanks for valuable comments to Deborah Benik, Christopher Miller, and Hugh Miller.

[1] Beth LeBlanc, *INSIDER: How Whitmer Swore to 'Fix the Damn Roads,'* Det. News (Nov. 15, 2018, 9:53 AM ET), https://www.detroitnews.com/story/news/local/michigan/2018/11/15/political-insider-how-whitmer-swore-fix-damn-roads/1998858002/ [https://perma.cc/79NJ-WS8R].

[2] *Id.*

[3] *Id.*

[4] *Id.*

[5] *Michigan Governor Election Results*, N.Y. Times (Nov. 28, 2022), https://www.nytimes.com/interactive/2022/11/08/us/elections/results-michigan-governor.html [https://perma.cc/QK4J-MANP].

[6] Executive Officer of the Governor, *Governor Whitmer Continues to Fix the Damn Roads with Projects Starting This Week in Seven Counties*, Governor Gretchen Whitmer (July 10, 2023), https://www.michigan.gov/whitmer/news/press-releases/2023/07/10/whitmer-continues-to-fix-the-roads-with-projects-starting-this-week-in-seven-counties [https://perma.cc/7DBU-GS7T].

© 2025 The Author(s). Published by Cambridge University Press on behalf of American Society of Law, Medicine & Ethics and Trustees of Boston University. This is an Open Access article, distributed under the terms of the Creative Commons Attribution licence (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted re-use, distribution, and reproduction in any medium, provided the original work is properly cited.

https://doi.org/10.1017/amj.2025.2 Published online by Cambridge University Press

state. But I do propose a partial roadmap for improvement. The most obvious solution would be some form of universal, government-sponsored insurance coverage that could administer payment across the board, such as Medicare for All.[7] Or at the very least put a toe in the water with something like a public insurance option at the federal level.[8]

But just writing those sentences brings home the futility of such an aspiration in the country's current political and economic climate. Too many players are too deeply invested in the lucrative but irrational *status quo* to surrender it quietly, and those seeking reform seem too diverse and too fragmented to achieve meaningful reform. Game, set and match. What nonetheless follows is a cautionary commentary on three different federal health sector payment approaches of the past half century. All were designed to entice private sector actors to invest in health care, and all were successful from that point of view.

The first two deal with public pricing gradually going sour in government-administered programs (Medicare and Medicaid). The third deals with the mostly private sector pricing of pharmaceuticals following enactment of the *Hatch-Waxman* and *Biologics Price Competition and Innovation Act*s. These examples, through which Congress intended to lure private sector assets into health care markets, illustrate some highs and some lows of our convoluted, tortuous, and often incomprehensible payment systems.

Some History and Background

A month after I graduated from law school, President Lyndon B. Johnson triumphantly signed the Social Security Amendments of 1965,[9] the midwife to modern Health Law. The Act gave birth to Medicare and Medicaid, which established health insurance for the poor and elderly, and those revolutionary programs were implemented a scant year later.[10] U.S. health care transformed itself completely in their wake.[11]

Before 1965, medical services were no sure thing for old and indigent people – care was sporadic and catch-as-catch-can for elderly and impoverished individuals lacking health insurance.[12] That meant that when serious illness struck, most of them were just a step or two removed from going up the river financially or into the ground. But everything changed thereafter for an obvious reason: open-ended financing for medical services abruptly released pent-up demand for those significant populations.[13] These newly-insureds could suddenly get medical services that would be reliably paid for; and the health sector got itself invigorated.[14]

---

[7]*See* Andrew Schuette and Peter Boumgarden, *Medicare for All Is About Trade-Offs, Not Rights and Privileges*, STAT (Jan. 10, 2019), https://www.statnews.com/2019/01/10/medicare-for-all-tradeoffs-health-care/.

[8]*See* Christine Monahan et al., *State Public Option Plans Are Making Progress on Reducing Consumer Costs*, Commonwealth Fund (Nov. 7, 2023), https://www.commonwealthfund.org/blog/2023/state-public-option-plans-are-making-progress-reducing-consumer-costs [https://perma.cc/RBF8-K4BG].

[9]*See* Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified as amended at 42 U.S.C. §§ 301–1397mm).

[10]*See generally* Wilbur J. Cohen & Robert M. Ball, *Social Security Amendments of 1965: Summary and Legislative History*, Soc. Sec. Bull., Sept. 1965, at 3.

[11]*See, e.g.*, Julia Paradise & Richard Garfield, *What Is Medicaid's Impact on Access to Care, Health Outcomes, and Quality of Care? Setting the Record Straight on the Evidence*, Kaiser Fam. Found. (Aug. 2, 2013), https://www.kff.org/report-section/what-is-medicaids-impact-on-access-to-care-health-outcomes-and-quality-of-care-setting-the-record-straight-on-the-evidence-issue-brief/.

[12]*See History of SSA During the Johnson Administration 1963-1968*, Soc. Sec. Admin., https://www.ssa.gov/history/ssa/lbjmedicare1.html [https://perma.cc/Y3CM-R63F] (last visited Nov. 8, 2024).

[13]*See* Karen Davis & Cathy Schoen, Health and the War on Poverty: A Ten-Year Appraisal 40–48, 63–67, 103–04 (1978).

[14]*See* Kimberly Leonard, *America's Health Care Elixir*, U.S. News & World Rep. (July 30, 2015), https://www.usnews.com/news/the-report/articles/2015/07/30/medicare-changed-health-care-in-america-for-the-better.

https://doi.org/10.1017/amj.2025.2 Published online by Cambridge University Press

The United States allocated only five percent of its gross domestic product (GDP) to health care back in 1960,[15] but ever since Medicare and Medicaid began remaking the health industry, spending on health services has grown almost twice as fast as has the U.S. GDP.[16] After peaking at 19.7% during COVID, health care still accounted for at least 17.3% of the country's output in 2022 and is predicted to keep rising absent significant structural reform.[17] Yet our indices of public health still lag behind those of the rest of the developed world's countries, which spend a far smaller share of GDP on the endeavor while insuring virtually their entire populations.[18] Indeed, about eight percent of the U.S. population *still* lacks reliable insurance protection[19] (even after the Affordable Care Act has expanded coverage to fifty million more Americans over the past decade),[20] and we spend at least one-and-a-half times as much money per capita in delivering health services to Americans than *any* other country does in providing such services to its citizens.[21] The United States is doing something really wrong here, and failing to cover our entire population is a big part of why we fare so badly in global public health comparisons.

We also fare badly in getting value for the money we do spend, in large part because of transactional and other costs associated with our highly fragmented payment system, which is layered with inefficiencies and perverse financial incentives.[22] Just over thirty-six percent of the insured U.S. population already enjoys government-sponsored health insurance through Medicare, Medicaid, VA and CHAMPVA for the military and veterans, as well as through various smaller government programs.[23] Employer-sponsored and individual private health insurance plans cover most of the rest of the population (except for that pesky eight percent that remains uninsured).[24] That means those providing health services to insured Americans must incur the staggering transactions costs associated with seeking reimbursement from an overwhelming array of different possible sources.[25] In a 2020 study of the sector's costs in 2017, administrative costs for private insurers were conservatively estimated to account

[15]Aaron C. Catlin & Cathy A. Cowan, Ctrs. for Medicare & Medicaid Servs., History of Health Spending in the United States, 1960-2013 3 (2015), https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/downloads/historicalnhepaper.pdf.

[16]*See* Preeti Vankar, *U.S. National Health Expenditure as Percent of GDP from 1960 to 2022*, statista, https://www.statista.com/statistics/184968/us-health-expenditure-as-percent-of-gdp-since-1960/ (last visited Nov. 8, 2024).

[17]*Id.* ("By 2031, it is expected that health care spending in the U.S. will reach nearly one fifth of the nation's gross domestic product.").

[18]*See* Munira Z. Gunja et al., *U.S. Health Care from a Global Perspective, 2022: Accelerating Spending, Worsening Outcomes*, Commonwealth Fund (Jan. 31, 2023), https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/us-health-care-global-perspective-2022 [https://perma.cc/NML9-G49K].

[19]*See* Off. of the Assistant Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Hum. Servs., HP-2024-02, National Uninsured Rate Remains Largely Unchanged at 7.7 Percent in the Third Quarter of 2023 1 (2024), https://aspe.hhs.gov/sites/default/files/documents/e497c623e5a0216b31291cd37063df1d/NHIS-Q3-2023-Data-Point-FINAL.pdf.

[20]*See U.S. Department of the Treasury Releases New Data Showing Nearly 50 Million Americans Have Been Covered Through Affordable Care Act Health Insurance Marketplaces Since 2014*, U.S. Dep't of the Treasury (Sept. 10, 2024), https://home.treasury.gov/news/press-releases/jy2567 [https://perma.cc/GN8Q-XDYR].

[21]*See* Emma Wager et al., *How Does Health Spending in the U.S. Compare to Other Countries?*, Peterson-KFF Health Sys. Tracker (Jan. 23, 2024), https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/ [https://perma.cc/G289-DJKJ].

[22]*See* Irene Papanicolas et al., *Health Care Spending in the United States and Other High-Income Countries*, 319 J. Am. Med. Ass'n 1024, 1025 (2018).

[23]Katherine Keisler-Starkey & Lisa N. Bunch, U.S. Census Bureau, P60-284, Health Insurance Coverage in the United States: 2023 3 (2024), https://www2.census.gov/library/publications/2024/demo/p60-284.pdf.

[24]*Id.*; *see also generally* Gary Claxton et al., *Employer-Sponsored Health Insurance 101*, *in* Kaiser Fam. Found., Health Policy 101 (Drew Altman ed., 2024), https://www.kff.org/health-policy-101-employer-sponsored-health-insurance/ [https://perma.cc/4TCL-PVSC].

[25]*See, e.g.*, Am. Hospital Ass'n, America's Hospitals and Health Systems Continue to Face Escalating Operational Costs and Economic Pressures as They Care for Patients and Communities 1–2, 4–5 (2024), https://www.aha.org/system/files/media/file/2024/05/Americas-Hospitals-and-Health-Systems-Continue-to-Face-Escalating-Operational-Costs-and-Economic-Pressures.pdf.

https://doi.org/10.1017/amj.2025.2 Published online by Cambridge University Press

for about 6.5% of national health expenditures,[26] whereas those for government-administered insurance programs accounted for only about 1.3%.[27]

Nursing Home Bed Supply

"*Follow the money*" has always been the mantra I give students seeking to understand the health sector. Watch what providers do when funding for health services becomes plentiful and watch what they fail to do when little or no money is available to pay for care. The supply of nursing home beds was an early case in point. Before Medicaid came on line as a source of reimbursement for nursing home resident care, the few available facilities were mostly small mom-and-pop operations financed primarily out of patients' and their families' pockets.[28] In the years immediately following Medicaid's passage, long term care services played an outsized role in rising health expenditures, with nursing care and home health care expenditures representing average annual growths of 19.8% and 15.1%, respectively, from 1966 to 1973.[29] By 1975, just under a decade after Medicaid became effective, "expenditures on … nursing home care were five times their 1966 level[.]"[30] This long term care was financed primarily by Medicaid's new federal-state cooperative insurance program for poor people,[31] which soon turned into the highest category of expense in most states' budgets.[32]

The private sector, enticed by freshly available payment resources, jumped into the market to propel nursing home bed supply dramatically upward.[33] This had both positive and negative ramifications,[34] but Medicaid essentially converted taking care of the elderly into a social responsibility rather than a family burden. Private actors responded to the public need, and many soon discovered they could do quite well by doing good, thanks to the loopholes and distorted financial incentives of early Medicaid reimbursement.[35] Many states then cracked down on supply through their Certificate of Need programs, and the federal-state funding partnership gradually reduced financing.[36] Now, fifty years later, Medicaid payments are routinely pilloried as shamefully low in relation to costs,[37] indicating a current payment system potentially ripe for revision.

[26]David U. Himmelstein et al., *Health Care Administrative Costs in the United States and Canada, 2017*, 172 Annals Internal Med. 134, 139–140 (2020).

[27]*Id.*; *see also generally* Juliette Cubanski & Tricia Neuman, *What to Know About Medicare Spending and Financing*, Kaiser Fam. Found. (Jan. 19, 2023), https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing/ [https://perma.cc/9SDP-YCVU]; Bds. of Trs. of the Fed. Hosp. Ins. & Fed. Supplementary Med. Ins. Tr. Funds, 2022 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (2022), https://www.cms.gov/files/document/2022-medicare-trustees-report.pdf.

[28]*See* Kirsten J. Colello, Cong. Rsch. Serv., R47881, Long-Term Services and Supports: History of Federal Policy and Programs 6–7 (2023), https://crsreports.congress.gov/product/pdf/R/R47881. For a more fulsome history of the nursing home industry's pre-Medicaid era, see Bruce C. Vladeck, Unloving Care: The Nursing Home Tragedy 41–48 (1980).

[29]*See* Catlin & Cowan, *supra* note 15, at 11.

[30]Judith Feder & William Scanlon, *Regulating the Supply of Nursing Home Beds*, 58 Milbank Mem'l Fund Q. 54, 54 (1980).

[31]*See* Catlin & Cowan, *supra* note 15, at 11.

[32]*See How Do States Pay for Medicaid?*, Peter G. Peterson Found. (Feb. 5, 2024), https://www.pgpf.org/budget-basics/budget-explainer-how-do-states-pay-for-medicaid [https://perma.cc/WBY6-B6X2].

[33]*See* Colello, *supra* note 28, at 7.

[34]*See generally* Davis & Schoen, *supra* note 13.

[35]*See generally* Mary Adelaide Mendelson, Tender Loving Greed: How the Incredibly Lucrative Nursing Home "Industry" Is Exploiting America's Old People and Defrauding Us All (1975).

[36]*See generally* Feder & Scanlon, *supra* note 30.

[37]*See, e.g.*, Paul Cuno-Booth, *NH Health Providers Say State's Low Medicaid Rates Add to Staffing 'Crisis,'* N.H. Pub. Radio (Feb. 2, 2023, 5:20 AM ET), https://www.nhpr.org/nh-news/2023-02-02/nh-health-providers-say-states-low-medicaid-rates-add-to-staffing-crisis, [https://perma.cc/6XSY-VH7A].

https://doi.org/10.1017/amj.2025.2 Published online by Cambridge University Press

Medicare Advantage

Private Medicare Advantage health insurance plans (Medicare Part C, established in 1997)[38] followed the same trajectory of private sector salvation for a public problem, followed by exploitation, that was seen with nursing homes. The federal government knowingly priced Part C plans (usually closed panel HMOs funded by capitation) extremely generously at the outset.[39] Capitated systems were thought to control costs better than had Medicare fee-for-service pricing.[40] Congressional largesse was again relied upon in 2004 specifically to bring more private sector insurance companies into this Medicare insurance market,[41] and the tactic continues to be spectacularly successful: fifty-four percent of Medicare beneficiaries are now currently enrolled in Medicare Advantage plans.[42] But a significant number of private insurance underwriters have abused their favored status, and headlines now rail against their fraudulent behavior.[43] Donald Berwick, the former head of the Centers for Medicare and Medicaid Services, recently excoriated Medicare Advantage plans for destabilizing Medicare funding by deceptive upcoding to get favorable rates.[44] The lesson from both these examples? Administered pricing *per se* constitutes no panacea for delivering cost-effective care. Overly generous reimbursement and fraud opportunities can always vitiate the most promising payment schemes. Vigilant regulatory oversight is thus essential to thwart abuse.[45]

Pharmaceutical Pricing

The often low prices for the more than ninety percent[46] of all U.S. prescriptions now filled by generic drugs are pretty much a modern miracle.[47] 1984's Hatch-Waxman Act was phenomenally successful in using market forces to reduce the prices of most drugs that our citizens consume.[48] Before Hatch-

[38]*See Health Plans - General Information*, Ctrs. for Medicare & Medicaid Servs., https://www.cms.gov/medicare/enrollment-renewal/health-plans (last visited Nov. 8, 2024). While Part C was not formally established until 1997, Medicare technically had authority to "contract with risk-based private health plans" since the passage of the Tax Equity and Fiscal Responsibility Act in 1982. Thomas G. McGuire et al., *An Economic History of Medicare Part C*, 89 Milbank Q. 289, 290 (2011).

[39]*See* McGuire et al., *supra* note 38, at 291 (explaining that, in order to meet policy goals and entice private insurer participation, Congress had to structure the program such that insurers would be paid enough "to make a profit sufficient to justify their participation" in accordance with regulatory requirements).

[40]*See id.* at 294 (noting that part of the motivation to expand Medicare to "include risk-based private plans" was research showing that "prepaid group practices paid by capitation … could provide more comprehensive coverage at less total expense than conventional health insurance could").

[41]Thomas L. Greaney, *Controlling Medicare Costs: Moving Beyond Inept Administered Pricing and Ersatz Competition*, 6 St. Louis J. Health L. & Pol'y 229, 240 (2013) (explaining Congress' goal of incentivizing private plans to return to Part C participation by "overpaying" them).

[42]Nancy Ochieng et al., *A Snapshot of Sources of Coverage Among Medicare Beneficiaries*, Kaiser Fam. Found. (Sept. 23, 2024), https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries/ [https://perma.cc/533Q-J7EF].

[43]*See, e.g.*, Reed Abelson & Margot Sanger-Katz *'The Cash Monster Was Insatiable': How Insurers Exploited Medicare for Billions*, N.Y. Times (Oct. 8, 2022), https://www.nytimes.com/2022/10/08/upshot/medicare-advantage-fraud-allegations.html ("By next year, half of Medicare beneficiaries will have a private Medicare Advantage plan. Most large insurers in the program have been accused in court of fraud.").

[44]*See* John Wilkerson, *A Former Medicare Official Says the Program Is in Trouble, and Medicare Advantage Is Largely to Blame*, STAT (Oct. 17, 2024), https://www.statnews.com/2024/10/17/donald-berwick-former-medicare-official-criticizes-ma-plans/.

[45]*Id.* (quoting Berwick as saying "[w]e gotta regulate the heck out of" MA plans).

[46]*See* Off. of Generic Drugs, U.S. Food & Drug Admin., Office of Generic Drugs 2022 Annual Report 1 (2023), https://www.fda.gov/media/165435/download?attachment.

[47]Ryan Conrad & Randall Lutter, U.S. Food & Drug Admin., Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices 2–3 (2019), https://www.fda.gov/media/133509/download.

[48]*See* Ravi Gupta et al., *Generic Drugs in the United States: Policies to Address Pricing and Competition*, 105 Clinical Pharmacology & Therapeutics 329, 330–31 (2019); *see also* Drug Price Competition and Patent Term Restoration Act of

https://doi.org/10.1017/amj.2025.2 Published online by Cambridge University Press

Waxman the generics market share was only thirteen percent, and only slightly more than a third of the top-selling branded drugs with expired patents had generic competition.[49] By 2023, FDA had approved more than 32,000 generics,[50] however, and the ninety-one percent of prescriptions filled with them accounted for a mere eighteen percent of all prescription drug costs.[51] A rousing success by anyone's calculation.

Hatch-Waxman established an abbreviated FDA approval pathway for generic small molecule drugs that bypassed the expensive and time-consuming clinical trials formerly hampering getting low-cost competitors to market.[52] In 2010, Congress passed the Biologics Price Competition and Innovation Act (the "BPCI Act") as part of the Patient Protection and Affordable Care Act (the "ACA"), establishing a parallel set of incentives for biologic drugs and their eventual "follow-on" biosimilar competitors.[53] The fruits of the latter legislation are ripening now as the first tranche of biologics following the new pathway have fallen over the patent cliff.[54]

In return for Congressional benevolence toward generics and biosimilars speeding them to market, Hatch-Waxman and the BPCI Act also increased the time that pioneer products (and their applications for new uses supplemented by new clinical studies) could enjoy their initial marketing monopolies.[55] This legislative compromise gave these reference products expanded patent protection and made them (and other special applicants for licensure like orphan drugs) eligible for a host of new marketing exclusivities.[56] One step backward for patients before the one step forward for consumerism. These statutorily-enhanced monopolies have proved extremely costly for consumers of new drugs, whose insurers have at least theoretically had to pay whatever the legislatively-created monopolist manufacturers charge.[57]

One might think that a monopsonistic buyer like Medicare could have cut a deal for its high-volume purchases of these new products, but Congress struck a devil's bargain with the pharmaceutical industry when Medicare's Part D prescription drug coverage for seniors was finally enacted in 2003.[58] Likely in order to secure passage of Part D over potential industry pushback, Congress included a "non-interference clause" prohibiting Medicare from using its monopsony power to negotiate price.[59] Almost

1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. §§ 68b-68c, 70b; 21 U.S.C. §§ 301 note, 355, 360cc (1994); 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282).

[49]Garth Boehm et al., *Development of the Generic Drug Industry in the US after the Hatch-Waxman Act of 1984*, 3 Acta Pharmaceutica Sinica B 297, 298 (2013); *see also* Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 Antitrust L.J. 585, 588–90 (2003) (describing the dearth of generics on the market pre-Hatch-Waxman); *Timeline: Generic Medicines in the US*, U.S. Pharmacopeia, https://www.usp.org/our-impact/generics/timeline-of-generics-in-us [https://perma.cc/5E9V-QSA9] (last visited Nov. 8, 2024).

[50]*See* Off. of Generic Drugs, *supra* note 46, at 1.

[51]*See Report: 2022 U.S. Generic and Biosimilar Medicines Savings Report*, Ass'n for Accessible Meds., https://accessiblemeds.org/resources/reports/2022-savings-report (last visited Nov. 8, 2024).

[52]*See* Weiswasser & Danzis, *supra* note 49, at 593–95.

[53]*See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. 119, 804–21 (2010) (codified at 42 U.S.C. § 262).

[54]*See* Sarah Yim et al., *A Milestone in Facilitating the Development of Safe and Effective Biosimilars*, U.S. Food & Drug Admin. (Apr. 26, 2024), https://www.fda.gov/news-events/fda-voices/milestone-facilitating-development-safe-and-effective-biosimilars.

[55]*See* Robin Feldman, *Patent Term Extensions and the Last Man Standing*, 42 Yale L. & Pol'y Rev. 1, 7–19 (2023) (explaining the provisions of Hatch-Waxman, including monopoly extensions); *Types of Marketing Exclusivity in Drug Development*, Allucent, https://www.allucent.com/resources/blog/types-marketing-exclusivity-drug-development (last visited Nov. 9, 2024) (describing marketing exclusivities available for biologics under the BPCI Act).

[56]*See Types of Market Exclusivity in Drug Development*, *supra* note 55.

[57]*See* Feldman, *supra* note 55, at 27–35.

[58]The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established Medicare Part D by amending Title XVIII of the Social Security Act. *See* Pub. L. No. 108-173, §§ 101–11, 117 Stat. 2066, 2071–176 (codified as amended at 42 U.S.C. §§ 1395w-101 to -154).

[59]Juliette Cubanski et al., *What's the Latest on Medicare Drug Price Negotiations?*, Kaiser Fam. Found. (July 23, 2021), https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/ [https://perma.cc/VVP2-6YZV] (describing the practical function of the noninterference clause prior to the passage of 2022's Inflation Reduction Act).

https://doi.org/10.1017/amj.2025.2 Published online by Cambridge University Press

twenty years later, President Biden's Inflation Reduction Act[60] has partially revoked that clause, enabling the government to bargain directly with manufacturers for certain high-priced drugs with no generic or biosimilar competitors.[61] The first round of those negotiations has recently concluded, producing a pricing agreement (to go into effect in 2026) on ten expensive drugs that would have saved Medicare $6 billion had it been operative in 2023.[62]

Governmental buying power has thus fittingly re-surfaced to level the formerly unbalanced Medicare drug purchasing market. The lesson here differs from that for direct government pricing: when government defers to the market to price the product it pays for, it should never tie one hand behind its back during the bargaining process.

Conclusion

The United States has never considered health care a basic human right, as does almost all the rest of the developed world; the cost in dollars and to U.S. citizens' health is unacceptably high. As the population ages over the next decade, health care costs are projected to outpace the economy and are soon expected to devour a fifth of the nation's output.[63] It may be politically impossible to switch the road we now travel, but we need tougher regulation to straighten out more of the curves and smarter strategies to fill the deepest potholes if we are to avoid an entirely predictable crash.

[60] *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (codified as amended in scattered sections across multiple U.S.C. titles).

[61] Juliette Cubanski et al., *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, Kaiser Fam. Found. (Jan 24, 2023), https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/ [https://perma.cc/8ENB-BQT7] ("The Inflation Reduction Act amends the non-interference clause by adding an exception that requires the Secretary of HHS to negotiate prices with drug companies for a small number of single-source brand-name drugs or biologics without generic or biosimilar competitors that are covered under Medicare Part D (starting in 2026) and Part B (starting in 2028).").

[62] *See Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*, Ctrs. for Medicare & Medicaid Servs. (Aug. 15, 2024), https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026 [https://perma.cc/UN72-5RVH].

[63] *Healthcare Spending Will Be One-Fifth of the Economy Within a Decade*, Peter G. Petersen Found. (Sept. 16, 2024), https://www.pgpf.org/blog/2024/09/healthcare-spending-will-be-one-fifth-of-the-economy-within-a-decade/ [https://perma.cc/55UG-S5UG].

Cite this article: Miller, F.H. (2024), 'Just Fix the Damn Payment System!', *American Journal of Law & Medicine*, **50**, pp. 161–167. https://doi.org/10.1017/amj.2025.2

https://doi.org/10.1017/amj.2025.2 Published online by Cambridge University Press