



***Free2Care's Rx for
Reforming America's Predatory
Healthcare System***

A Physician-Led Roadmap to Patient-Centered Medical Care

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to Patient-Centered Medical Care**

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TABLE OF CONTENTS

PREFACE	7
An Unsustainable Status Quo	7
An Appeal to the Reader	10
A. PROMOTE COMPETITION AND AFFORDABILITY	11
Where the Money is Going... We Think	11
The Itch to Consolidate	13
Just Tell Us Ahead of Time What It Will Cost	14
<i>Reform 1. Provide true price transparency for patients</i>	16
The Profitability of Non-Profit Status	17
<i>Reform 2. Stop the abuse of the tax-exemption enjoyed by non-profit hospitals</i>	17
Confounded Consolidation.....	18
<i>Reform 3. Prohibit mergers that limit patient choice</i>	18
A Profile in Waste: the 340B Program.....	19
<i>Reform 4. Provide transparency for 340B and redirect money to serve the economically disadvantaged</i>	23
B. DETOXIFY AMERICA’S MEDICINE CHEST	24
A Glossary of Self-Sabotage, Scarcity, and Inflation	24
Meet the Parasites—Middlemen, Agents of Opacity, Consolidation, and Scarcity	27
<i>The PBMs</i>	28
<i>The PBMs’ Sketchy Practices</i>	29
<i>The PBMs and Vertical Integration</i>	32
<i>The GPOs</i>	34
Insulin: The Scandalous Rise in Price.....	37
<i>Reform 5. Repeal the “Safe Harbor” law, inter alia</i>	39
Addressing Mental Health and Putting a Dent in Drug Prices.....	40
<i>Reform 6. Increase pressure on the PBMs for transparency and for reducing the prices of drugs through proper use of kickback money</i>	41
BIG PHARMA is Not Blameless.....	42
<i>Reform 7. Enforce and reform patent law for pharmaceuticals and medical devices</i>	43
American Health Care’s “China Syndrome”.....	44
<i>Reform 8. Address national security and health risks from over- reliance on pharmaceuticals produced in China</i>	48

TABLE OF CONTENTS

(continued)

C. REVERSE OUR PHYSICIAN SHORTAGE	49
The Drain of DRexit.....	49
<i>Reform 9. Reverse the ban on physicians owning hospitals.....</i>	51
Physicians’ Legal Vulnerability as Employees and Due Process Rights	52
<i>Reform 10. Protect physicians employed by hospitals</i>	
<i>and private equity groups</i>	53
<i>Reform 11. Restore the right of due process to our doctors</i>	53
Knowing the Training of the Person Treating You.....	54
<i>Reform 12. Ensure transparency of training of clinician to</i>	
<i>all Americans.....</i>	56
Strangulation by Medical Certification Board	57
<i>Reform 13. Allow choice and competition in recertification</i>	
<i>of physicians</i>	58
Level the Playing Field in Disputes Over Surprise Medical Bills	59
<i>Reform 14. Enforce parity (stop favoring insurers) in the</i>	
<i>NSA’s IDR process and conduct a fact-finding mission</i>	
<i>into why the current administration favors insurers.....</i>	61
What’s to Be Done With the Surplus of Med School Graduates?	63
<i>Reform 15. Increase the number of residency positions.....</i>	63
Make Med School Grads Useful as They Await Open Residencies	64
<i>Reform 16. Increase “physician graduate” positions in the U.S.....</i>	64
Where Does the Money that Funds Residencies Really Go?	65
<i>Reform 17. Account fully for how taxpayer funding is used</i>	
<i>for medical residents.....</i>	65
A Prescription to Prevent the Pain of “Prior Authorization?”	66
<i>Reform 18. Prevent Prior Authorizations from impeding patient-care</i>	
<i>and increasing the administrative burden</i>	
<i>on physicians’ offices</i>	67
Get Out of the Way of the Direct Primary Care (DPC) Movement.....	68
<i>Reform 19. Foster unobstructed expansion of Direct Patient Care</i>	
<i>in its pure form</i>	70
Ban Non-Compete Agreements for Medical Professionals	71
<i>Reform 20. Ban Non-Compete Agreements for</i>	
<i>Medical Professionals</i>	71

TABLE OF CONTENTS

(continued)

D. STRENGTHEN ACCESS TO CARE FOR ALL	72
Radical Rethinking of How and Where Taxpayer Money Flows	72
<i>Reform 21. Allow use of Medicare and Medicaid funds for direct payment for medical care.....</i>	<i>72</i>
Closing the Gaps in Care.....	73
<i>The Potential of Telehealth with Real Physician Involvement</i>	<i>76</i>
<i>Reform 22. Incentivize physicians in rural areas to stay there</i>	<i>76</i>
<i>Reform 23. Remove barriers to the practice of telehealth</i>	<i>76</i>
E. MONEY MOVES IN MYSTERIOUS WAYS.....	77
How Did We Get Here?	77
<i>Reform 24. Adopt a strong “Sunshine for <u>ALL</u> Act”.....</i>	<i>82</i>
Appendix A: Repeal the Safe Harbor for GPO/PBM Kickbacks: Save Billions, Save Lives	83
Proposed Language	83
Appendix B: Authors.....	84
Appendix C: Contributors	85

TABLE OF CHARTS & GRAPHICS

Pie Chart: National Health Expenditures in 2020	11
Graph: Bureau of Labor Statistics on Inflation for Multiple Industries Since 2000	12
Graph: Rise in 340B Program Purchases from 2005 to 2020	20
Chart: Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2022	33
Chart: Flow of Money Through the Pharmaceutical Distribution System	37
Graph: Insulin Cost Over Time	38
Chart: American Board of Medical Specialties (ABMS) and its Affiliated Boards	58
Graph: Physicians per 10,000 people in Metro and Nonmetro counties, 2019.....	73
Chart: Accreditation Council for Graduate Medical Education (ACGME) and its Affiliated Organizations	77

PREFACE

Predatory.

Wealth-devouring.

Inequitable.

All are fair descriptions of the system for delivering *medical* care in the United States.

Incessant legislative meddling and overreach over the last 75 years have unleashed perverse economic forces, yielded unanticipated consequences, and increased consolidation among healthcare corporations.

We now have a healthcare system that is unique in the world—a bizarre hybrid of corporate oligopoly and government regulation.

Let us be clear about a distinction that is not widely understood.¹ When we hear politicians talk about “health care,” we should understand that they are actually talking about “health insurance.” No informed person would ever confuse “health insurance” with actual *medical* care or with an assured path to *medical* care.

Physicians provide *medical* care. This paper amplifies their voice.

An Unsustainable Status Quo

The student of the healthcare system in the United States sees an unsustainable status quo.

- The cost constitutes almost a fifth of our economy. The annual cost² has thus far never shrunk from one year to the next. It knows only one direction: UP. It is a powerful drag on growth in the larger economy, particularly for small and mid-sized businesses; and it stifles growth in household income. Half of all Americans labor under the weight of medical debt.³

¹ <https://www.forbes.com/sites/debgordon/2021/02/08/health-insurance-confusion-continues-to-plague-americans-new-data-show/?sh=1d1189854667>

² <https://www.usatoday.com/story/opinion/2019/09/16/spend-about-half-federal-tax-dollars-health-care-ridiculous-column/2301040001/>

³ <https://www.forbes.com/sites/debgordon/2021/10/13/50-of-americans-now-carry-medical-debt-a-new-chronic-condition-for-millions/?sh=e11c12c5e5dd>

PREFACE

(continued)

An Unsustainable Status Quo (continued)

- Decades of healthcare legislation have routinely enriched large corporations, making them more powerful and able to use their wealth to cripple or eliminate competition.
- Corporations with names the public rarely hears—working in league with private insurers and government regulators—have also been merging and acquiring (consolidating) in a healthcare marketplace characterized by perverse incentives and relentless inflation.
- Consolidated third-party payers for *medical* care—whether the government or private insurers—now intrude on, control, and sometimes even obstruct the *medical* care a patient may seek and that physicians sincerely believe to be in the patients’ interest.
- The supply of physicians, especially primary-care physicians^{4,5} and bedside nurses⁶ per capita is falling in a trend that has been under way for years, and has only deepened during the COVID-19 pandemic.
- In cameos that capture the larger reality, dissatisfied patients grumble over the perfunctory attention they receive during shorter and shorter visits⁷ with physicians whose attention seems fastened on a computer monitor and appear driven to meet a productivity quota mandated by their corporate employers. *Patients want their care to be personal.*
- The “little people” receive less and less as more and more of their income disappears into a black hole. Studies have shown that fear of cost prevents almost two-thirds of Americans⁸ from even attempting to obtain needed *medical* care. The same fear keeps a substantial number⁹ of people from acquiring needed medication. Those fears delay attention to medical problems, which only *compounds* those problems.

Virtually every trend line predicts crises in the system, and an inexorable march toward collapse.

⁴ <https://pcpcc.org/2020/07/10/new-report-confirms-growing-shortage-primary-care-physicians>

⁵ <https://aamc.org/system/files/2020-06/stratcomm-aamc-physician-workforce-projections-june-2020.pdf>

⁶ <https://aacnnursing.org/news-information/fact-sheets/nursing-shortage>

⁷ <https://well.blogs.nytimes.com/2013/05/30/for-new-doctors-8-minutes-per-patient/>

⁸ <https://patientengagementhit.com/news/64-of-patients-avoid-care-due-to-of-high-patient-healthcare-...>

⁹ <https://kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-...>

PREFACE

(continued)

An Unsustainable Status Quo (continued)

REMEMBER: Physicians provide *medical* care. “Health care” is something else—what third-party payers may cover, what one may dispense to oneself, what one may obtain from any of several categories of “providers.”

Again, this paper amplifies the voice of physicians and others who have studied this country’s increasingly predatory system closely. Together, they advocate something *radical* and *extreme*—a patient-centered system. Together, they provide this roadmap to arriving at such a system.

Unless we take *radical* and *extreme* steps to push back against the suffocating forces now profiteering and living parasitically from the delivery of *medical* care in this country, nothing will change.

By *radical* and *extreme*, we mean:

- Urging Americans to become informed shoppers for and consumers of *medical* care and informed voters who will make it abundantly clear to their lawmakers that the public understands what has gone wrong and what is needed to fix it.
- Making the hard decisions at the political level to expose the consolidated special interests that now control and siphon wealth out of a predatory healthcare system. Control must go back to the patient and the physician.
- Supporting and enabling innovations that provide patients with affordable choices when they search for *medical* care.

A sustainable system will *not* come from consolidating corporations on their way to monopoly status, nor from government policies that allow those gestating monopolies to prosper.

A sustainable system must grow out of the needs of patients served by trustworthy, autonomous physicians who are free to care for those patients.

PREFACE (continued)

An Appeal to the Reader

Patients and a great many physicians must wake up, not only to understand how we got here, but also to energize **A GREAT REFORMATION**.

They are the *primary* stakeholders in a healthier marketplace for the delivery of *medical* care.

Since April 2019, when a first paper accompanied a conference in Washington, D.C., the *Free2Care* coalition has expanded to include 34 like-minded groups, representing over 8 million citizens, including more than 70,000 physicians.

Free2Care presents this second paper to those who shape public policy and to the public itself as an exposé on the inner workings of our predatory healthcare system.

It is also a roadmap to a better system, rooted in the principle that our best hope for wider access to high-quality *medical* care at a sustainable cost is a **COMPETITIVE MARKETPLACE**.

A marketplace that is as **TRANSPARENT** and fair as possible.

A marketplace that disciplines the behavior of service providers who must compete and empowers consumers who can freely choose among them.

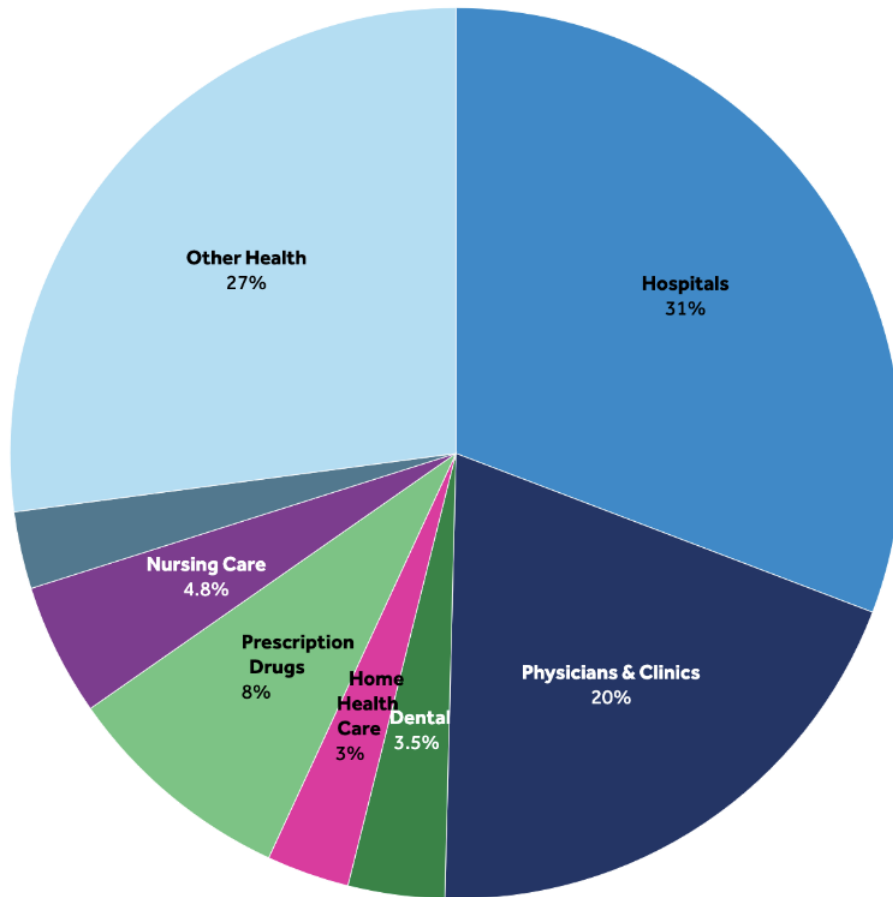
WE APPEAL TO ALL READERS OF THIS PAPER to bring their influence and persuasive power to bear on lawmakers whose ears, at long last, must turn away from the predators and listen to physicians who speak on behalf of patients.

A. PROMOTE COMPETITION AND AFFORDABILITY

Where the Money is Going... We Think

Hospital costs are the largest component (31%) of the \$4 trillion annual cost of health care. Hospitals now own a great many physician clinics, and account for over 50% of services provided in markets where hospitals are the main players.¹⁰

Hospitals and clinics make up the majority of national health expenditures in 2020



Source: Health System Tracker

Free2Care

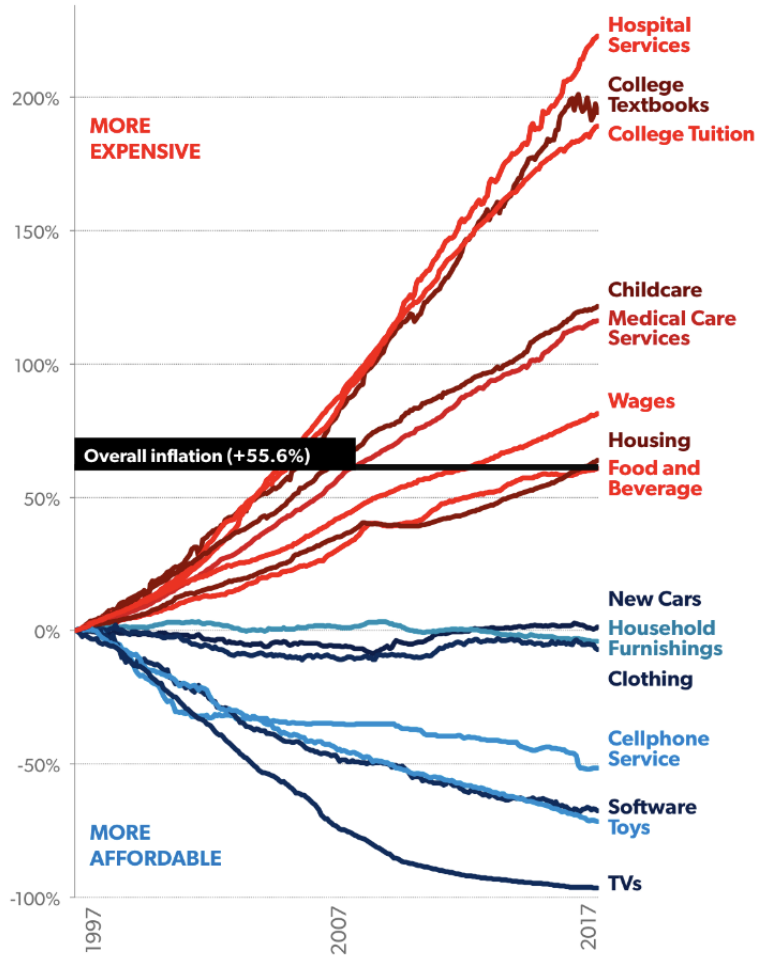
Inflation in the price of hospital services has outpaced that of food, housing, and even college tuition.

¹⁰ <https://podcasts.apple.com/us/podcast/relentless-healthcare-value/id892082003?i=1000569888336>

A. PROMOTE COMPETITION AND AFFORDABILITY

Where the Money is Going... We Think *(continued)*

Hospitals prices have been growing more rapidly than those of other goods and services since 2000



Source: Bureau of Labor Statistics

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A. PROMOTE COMPETITION AND AFFORDABILITY

The Itch to Consolidate

When hospitals merge, price increases of 20% to 30% are common. Increases of 50% and greater are not unheard of.¹¹

Recent decades have witnessed thousands upon thousands of mergers of hospitals, the acquisition of formerly independent medical practices and a change of their physicians from independent status to that of employees.¹² During the pandemic, the pace of these shifts accelerated.

Over the 18 months from July 2016 to January 2018, hospitals acquired 8,000 medical practices. This trend has translated directly into both greater control over physicians *and* an increase in the overall cost of medical care. This is no accident. The increased cost has been carefully calculated and systematically managed.

Whether a hospital's tax status is "for-profit" or "not-for-profit," it makes little difference. Both categories have seen huge gains in revenue, which helps them to maintain a good philanthropic front by expanding their charitable foundations.

"Regional healthcare systems" have become commonplace.

For the first time in the nation's history, more than half of physicians have become corporate employees.

The public perception is that practicing physicians run hospitals. This is a fantasy. An administrative class (colloquially known as "suits") run hospitals. Physicians, *who actually provide care to patients*, are the "scrubs."

Mergers and acquisitions leave the "suits" more-fully in charge than ever.

Friction between suits and scrubs is continuous; estrangement is common. There are books about it. The entertainment industry has made movies and television series—both dramas and comedies—about it.

¹¹ https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3287848

¹² <https://www.beckersasc.com/asc-news/108-700-physicians-move-to-employment-in-the-last-3-years-6-findings.html>

A. PROMOTE COMPETITION AND AFFORDABILITY

The Itch to Consolidate *(continued)*

Here are additional doses of reality:

- In non-profit hospitals, lavish salaries among administrators are the norm.
- Institutions originally meant to be charitable have become lucrative businesses.
- Employed staff are reluctant to speak out.
- Patients continue to pay more, and trust in the hospital system itself erodes.¹³
- Contracts between third-party payers and hospital systems have enabled the third-party payers to steer patients into their in-network hospital systems, and empowered those systems to extract higher payments, which the third-party payers fund through increasing premiums or taxes.
- There is no evidence of improved patient outcomes in consolidated, non-competitive healthcare markets.
- The actual prices for services in consolidated healthcare markets have been difficult, if not impossible, to know, a phenomenon known as **PRICE OPACITY**.

Just Tell Us Ahead of Time What It Will Cost

A recent Marist survey¹⁴ found that 91% of Americans believe hospitals *should* be required to post their prices in an easy-to-access format.

No wonder.

A colonoscopy by an independent doctor in an independent clinic in Virginia costs \$775. The same procedure performed by the same doctor across the street in a hospital-owned clinic costs \$4,000.¹⁵

You are dreaming if you think this is an isolated example.

The power of an informed public making smart choices as consumers of services would be the most effective mechanism for bringing sanity to the costs of American health care.

There is bipartisan support for price **TRANSPARENCY**.¹⁶

¹³ <https://beckershospitalreview.com/hospital-management-administration/70-of-americans-trust...>

¹⁴ <https://www.patientrightsadvocate.org/blog/blog-post-title-one-d23bk>

¹⁵ <https://www.pilotonline.com/opinion/columns/vp-ed-column-berger-0810-20200809-fz3qxa37q5fd7hs3xd6kj7pd7q-story.html>

¹⁶ <https://www.patientrightsadvocate.org/blog/blog-post-title-one-d23bk>

A. PROMOTE COMPETITION AND AFFORDABILITY

Just Tell Us Ahead of Time What It Will Cost *(continued)*

It would rebuild a measure of trust in the healthcare system, including hospitals.

Its cost to taxpayers should be next to nothing.

So, what is the problem?

An executive order in 2019 from the White House¹⁷ imposed transparency in pricing on hospitals and insurers when it came to services paid for by the federal government, i.e., the taxpayer.

However, the order has been met with a breathtakingly low level of compliance—less than 15%.

Wall Street Journal reporters have even found hospitals employing software that prevents Google search engines from uncovering prices.¹⁸

The current administration has increased the fine for non-compliance to a maximum of \$5,500 per day for hospitals with more than 30 beds.¹⁹

Imagine the depths of the coffers that hospitals must have if they consider paying such fines preferable to complying with a requirement to post their prices so that people can find them easily.

The American public needs an end to this nonsense of not knowing what things cost.

TRANSPARENCY must replace **OPACITY**.

¹⁷ <https://public3.pagefreezer.com/browse/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/about/news/2019/11/15/trump-administration-announces-historic-price-transparency-and-lower-healthcare-costs-for-all-americans.html>

¹⁸ <https://www.wsj.com/articles/hospitals-hide-pricing-data-from-search-results-11616405402>

¹⁹ <https://www.cnn.com/2021/07/19/politics/hospitals-prices-transparency/index.html>

A. PROMOTE COMPETITION AND AFFORDABILITY

Just Tell Us Ahead of Time What It Will Cost (*continued*)

Reform 1. Provide true price transparency for the public.

To enact this reform, *Free2Care* calls for legislation that will accomplish the following.

- **Codify the 2019 price-transparency rule for hospitals and insurers.**
- **Increase penalties for non-compliance.**
- **Grant no exception for Medicare Advantage plans.**

- **Require all medical care providers, both hospitals and independent physicians, to provide an itemized bill, within 30 days of a request for the bill, showing services rendered and their respective prices. Without using abbreviations, the itemized elements must identify:**
 - **Each billed item of medical care.**
 - **The related five-digit Common Procedural Technology medical billing code.**
 - **The retail charge.**

Failure to provide an itemized bill must exempt the patient from being taken to court or reported to a credit bureau.

- **Create a Claims Review Law requiring that twice per year or within 30 days of receiving a written request from fully insured or self-insured employers, their health insurers and third-party administrators document at no charge and by line item all medical and pharmaceutical claims data, accompanied by all information contained within the associated claim forms.**

Failure to comply with the Claims Review Law should result in a fine of \$10,000 per day, made payable to the employer requesting its data.

A. PROMOTE COMPETITION AND AFFORDABILITY

The Profitability of Non-Profit Status

Nearly two-thirds of American hospitals are in the “non-profit” category.²⁰

The popular understanding is that they provide charitable care.

They pay no taxes.

The purchase by these hospitals of independent medical practices and imaging centers, previously tax-paying entities, extends the non-profit umbrella to those enterprises. The taxes they once paid stop flowing.

There are two enormous ironies here.

- (1) For-profit hospitals provide more charitable care than non-profit hospitals.²¹
- (2) Across multiple states, non-profit hospitals bring thousands of lawsuits each year *against* financially disadvantaged patients.²²

Somehow, the intent behind the law that defines the difference between for-profit and non-profit hospitals has flipped upside-down.²³

The abuse by non-profit hospitals of their tax-exempt status must stop.

Reform 2. Stop the abuse of the tax-exemption enjoyed by non-profit hospitals.

To enact this reform, *Free2Care* calls for legislation that will accomplish the following.

End the tax exemption for non-profit hospitals.

Alternatively, (1) require that they provide accurate figures on charitable care calculated at Medicare-allowable prices; and (2) while they continue to enjoy their tax-exempt status, prohibit them from “double-dipping” (receiving taxpayer-funded Disproportionate Share (DSH) reimbursements for the cost of the charity care they provide.

²⁰ <https://www.aha.org/statistics/fast-facts-us-hospitals>

²¹ <https://www.fiercehealthcare.com/hospitals/health-affairs-nonprofit-hospitals-spend-less-charity-care-than-for-profits-compared-to>

²² <https://propublica.org/article/thousands-of-poor-patients-face-lawsuits-from-nonprofit-hospitals-that>

²³ <https://www.medicaleconomics.com/view/how-nonprofit-hospitals-get-away-biggest-rip-america>

A. PROMOTE COMPETITION AND AFFORDABILITY

Confounded Consolidation

In July 2021, an Executive Order²⁴ from the White House encouraged the Department of Justice (DOJ) and Federal Trade Commission (FTC) to review and revise their guidelines on mergers in multiple sectors of the American economy, including health care. The stated aim was to foster competition.

In response to that order, the FTC has stopped a merger in New Jersey that would have consolidated two large healthcare systems.^{25, 26}

The FTC's argument was that consolidation would reduce competition in the area. The two systems planning to merge had a history of competing against each, driving each to improve quality and service. The FTC argued that such a merger would harm physicians and patients²⁷ and lead to higher costs, not lower ones.

To increase pressure against anti-competitive mergers and acquisitions, *Free2Care* recommends that the **Affordability Subcommittee of the Healthy Future Task Force in the House of Representatives continue to examine mergers and acquisitions across the healthcare sector between and among insurers, providers, pharmacies and pharmaceutical companies, Pharmacy Benefit Managers (PBMs), technology companies, and medical device manufacturers.**

Reform 3. Prohibit mergers that limit patient choice.

To enact the reform of prohibiting mergers that limit patient choice, *Free2Care* calls for legislation that will accomplish the following.

Require the Federal Trade Commission (FTC) to do its duty by exercising its authority to review mergers and acquisitions planned by insurers and hospital systems and to prohibit activity that would limit competition and inflict financial harm on the served communities.

²⁴ <https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/>

²⁵ <https://www.fiercehealthcare.com/hospitals/executive-order-calls-for-doj-ftc-to-review-hospital-merger-guidelines>

²⁶ <https://news.bloomberglaw.com/antitrust/ftc-convince-court-to-block-new-jersey-hospital-acquisition>

²⁷ <https://medcitynews.com/2022/06/ftc-blocks-merger-of-two-nj-hospitals-less-than-a-mile-apart/>

A. PROMOTE COMPETITION AND AFFORDABILITY

A Profile in Waste: the 340B Program

When created 30 years ago, the intent of the **340B program** was to fund certain hospitals and other providers of safety-net services in extending help to economically disadvantaged patients.²⁸

The program’s focus, under the oversight of the Health Resources and Services Administration (HRSA), was to be narrow, with funds going to hospitals that had a “disproportionate share” of low-income Medicare or Medicaid patients, federally qualified health centers (FQHCs), FQHC look-alikes, and specialty centers that served Native Americans and HIV patients.

In the last 30 years, the number of participating hospitals and pharmacies has exploded.

In 2006 and again in 2010, at the initiative of the HRSA, the requirements for participating in the 340B program were loosened to include a myriad of hospitals and their “child sites”—related outpatient clinics.

Explosive growth followed in the number of participating hospitals and child sites²⁹—from about 12,000 in 2006 to 50,000 by 2021.³⁰

The number of participating pharmacies has also skyrocketed. At the start of the 340B program, patients obtained medication only through a participating hospital’s in-house pharmacy. In 1996, however, the program began to allow facilities that lacked an in-house pharmacy to use a single, external, “contract pharmacy” to distribute medications.

When the Affordable Care Act took effect, it became possible for participating facilities without an in-house pharmacy to have an unlimited number of “contract pharmacies.”

²⁸ <https://www.hrsa.gov/opa>

²⁹ <https://www.gao.gov/assets/gao-18-480.pdf>

³⁰ <https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments/#:~:text=Between%202000%20and%202020%2C%20the.to%20%2438%20billion%20in%202020>

A. PROMOTE COMPETITION AND AFFORDABILITY

A Profile in Waste: the 340B Program (*continued*)

Total Discounted 340B Purchases, 2005-2020



Sources: Drug Channels Institute (2016, 2020)^{31,32}

Like other key elements of the American system of health care, the contract pharmacies in the 340B program have become highly consolidated. Only four chains—CVS, Walgreens, Rite Aid, and Walmart—account for 64% of that market. Those who are familiar with the history of mergers and acquisitions in the healthcare sector will notice the economic integration, both horizontal and vertical,³³ in which these pharmacy chains have participated. With that integration, there is inevitable increase in the likelihood of conflicts of interest; and with the 340B program’s expansion, that likelihood has only intensified.

³¹ <https://www.drugchannels.net/2016/07/reality-check-340b-is-4-not-2-of-us.html>

³² <https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html>

³³ <https://www.investopedia.com/ask/answers/051315/what-difference-between-horizontal-integration-and-vertical-integration.asp>

A. PROMOTE COMPETITION AND AFFORDABILITY

A Profile in Waste: the 340B Program *(continued)*

The law's ambiguity enables participating hospitals to purchase medications at very low prices. However, rather than passing those low prices on to the impoverished or underserved, the hospitals bill patients, employers, and insurers at higher prices for those medications. Some hospitals have even set up 340B pharmacies in wealthier communities to take full advantage of the law's ambiguity and create an added stream of revenue.

Those who have studied³⁴ the program critically, including the Government Accountability Office (GAO) and the Department of Health and Human Services Office of Inspector General (HHS OIG), have noted the following:

- Legislative parameters were unclear.
- Regulation has been informal.
- Oversight has been inadequate.
- Enforcement is weak.
- The program's operation lacks transparency.

There is now little doubt that these flaws have created a situation in which the program too-frequently betrays its mission of helping the economically disadvantaged.

Instead, tax dollars have flowed into the wrong hands as the 340B program has mutated into a potential revenue stream for thousands upon thousands of hospitals and pharmacies that are largely free of accountability. Participating hospitals are not required³⁵ to use 340B savings to serve vulnerable populations, nor are they required to report in detail how 340B revenues are used.³⁶

The program's expansion, coupled with the lack of oversight and accountability, have led to skyrocketing cost in the pharmaceutical part of the program, from \$2.4 billion in 2005 to \$38 billion in 2020—a figure approaching 8% of the total spending in the American pharmaceutical market.

³⁴ <https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments/>

³⁵ https://docs.google.com/gview?url=http://www.tiicann.org/pdf/docs/2019_CANN_340B_Commission_Final-Report-v5_03-07-19.pdf&embedded=true.

³⁶ https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf

A. PROMOTE COMPETITION AND AFFORDABILITY

A Profile in Waste: the 340B Program *(continued)*

Academic and government studies^{37, 38} of the 340B program have trained a spotlight on another significant concern: **duplicate discounts**.

To serve Medicaid patients, pharmaceutical companies sell drugs to participating entities at a deep discount. Regulation prohibits a state's Medicaid agency from receiving additional "rebate" payments (a **duplicate discount**) from the pharmaceutical company.

But it happens.

In audits conducted from 2012 to 2019 and intended to sample actual conduct within the 340B program, the auditors found 429 instances of duplicate discounting.³⁹

And there's more.

A detailed report,⁴⁰ dated September 2021, from the Community Oncology Alliance identified another irregularity, declaring that 340B hospitals are perversely incentivized to use medications they receive at the deeply discounted price to treat ***commercially insured*** patients. For example, a single discounted cancer medication for one such patient in one 340B hospital can create a profit of over \$200,000 in a year because of the higher payments received from the commercial insurer. In contrast, an independent, community oncology center paid under Medicaid for the same medication used by the same patient could realize less than \$8,000. The small operating margins of the community oncology center leaves it, like other independent entities, with its survival at risk.

The same report also documented 340B hospitals failing to charge uninsured patients the 340B discount price medication, thus betraying the mission of serving the economically disadvantaged.

There must be patient-centered reform of the 340B program if it is to realize its original intention. In the absence of transparency and oversight, the exploitation of the programs' perverse incentives will continue, along with looting of the public treasury and the diversion of money meant for the economically disadvantaged into profiteering hands.

³⁷ <https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges...>

³⁸ <https://drugchannels.net/2020/07/how-hospitals-and-pbms-profitand.html>

³⁹ <https://www.gao.gov/assets/gao-21-107.pdf>

⁴⁰ <https://communityoncology.org/featured/hospital-340b-drug-profits-report/>

A. PROMOTE COMPETITION AND AFFORDABILITY

A Profile in Waste: the 340B Program *(continued)*

Reform 4. Make the 340B program operate transparently and redirect money to serve the economically disadvantaged.

To address the full range of problems identified with the 340B program, *Free2Care* calls for legislation that will accomplish the following.

Amend the law governing the 340B program to:

- **Make its intent clear.**
- **Remove ambiguities that participating hospitals exploit.**
- **Eliminate practices that are inconsistent with the program's intent.**
- **Require strict oversight and enforcement from the responsible federal agencies.**

Require complete, public accounting of how participating entities use their 340B dollars.

Those entities must document how much money they accrue from the program in the form of lower costs for their prescription drugs; the served 340B patients must be categorized according to payer type; the names of contract pharmacies and arrangements with third-party vendors must be provided; and there must be annual reports on Medicare Part B claims subject to 340B.

B. DETOXIFY AMERICA’S MEDICINE CHEST

A Glossary of Self-Sabotage, Scarcity, and Inflation

America’s medicine chest... what a mess.

Infested with parasites; stocked at outrageous cost; chronically short of needed supplies; able to be stocked **only** through agreeing to be captive to the low manufacturing standards and good will of an unreliable, menacing adversary.

When trying to understand this convoluted subject, it helps to master certain terms in the vocabulary of the American healthcare system. What follows is a glossary that should be useful for understanding our complex pharmaceutical system. The reader will likely need to refer to it more than once during this discussion

Biosimilar.⁴¹ A drug made from living organisms and largely identical to an original drug developed by a different company and already approved for use by the Food and Drug Administration. The *biosimilar* drug will differ from the original in minor details of its manufacture and is frequently cheaper.

Clawback. Money that a buyer has paid to a seller, but which the buyer must return, in whole or in part, because a contractually defined circumstance has developed that enables the seller to demand the return of the money. The seller “claws back” the payment after the service was provided.

Direct and Indirect Remuneration (DIR).⁴² A complex feature of the regulations governing Medicare Part D under which Pharmacy Benefit Managers (PBMs) can demand additional fees from pharmacies **after** the pharmacies have already paid for drugs and dispensed them.

Evergreening.⁴³ Acquiring fresh patents for versions of existing drugs by virtue of minor, inconsequential adjustments in a drug’s composition. The aim is to extend indefinitely the exclusive right to manufacture a drug and delay the development of a drug’s generic, much cheaper counterparts.

Formulary.⁴⁴ The list of prescription drugs that a third-party payer, whether a commercial insurer or the government, will pay for, wholly or partially, under the provisions of a prescription plan. Pharmacy Benefit Managers (PBMs) control the content of formularies.

⁴¹ <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/biosimilar-drug>

⁴² <https://www.nacds.org/dir-fees/>

⁴³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/>

⁴⁴ <https://www.healthcare.gov/glossary/formulary/>

B. DETOXIFY AMERICA'S MEDICINE CHEST

A Glossary of Self-Sabotage, Scarcity, and Inflation (*continued*)

Group Purchasing Organization (GPO). A type of lesser-known, sometimes gigantic, corporate middleman that controls the contracts under which medical supplies, devices, and drugs are supplied to hospitals, nursing homes, and other medical institutions. Note that GPOs do not actually purchase these supplies, nor do they handle them physically.

Horizontal Integration. (Compare *vertical integration*.) Companies acquiring companies engaged in making the same product or providing the same service. It is a mechanism for achieving certain business objectives, the foremost being killing off competitors.

Kickback.⁴⁵ An illegal payment for preferential treatment, such as shelf space, for a product. Paying or receiving kickbacks is a corrupt practice that interferes with making unbiased decisions. (Compare *rebate*.)

Non-medical switching. A change by a Pharmacy Benefit Manager (PBM) and insurance company *from* one medication a patient is taking *to* another during the term of the patient's insurance coverage. The change does not take into account the physician's opinion, nor is it related to the medication's effectiveness in maintaining the patient's stability. Financial factors may drive the switch.

Pharmacy Benefit Manager (PBM). A type of corporate middleman that decides what medications will be included in and excluded from the formularies covered by insurers. PBMs manage the prescription drug benefits for health insurance companies, employers, Medicaid, Medicare Part D drug plans, and others. PBMs receive money from insurance companies, employers and Medicaid, and are responsible for paying pharmacies to dispense medication to patients.

Pay for delay.⁴⁶ "Bribing" a competing manufacturer that has a legal right to produce a generic version of a drug **NOT** to do it, at least for a time.

Prior authorization. A utilization tool by which an insurer controls costs. The insurer decides whether it will pay for (authorize) a treatment that recommended (not yet carried out) by a physician for a patient enrolled in one of the insurer's plans.

⁴⁵ <https://www.investopedia.com/terms/k/kickback.asp>

⁴⁶ <https://lawreview.law.miami.edu/pharmaceutical-pay-for-delay-deals/>

B. DETOXIFY AMERICA’S MEDICINE CHEST

A Glossary of Self-Sabotage, Scarcity, and Inflation (*continued*)

Rebate. Generally understood to be a portion of a purchase price returned by a seller to a buyer, provided that the buyer meets certain conditions. In the American healthcare system, federal law permits manufacturers of drugs and medical devices to pay kickbacks—commonly referred to as “rebates”—to GPOs and PBMs.

Safe Harbor. A provision in the law that protects a company from liability when the company engages in a practice otherwise considered illegal in the conduct of business.

Specialty Pharmacy.⁴⁷ A pharmacy for dispensing medicines that tend to require handling and storage under special physical conditions. Note these are usually medications taken by the chronically, severely ill, such as those with cancer or other autoimmune illness.

Spread pricing.⁴⁸ A practice of Pharmacy Benefit Managers (PBMs) in charging state Medicaid programs a higher price for a medication dispensed to a covered patient than the PBM pays to the dispensing pharmacy. The PBM then relies on the state’s ignorance of this “spread” to allow the PBM to pocket the difference between the two prices. The practice may extend beyond state Medicaid programs.

Step therapy. A sequence of treatment steps required by an insurer, beginning with the least costly and proceeding to the most costly. The insurer’s hope is that the cheapest therapy will either work or placate a patient and physician for a time before they insist on the costliest—and often most-effective—treatment, which the physician would have preferred to apply at the start.

Utilization tools. Procedural hurdles controlled by insurers and aimed at controlling costs. (See *Step therapy*, *Prior authorization*, and *Non-medical switching*.)

Vertical Integration. (Compare *horizontal integration*.) Companies acquiring companies to gain the highest degree of control over their business, from ownership of the processes that generate the raw materials for their products all the way to the sale of those products to buyers. For example, in pursuit of complete vertical integration, a pharmacy chain may acquire a drug manufacturer, a Pharmacy Benefit Manager (PBM), an insurance company, a healthcare system, and the services of a variety of medical professionals.

⁴⁷ <https://www.pharmacist.com/Practice/Patient-Care-Services/Specialty>

⁴⁸ <https://arayarx.com/pbm-spread-pricing-explained/>

B. DETOXIFY AMERICA’S MEDICINE CHEST

Meet the Parasites—Middlemen, Agents of Opacity, Consolidation, and Scarcity

Pharmaceutical companies, often referred to as “BIG PHARMA,” conduct research to develop drugs. It’s an expensive undertaking, requiring huge investments in specialized skills, testing, and time.

Bringing those drugs to market is no easy task. A slow-moving, overburdened bureaucracy must be satisfied of the drug’s safety. Within the federal government’s Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), originally charged only with ensuring the safety of medications, is now also in the business of approving pharmaceutical products and medical devices.

In the popular mind, BIG PHARMA is a villain. To be sure, they are not blameless. Some of their business practices enhance their profits without putting the patient first. We will say more on that subject later in this section.

However, one of the least understood features of American health care is the role played by some of the wealthiest corporations in stocking the national medicine chest.

These corporations conduct no research and manufacture nothing.

They are middlemen that have morphed into parasites, adding a draining overhead that can only be guessed at to the total cost of the system. Their power extends from helping to decide which drug makers survive to how much a government program or private citizen will pay for a drug or medical device. They control whether an insurer will even cover the cost of a drug or product.

Now, that’s power.

Who are they? What do we call them?

They are the Pharmacy Benefit Managers (**PBMs**) and the Group Purchasing Organizations (**GPOs**).

In recent decades, these companies have grown through consolidation. They have achieved a degree of concentrated power, trending toward the monopolistic in certain regions of the country.

The federal government has abetted this trend through indifferent oversight of the effects of its own regulation.

B. DETOXIFY AMERICA’S MEDICINE CHEST

Meet the Parasites—Middlemen, Agents of Opacity, Consolidation, and Scarcity *(continued)*

Make no mistake, these corporate giants are as big as it gets. They have spots in the Fortune 500’s top 20. And like all parasites, they face certain challenges—how to anesthetize the host against the pain of infestation while satisfying their own appetites; not killing the host; and making it hard to see what they’re doing.

The PBMs

The first PBM was created in 1968 to help health insurers reduce what they had to spend for prescription medicines.⁴⁹ The PBMs would arrange bulk purchases and handle the paperwork of claims.

At first, these middlemen achieved their purpose, and their numbers grew.

But as the decades passed, their role expanded; their accumulated wealth exploded; and a process of consolidation and concentration set in.

Eventually, they not only administered drug claims, they controlled the insurers’ formularies (the drugs that would be covered), and the utilization tools (*remember your glossary*). And they were doing it for everybody—for commercial third-party payers (insurers) and large employers, and for taxpayer-funded programs: Medicare Part D and Medicaid-managed care. Quite a lucrative gig, if you can get it.

Then, in 2003, the federal government granted the PBMs a legislative “safe harbor”—specifically, freedom from the anti-kickback law in their dealings with BIG PHARMA.

Ever since, the prices for prescription medicines have soared and the list of essential drugs in chronically short supply has grown.

By early 2020, according to one study, the combination of legislation and the growth of the PBMs’ power led to —

53% of Americans declining to fill a prescription because of the cost.⁵⁰

A person who isn’t fussy about grammar could be excused for thinking: “Somebody’s makin’ money somewhere, but this system ain’t workin’ for the rest of us.”

⁴⁹ <https://www.reuters.com/article/us-valeant-pharmacies-expressscripts-exc-idUSKCN0SO2NE20151031>

⁵⁰ <https://patientengagementhit.com/news/medication-adherence-falters-as-out-of-pocket-patient-costs-soar>

B. DETOXIFY AMERICA’S MEDICINE CHEST

Meet the Parasites—Middlemen, Agents of Opacity, Consolidation, and Scarcity *(continued)*

The PBMs’ Sketchy Practices

The profiteering and questionable practices of the largest PBMs come at the expense of all Americans, but most especially those with chronic illness and the greatest need for affordable medication.

Here are five practices that diligent investigators of the subject have identified. (NOTE: There are smaller PBMs that do not engage in such practices, but that remain true to the mission of the original PBMs.)

1. **Spread pricing** is a device by which a PBM retains a portion of the money paid to it by a third-party payer (for example, a state’s Medicaid program) and meant for the dispensing pharmacy.

In Ohio’s Medicaid program alone, the state found that two of the nation’s largest PBMs had helped themselves to \$224 million per year by this method, charging the state six times the going rate for their services.

Investigators in Iowa discovered that CVS Caremark would bill a county’s Medicaid program as much as \$124 for having a local pharmacy dispense a medication—a transaction for which CVS Caremark paid the pharmacy \$2.69. CVS Caremark pocketed the other \$121.31.⁵¹

As this issue has emerged from the shadows, other states and even some federal lawmakers have developed enough spine to do something about it.⁵²

2. **Direct and Indirect Remuneration (DIR)** are “clawback” fees imposed by PBMs on pharmacies. The mechanism is a product of a loophole in Medicare regulation that allows a PBM to cite quality metrics—unpredictable, inconsistent, and poorly defined—as a basis for the demanded remuneration. The act of clawing the money back from the pharmacies can occur months after patients have paid for and received their medications. The pharmacies’ books are left with the scars from the claws.

⁵¹ <https://www.desmoinesregister.com/story/news/investigations/2018/04/18/iowa-taxpayers-being-overbilled-prescription-drugs-question-sparks-heated-debated-iowa-capitol/527643002/>

⁵² <https://www.whitecase.com/publications/alert/federal-legislators-and-ftc-keep-pbms-center-stage-drug-pricing-debate>

B. DETOXIFY AMERICA’S MEDICINE CHEST

Meet the Parasites—Middlemen, Agents of Opacity, Consolidation, and Scarcity *(continued)*

The PBMs’ Sketchy Practices *(continued)*

Some PBMs have close ties to or even own a BIG BOX pharmacy chain. There is no transparency to what these PBMs pay these pharmacies for medications versus what they pay independent pharmacies. Also in the dark are what the PBMs retain via spread pricing and how much they receive in clawbacks. But we know this much—some PBMs overpay their associated pharmacies while underpaying the independents.⁵³ That is a highly anti-competitive practice.

3. **Specialty and Mail-Order Pharmacies** are the creations of PBMs⁵⁴ for delivering to patients those drugs that must be stored under specific environmental conditions. The PBMs have “locked up” huge chunks of the this market by contractual arrangements with the following: the federal government’s Medicare program; state Medicaid programs; insurers; and the hospitals that participate with the 340B program. With exclusive access to such large shares of the market, price manipulation and other shenanigans become not only irresistible, but essential to conceal. Hence, the resistance to investigation.⁵⁵

The three biggest PBMs—CVS Caremark, Express Scripts, and OptumRx⁵⁶— took in over 70% (\$113 billion) of mail-order prescription revenue in 2019. But there have been troubling reports that the medications have sometimes been unviable, damaged, or late to arrive, affecting the wellbeing of patients, including the insulin-dependent.⁵⁷ This would be unthinkable and rapidly rectified in a more-competitive, more-free marketplace.

4. **Utilization tools** include such things as prior authorization, step therapy, and non-medical switching. PBMs administer and control these mechanisms, which restrict the freedom of patients and physicians while maximizing the profitability of the business controlling the tools.

⁵³ <https://businessinsider.com/cvs-squeezing-us-mom-and-pop-pharmacies-out-of-business-2018-3>

⁵⁴ <https://www.drugchannels.net/2020/07/pbm-owned-specialty-pharmacies-expand.html>

⁵⁵ <https://www.paauditor.gov/press-releases/auditor-general-depasquale-calls-on-senate-to-join-fight-for-lower-prescription-costs-by-passing-bills-to-increase-oversight-of-pbms>

⁵⁶ <https://www.beckershospitalreview.com/pharmacy/pbms-ranked-by-market-share-cvs-caremark-is-no-1.html>

⁵⁷ <https://www.nbcnews.com/specials/millions-of-americans-receive-drugs-by-mail-but-are-they-safe/>

B. DETOXIFY AMERICA’S MEDICINE CHEST

Meet the Parasites—Middlemen, Agents of Opacity, Consolidation, and Scarcity *(continued)*

The PBMs’ Sketchy Practices *(continued)*

5. “**Rebates.**” An especially opaque activity in the dealing between PBMs and BIG PHARMA is the flow of money to PBMs in the form of rebates protected by the “safe harbor.” Except for this legal protection, the “**rebates**” that the PBMs extract from BIG PHARMA are indistinguishable from **kickbacks**. The industry association and lobbyists representing the PBMs claim that the PBMs pass these rebates on to consumers. The energy of the PBMs in providing proof along with the zeal of government regulators in verifying the claim has been less than impressive.

The legalized kickback system creates “rebate walls” also, barring entry into the market. Drug manufacturers outbid each other to become the sole or nearly sole suppliers of many medications. This favors the biggest manufacturers, which are flush enough to afford kickbacks. Smaller manufacturers, unable to climb over the “rebate wall” are unable to compete.

The practices enumerated above threaten to continue the destruction of independent pharmacies and small businesses—all highly trusted by the patients they serve, or by their employees. They are profoundly anti-competitive practices; they drive inflation; and they contribute to shortages.

The American public pays a very steep price for whatever savings the industry association and lobbyists representing the PBMs claim to deliver.

B. DETOXIFY AMERICA’S MEDICINE CHEST

Meet the Parasites—Middlemen, Agents of Opacity, Consolidation, and Scarcity *(continued)*

The PBMs and Vertical Integration

The aim of “vertical integration” is to eliminate competition and accumulate power and control. Its tendency is toward the formation of a monopoly.

The phenomenon of “vertical integration” among corporations has led to some of the most dramatic changes in the history of American business, for example, the breaking up of vertically integrated organizations to create freer, more-competitive markets.⁵⁸

Because it is a natural drive in business to be free of competition and establish market dominance, managing this drive has long been regarded as the job of America’s rule makers (our legislators and bureaucratic administrators) and umpires (the courts and the executive branch’s departments for enforcing the law).

The history of America’s healthcare system as we know it today is a history of vertical integration over 60 to 70 years, of consolidation and concentration, of increasingly entangled conflicts of interest. We now behold a healthcare system dominated by corporate colossi, entities of monstrous size comprised of insurance companies, PBMs, BIG BOX pharmacy chains, specialty pharmacies, and clinical services staffed by physicians and every category of nurse and therapist.

In the table presented on the next page, we show how the decreasing number of these vertically integrated entities have arranged themselves.

⁵⁸ <https://hbr.org/2017/12/the-rise-fall-and-rebirth-of-the-u-s-antitrust-movement>

B. DETOXYFY AMERICA’S MEDICINE CHEST

Meet the Parasites—Middlemen, Agents of Opacity, Consolidation, and Scarcity (continued)

The PBMs and Vertical Integration (continued)

NOTE: *Free2Care* is grateful to Adam J. Fein, Ph.D., of the Drug Channels Institute in Philadelphia for permission to use the latest version of the table below.

Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2022

Insurer	aetna®	Elevance Health	BlueCross BlueShield	CENTENE Corporation	Cigna	Humana	UnitedHealthcare®
PBM (GPO)	CVS caremark™ Zinc	ingenioRx™	PRIME THERAPEUTICS®	envolve™ ³ Pharmacy Solutions	EXPRESS SCRIPTS® Ascent Health Services ⁵	Humana Pharmacy Solutions.	OPTUMRX® EMISAR
Specialty Pharmacy	CVS specialty™	CVS specialty™	allianceRx ² Walgreens + PRIME accredo®	AcariaHealth™ An envolve Pharmacy Solution	accredo®	CenterWell Specialty Pharmacy	OPTUM® Specialty Pharmacy
Provider Services	minute clinic® Health HUB.	CareMore HEALTH Aspire Health		USMM. ⁴ U.S. Medical Management® Community Medical Group	Cigna Medical Group. Cigna Collective Care ¹	Partners in Primary Care. CONVIVA Care Center Kindred at Home ⁶	OPTUM Care®

1. Cigna also partners with providers via its Cigna Collaborative Care program.
 2. Since January 2021, Prime’s Blue Cross and Blue Shield plans have had the option to use Express Scripts or AllianceRx Walgreens Prime for mail and specialty pharmacy services. In December 2021, Walgreens Boots Alliance purchased Prime Therapeutics’ 45% ownership in AllianceRx Walgreens Prime.
 3. In 2021, Centene has announced its intention to consolidate all PBM operations onto a single platform and outsource its PBM operations to an external company.
 4. In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.
 5. Since 2020, Prime has sourced formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.
 6. In 2022, Humana announced an agreement to divest its majority interest in Kindred at Home’s Hospice and Personal Care Divisions to Clayton, Dubilier & Rice.
 Source: *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Exhibit 212. Companies are listed alphabetically by insurer name.

B. DETOXIFY AMERICA’S MEDICINE CHEST

The PBMs and Vertical Integration *(continued)*

Meet the Parasites—Middlemen, Agents of Opacity, Consolidation, and Scarcity *(continued)*

The GPOs

The other class of middleman contributing to inflation and shortages in American health care is the Group Purchasing Organization (GPO).

Although it is hard to rank them according to a single metric,⁵⁹ multiple sources agree that the three largest GPOs are: Vizient, Inc.; Premier; and Healthtrust Purchasing Group, LP.⁶⁰

They write the exclusive contracts that energize the movement of all supplies—masks, gowns, medical devices, sterile solutions, and medications—through distributors into hospitals, hospital-owned clinics, and nursing homes. These supplies can account for up to 40% of a hospital’s overhead,⁶¹ second only to payroll. If a physician in a hospital or clinic wants to use a product that a designated distributor of the contracting GPO does not furnish, that physician is out of luck.

The GPOs have enjoyed the “safe harbor” as far back as 1987, effectively reversing a 15-year-old anti-kickback law that Congress enacted with the very intent of protecting the public in its pursuit of medical services and products at affordable cost.

We can find no evidence that the HHS OIG has *ever* exercised its statutory responsibility and power for ensuring that the kickbacks remained at or below 3% of the cost of the medication or device in question.

⁵⁹ One method is to rank them by the number of beds in the hospital systems and nursing homes supplied by the GPOs. <https://www.definitivehc.com/blog/top-10-gpos-by-staffed-beds>

⁶⁰ <https://www.salesdatagenerator.com/blog/top-10-hospitals-gpos/>

⁶¹ https://www.researchgate.net/publication/318660591_Hospital_Supply_Expenses_An_Important_Ingredient_in_Health_Services_Research

B. DETOXIFY AMERICA’S MEDICINE CHEST

Meet the Parasites—Middlemen, Agents of Opacity, Consolidation, and Scarcity *(continued)*

The GPOs *(continued)*

In any case, these kickbacks remain a perverse incentive to the GPOs (as they are to the PBMs) toward choosing more-expensive products for inclusion in their catalogues and formularies.

In 2012, a GAO report found that six GPOs (since consolidated into four), controlled 90%⁶² of the supply chain for the products needed in hospitals, hospital-owned clinics, and nursing homes.

The burden of rebates/kickbacks on the nation’s annual healthcare bill has tended to reduce the number of manufacturers for supplies and medicines.

The wealthiest manufacturers of medical supplies and devices can afford the kickbacks expected by the GPOs. Smaller competitors have tended to disappear or never enter the market in the first place.

The effect of this winnowing by kickback has been a brittle supply chain with known shortages of hundreds of products. Over 200 are now on the list⁶³ of drugs and solutions in short supply—chemotherapies, antibiotics, and anesthetics, even generics. Many more have been on and off that list chronically for decades.

Does the reader remember the shortages of personal protective equipment (PPE), masks and surgical gowns) in the early stage of the pandemic? Does the reader remember the firing of whistle-blowing physicians and nurses who used their own PPE, thus drawing attention to how the institutions they worked for were short of the PPE⁶⁴ that the contracting GPOs should have supplied via their chosen distributors?

These products should be plentiful and inexpensive because of a crowded field of competitive producers.

The mere fact that shortages exist, ***especially for generics and basic supplies***, is a huge red flag, signaling that a gross distortion of market forces has forced the misallocation of resources (like available money) in the marketplace.

⁶² Ibid.

⁶³ <https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=CurrentShortages&loginreturnUrl=SSOCheckOnly>

⁶⁴ <https://www.washingtonpost.com/outlook/2020/04/07/hospitals-are-censoring-doctors-theyre-endangering-rest-us/>

B. DETOXIFY AMERICA’S MEDICINE CHEST

Meet the Parasites—Middlemen, Agents of Opacity, Consolidation, and Scarcity *(continued)*

The GPOs *(continued)*

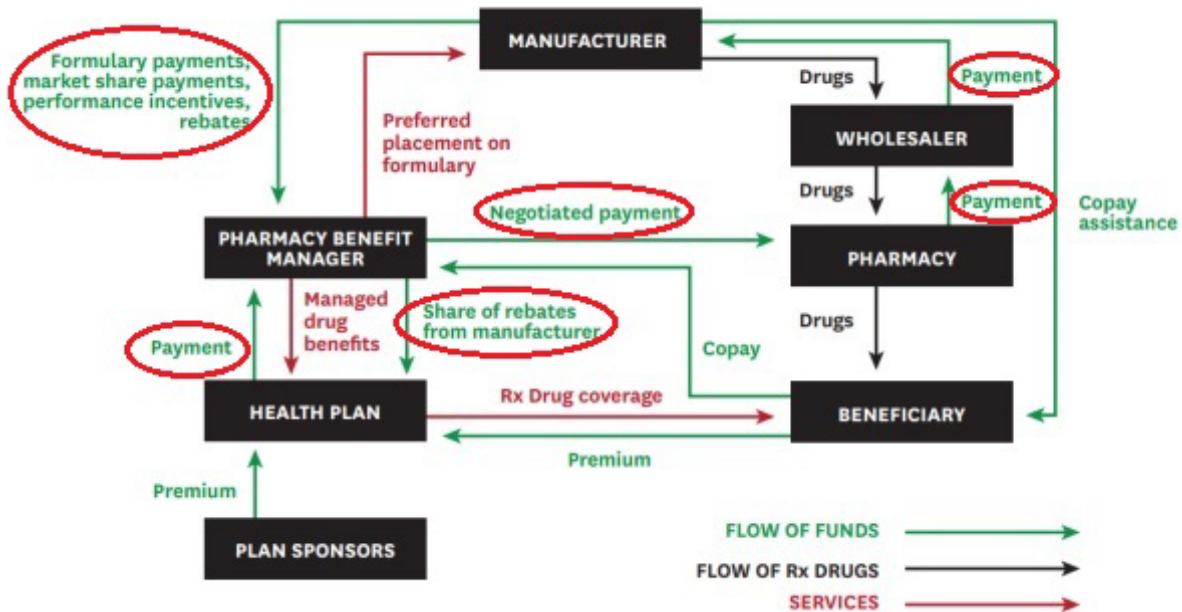
The biggest and wealthiest manufacturers can afford the ever-increasing kickbacks. By paying for market share, they can become one of a few suppliers—if not the sole supplier—for a single medical product. Then, if a pandemic, a natural disaster, or contamination suddenly interrupts the supply chain, there are no other manufacturers to alleviate the shortage.

Shortages are an inevitable consequence of some entities vacuuming up too much money and creating a distorted marketplace; and in distorting the marketplace, those entities create a freakishly high annual bill for health care in the United States.

B. DETOXIFY AMERICA’S MEDICINE CHEST

Insulin: The Scandalous Rise in Price

Choosing just one high-profile, essential medication, *insulin*, the Senate Finance Committee, working in a bipartisan spirit, shed light in 2021 on part of the tangled process that has led to its scandalous rise in its price.⁶⁵ Study the image below. Now imagine that “process” governing the cost not only of insulin, but of nearly the entire American prescription pharmacopeia.



Source: Sood, et al., *The Flow of Money Through the Pharmaceutical Distribution System*, USC SCHAEFFER CENTER FOR HEALTH POLICY & ECONOMICS 2 (2017)

Net price: the price paid to the drug’s manufacturer.

List price: the price paid by a patient or a third-party payer. It is the net price plus all of the kickbacks and fees collected by a middleman. In the image above, everything inside a red oval lacks transparency.

In the case of *insulin* most of the list price (as much as triple the net price) comes from the activity of the PBMs and third-party payers (commercial insurers and the government).

However, we must point out that the manufacturers of *insulin* are willing to pay to play in this broken marketplace. It is the path not only to being included in the formularies of insurers, but also to freezing competing manufacturers out of the marketplace.

⁶⁵ [https://finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf)

B. DETOXIFY AMERICA'S MEDICINE CHEST

Insulin: The Scandalous Rise in Price (*continued*)

The next graph shows just how steep the rise in the list price of *insulin* has become since 2012 and how wide the gap has grown between the net and list prices.

Insulin cost over time



Source: Drug Channels

Free2Care

As reported by the Senate Finance Committee, it appears that the three companies making most of the *insulin* set their prices not with reference to an acceptable margin of profit, but in possible collusion with each other.

This inflationary constellation of forces can operate against every drug manufactured by competing pharmaceutical companies.

Again, increases in a list price for any drug feed *only* those corporate entities that conduct *no* research, *no* development, *no* testing, and *no* manufacturing.

The horizontal and vertical integration that has occurred among BIG BOX pharmacy chains, specialty pharmacies, insurance companies, and the largest PBMs, enables these companies to generate vast streams of revenue.

They then use that revenue to knock competition from smaller PBMs out of the marketplace, along with smaller manufacturers, independent pharmacies, and others. This greases the road to increased consolidation and monopolization.

B. DETOXIFY AMERICA’S MEDICINE CHEST

Insulin: The Scandalous Rise in Price *(continued)*

Lest we leave the reader with a mistaken impression, we must say here that the large pharmaceutical manufacturers, although burdened by the kickbacks paid to GPOs and PBMs, are by no means helpless innocents in this profiteering, predatory, and corrupted system.

Reform 5. Repeal the “Safe Harbor” law, inter alia.

To address the anti-competitive and inflationary practices of the middlemen in the American healthcare industry, and to attack the problem of high prices for insulin and injectable epinephrine, *Free2Care* calls for legislation that will accomplish the following.

Repeal the “Safe Harbor” protection of kickbacks that PBMs and GPOs enjoy. (Proposed language for the repeal can be found in Appendix A on page 83.)

Demand transparency for ALL monies—including DIR fees, performance incentives, and payments to pharmacies—flowing into PBMs, GPOs, and other intermediaries in the supply chain.

Support Senator Ron Wyden’s (D-OR) call for the FTC to investigate DIR fees.

Support the rule proposed by the CMS to allow DIR fees to pass through to the beneficiaries of the Medicare Part D program.

Enable patients to pay their coinsurance and copays based on the net price of prescription medications, not the list price.

Ban the practice of non-medical switching and price increases for medications during a commercial health insurance policy’s plan year in the cases of policyholders having complex, chronic, or rare medical conditions. For such policyholders, ban also the movement of medications to a costlier tier during that plan year. The out-of-pocket cost set at open enrollment must not rise during the plan year.

Pass the bipartisan “Pharmacy Benefit Manager Transparency Act of 2022.”

Require that the Director of the OMB and the White House exclude from the freeze imposed on Executive Order 13937 both insulin and injectable epinephrine. Moreover, they must direct FQHCs immediately to dispense these medications at cost or suffer the loss of grant money.

Require a full, public accounting of the true cost of insulin, injectable epinephrine, OxyContin®, Naloxone, and Humira.

Require that HHS OIG and several independent entities without conflicts of interest study (a) all contracts related to OxyContin®, (b) contracts for every drug currently or previously in short supply, and (c) all previous contracts for these medications since the “Safe Harbor” for legalized kickbacks was enacted in 1987 and then expanded in 2003. The study’s findings and contracts must be released to the public.

B. DETOXIFY AMERICA’S MEDICINE CHEST

Addressing Mental Health and Putting a Dent in Drug Prices

On June 22, 2022, H.R. 7666,⁶⁶ a bipartisan bill addressing mental health needs, passed with over 400 votes in the 435-seat House of Representatives. This degree of bipartisan support should make it impossible for the Senate to ignore this legislation.

This bill not only seeks to improve access to medical care in this country for people suffering from mental illness, but Section 602, introduced by Rep Michael Burgess, M.D. (R-TX, 26th District), imposes transparency requirements on PBMs.

Specifically, Section 602 requires that PBMs explain why they have included drugs in (and excluded drugs from) the formularies of insurers. They must disclose also the financial information that drove those decisions.

Free2Care welcomes this news. Physicians and patients should be able to see exactly how and why PBMs make clinical decisions about the medications to which patients can have cost-effective access. Moreover, *Free2Care* strongly opposes any watering down of the requirements placed upon PBMs and the penalties for non-compliance.

As of late, three bills—one on infrastructure,⁶⁷ another on guns,⁶⁸ and a third on insulin⁶⁹— have passed in the House, but they have delayed implementation of a Trump Rebate Rule⁷⁰ to ensure that “rebates” enjoyed by PBMs really go toward lowering drug prices for seniors.

Support for the continued delay in implementing the Trump Rebate Rule has been justified on the ground that the delay saves the taxpayers’ money. It does not; and any who advocate that the delay saves taxpayers’ money are relying on nothing more than accounting gimmickry. This is shameful and deserves to be exposed. The future use of the gimmick should be a cause for disgrace.

⁶⁶ <https://www.congress.gov/bill/117th-congress/house-bill/7666>

⁶⁷ <https://www.newsweek.com/drug-rebate-rule-deserves-standeven-if-it-came-trump-opinion-1616778>

⁶⁸ <https://thehill.com/opinion/healthcare/3539743-gun-legislation-provision-puts-drug-supply-chain-profits-over-patients/>

⁶⁹ <https://www.buckscountycouriertimes.com/story/opinion/editorials/2022/04/11/our-view-affordable-insulin-now-act-doesnt-live-up-to-its-name/65348843007/>

⁷⁰ <https://www.hhs.gov/sites/default/files/rebate-rule-discount-and-pbm-service-fee-final-rule.pdf>

B. DETOXIFY AMERICA’S MEDICINE CHEST

Addressing Mental Health and Putting a Dent in Drug Prices *(continued)*

Free2Care believes that legislation and a rebate rule exist to achieve quick wins in the struggle against the healthcare oligarchy. Until the legislative branch musters the will to repeal the “Safe Harbor” for kickbacks, the Trump Rebate Rule would at least force PBMs to use the kickback money for its original purpose.

Reform 6. Increase pressure on the PBMs for transparency and for reducing the prices of drugs through proper use of kickback money.

To achieve the quick wins mentioned above, *Free2Care* calls for the following.

Passage by the Senate of a Senate-version of H.R. 7666.

An end to delay in implementing the Trump Rebate Rule.

B. DETOXIFY AMERICA'S MEDICINE CHEST

Big Pharma is Not Blameless

The profitability of a patent-protected monopoly obviously spurs innovation by the pharmaceutical industry. Protection by patent law helps a pharmaceutical company recover its investments in developing a prescription drug and bringing it to market by keeping the price high, at least for a time. The United States obviously has standards in place to protect both the inventor's business interest *and* the consumers' safety.

The problem, however, is that patents are unreasonably prolonged by rather sketchy techniques.

One is *evergreening* (*remember your glossary*), the acquisition of a new patent for an old medication—modestly tweaked in some respect—that offers *no* new breakthrough in care and no new pharmacological benefit.

A 2022 report⁷¹ on the 50 best-selling drugs in the United States revealed that many were little more than modestly tweaked versions of old drugs and had patents that had been extended beyond the usual seven years. The maker of Humira, for instance, has enjoyed an exclusive right of production for nearly 20 years.

Would the reader be aghast at learning that between 2005 and 2015, 74% of the patents granted to the pharmaceutical industry were for *evergreened* drugs?⁷²

BIG PHARMA will sometimes market combinations of two drugs as one “new” drug, but this, too, is mere gamesmanship. Examples are medications for migraines, acne, and birth control. After combination, they are then artfully marketed in direct-to-consumer (DTC) advertising campaigns. Physicians must then explain to patients that a drug called DUEXIS® will not provide enough relief from rheumatoid arthritis and acid reflux to restore one's ability to skip joyously through a field of goldenrod.

Pay for delay is a second technique to prevent manufacture of a generic version of a formerly patent-protected drug. The holder of the expired patent that formerly protected a monopoly on manufacturing pays other companies that now have the legal right to produce a generic version of the drug *NOT* to do it, at least for a time.

⁷¹ <https://truecostofhealthcare.org/pharmas-50-best-sellers/>

⁷² <https://www.fiercepharma.com/pharma/pharma-s-pervasive-evergreening-driving-prices-up-study-says>

B. DETOXIFY AMERICA’S MEDICINE CHEST

Big Pharma is Not Blameless *(continued)*

Biosimilars These present a significant opportunity for cost-savings in the United States because they can introduce competition for some of the most expensive and widely used prescription drugs on the market. But thickets of patent protection—the deliberate anti-competitive creation of BIG PHARMA—have slowed the introduction of this class of drugs into the American market.

Those thickets preserve the high profits from the “reference biologics” that the **biosimilars** could replace.

The harm to the public from this gamesmanship is multifaceted. Not only are savings never realized, so, too, are the jobs that could have been created by competing domestic manufacturers as they make the generics and **biosimilars**.

Reform 7. Enforce and reform patent law for pharmaceuticals and medical devices.

To address the anti-competitive abuses and weaknesses in the enforcement of patent law related to the invention of pharmaceuticals and medical devices, *Free2Care* calls for legislation that will accomplish the following.

Enforce the existing standards in patent law requiring that patents be granted solely for inventions that are:

- ***Clearly novel; and***
- ***Built and working.***

Establish a standard of safety for the FDA that will make it possible to approve pharmaceuticals and medical devices at a faster rate, similar to that of Operation Warp Speed.

Enact reforms to ban process patents that block competitive activity, particularly for biologics and biosimilars.

Now we turn to another reason that America’s medicine chest needs detoxifying—BIG PHARMA’s outsourcing of pharmaceutical manufacture to China.

B. DETOXIFY AMERICA’S MEDICINE CHEST

American Health Care’s “China Syndrome”

Among the most striking effects of the overhead built into the annual national cost of our dysfunctional healthcare system, has been the outsourcing to China of the manufacture of many pharmaceuticals and medical supplies used here at home.

Part of that historic shift has been a change in the sourcing of the active pharmaceutical ingredients (APIs) that go into our medicines and vitamins.

In the 1990s, 90% of the world’s APIs came from the US, Europe, and Japan.

China is now the largest global supplier of APIs.

The effect on the quality of the supplies in America’s medicine chest has been alarming.

Shortages and contaminated products are chronic and constitute a slowly unfolding healthcare crisis for the United States.

But a *national security threat* of incalculable measure has developed out of our country’s reliance on China for drugs, protective equipment, and medical supplies.

By driving up all of the costs of needless overhead in our healthcare system, we compelled our manufacturing sector to seek lower labor costs in China.

We now see that this manufacturing must be brought home or placed within the borders of staunch allies.

Despite the many obstacles that stand in that way of doing that, it would be a supreme, historic folly to delay.

We cannot wait until the next pandemic to address this threat.

In their 2018 book, *China Rx: Exposing the Risks of America’s Dependence on China for Medicine*,⁷³ Rosemary Gibson and Janardan Prasad Singh painted a profoundly ominous picture of a world that had changed over the preceding 25 years.

⁷³ <https://www.chinarxbook.com/>

B. DETOXIFY AMERICA’S MEDICINE CHEST

American Health Care’s “China Syndrome” (*continued*)

No longer did the United States, Europe, and Japan supply 90% of “the key ingredients for the world’s medicines and vitamins.” Instead, “China,” they wrote, “is the largest global supplier of the active ingredients needed to make many prescription drugs, over-the-counter products, and vitamins.”

In 2022, China has become the source for approximately 40% of the world’s Active Pharmaceutical Ingredients (APIs),⁷⁴ the chemical building blocks that are critical to making drugs.

Few in the United States, even among physicians, are fully aware of just how drastic our dependence has become. Here are just a few examples.

- About 97% of antibiotics⁷⁵ used in the United States, including drugs as basic as penicillin and amoxicillin, now come from China.
- Almost all of the contrast dye needed for many diagnostic procedures originates in a single facility in Shanghai, recently closed because of a COVID-related lockdown. Across the United States, physicians now warn that rationed and deferred diagnostic procedures⁷⁶ will inevitably have medically unfortunate consequences.
- Much of the personal protective equipment (PPE), so much in the forefront of the news during the worst of the pandemic in 2020, also originates in China. The country where the pandemic erupted suddenly needed the PPE in short supply in the United States.

But of equal seriousness to the risks associated with reductions in or cutoffs of these desperately needed supplies exported from China⁷⁷ is the chronically vexing question of the quality and safety of those exports.

⁷⁴ <https://daxueconsulting.com/api-industry-in-china/>

⁷⁵ <https://www.cfr.org/blog/us-dependence-pharmaceutical-products-china>

⁷⁶ <https://www.nbcnews.com/news/us-news/shortage-contrast-dye-hospitals-ration-ct-scans-procedures-rcna29379>

⁷⁷ <https://apnews.com/article/us-news-ap-top-news-international-news-global-trade-virus-outbreak-bf685dcf52125be54e030834ab7062a8>

B. DETOXIFY AMERICA’S MEDICINE CHEST

American Health Care’s “China Syndrome” (*continued*)

A few examples:

- Chinese-made KN95 masks were found to be substandard⁷⁸ during the pandemic.
- Just before COVID-19 struck, eight million Chinese-made surgical gowns were recalled⁷⁹ for not having been produced under sterile conditions.
- In 2019, three commonly used blood pressure medications manufactured in China were found to be tainted with carcinogens.⁸⁰
- In 2008, news reports compelled the Food and Drug Administration (FDA) to acknowledge that 81 deaths from contaminated *heparin*—made in China and sold worldwide—had been produced in a facility the FDA had not inspected.⁸¹

Given the dramatic shift by the United States to foreign-made medications and supplies, it is not surprising that the FDA has struggled to keep up⁸² with its legally required inspections of manufacturing facilities overseas.

And when the pandemic hit, inspections stopped.⁸³

The implications for public health and national security are staggering. By inspecting only a small fraction of Chinese manufacturing plants and their output, the FDA fails to perform its primary duty of ensuring drug and product safety. This puts Americans in harm’s way.⁸⁴

Medications with ingredients from China are used in the United States for routine surgeries, common and less-common infections, psychiatric disorders, cancer, and seizures. Those with chronic diseases who must take medication and the young

⁷⁸ <https://www.forbes.com/sites/robertglatter/2020/09/25/almost-70-of-chinese-kn95-masks-dont-meet-minimum-safety-standards/?sh=5457957148b9>

⁷⁹ <https://www.cbsnews.com/news/surgical-gown-recall-leaves-medical-centers-scrambling-2020-01-31/>

⁸⁰ <https://www.bloomberg.com/news/features/2019-09-12/how-carcinogen-tainted-generic-drug-valsartan-got-past-the-fda>

⁸¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2249657/>

⁸² <https://www.fda.gov/news-events/congressional-testimony/covid-19-and-beyond-oversight-fdas-foreign-drug-manufacturing-inspection-process-06022020>

⁸³ https://files.gao.gov/reports/GAO-21-265/index.html?fbclid=IwARIYGO55LBVvbEqYLxO5VyYbQ84T1kR5mXSTlyYP5fEfThPWn4aTbuT_HLOo

⁸⁴ <https://www.wsj.com/articles/how-the-u-s-ceded-control-of-drug-supplies-to-china-11596634936>

B. DETOXIFY AMERICA’S MEDICINE CHEST

American Health Care’s “China Syndrome” *(continued)*

who have years ahead of taking these medications are most at risk of developing cancers and other long-term complications from possibly tainted products that have not yet been detected.

When pondering the consequences of China cutting off supplies, the authors predicted, “Surgeries would be canceled, cancer treatments halted, kidney dialysis rationed. Infections would spread.”

Some officials in Washington and representatives in Congress have started to pay attention,⁸⁵ to study the issue and generate reports.

In May 2020, Sen. Marco Rubio (R-FL) and Sen. Elizabeth Warren (D-MA) introduced a bipartisan bill—the “Strengthening Supply Chains for Service Members and Security Act” (H.R.6374). The bill would implement the recommendations from a previous Department of Defense Office of Inspector General (DOD OIG) report to address the nation’s overreliance on foreign-made pharmaceuticals.

Tariffs imposed during the Trump years and sustained, at least so far, by the Biden administration were a step in the direction of stimulating domestic production of the class of products discussed above.

But to borrow a phrase, let’s cut to the chase.

- America *must* reclaim the manufacture of its medical supplies and critical drugs made from safe APIs.
- Those who shape our trade policy and create the ground rules that have driven the decisions of American corporations to send manufacturing abroad *must* act now to reverse course.
- The FDA *must* strengthen its staffing for auditing foreign manufacturers that are significant vendors in our supply chain.
- Any foreign country’s refusal to allow free and timely access to production facilities *must* be fined and either suspended or terminated as a vendor.

⁸⁵ <https://www.nbcnews.com/health/health-care/u-s-officials-worried-about-chinese-control-american-drug-supply-n1052376>

B. DETOXIFY AMERICA’S MEDICINE CHEST

American Health Care’s “China Syndrome” *(continued)*

A survey of the past 30 years shows that our wildly excessive reliance on a geopolitical “frenemy” devoted to surpassing the United States as an economic and military leader has put us in an untenable position.

The proverbial Sword of Damocles dangles above us.

To the greatest degree and by any policy and regulatory means, including taxation rates, the United States must bring home the production of the ingredients that go into a revitalized domestic manufacture of the tools we use to care for our sick.

Posthaste.

Reform 8. Address national security and health risks from over-reliance on pharmaceuticals produced in China.

To address the full range of problems posed by our “China Syndrome,” *Free2Care* calls for legislation that will accomplish the following.

Require the Defense Logistics Agency (DLA) to modify:

- ***DLA Instructions 3110.01 to include the “contract responsiveness testing” results reported by Military Service customers;***
- ***DLA Instructions 5025.03 to require DLA Troop Support to coordinate annually with Military Service customers to conduct responsiveness testing of the DLA's contingency contracts for pharmaceuticals.***

Require the FDA to strengthen its infrastructure and staffing to audit foreign manufacturers that are significant vendors in our supply chain, to impose fines for any refusal to allow free and timely access and, with repeated infarctions leading to termination as a vendor.

Require the Department of Homeland Security (DHS) to place pharmaceuticals in the same category as semiconductors, microelectronics, and rare earth minerals—as essentials for national security—and therefore demanding attention to the repair of vulnerable supply chains.

Require a review of existing arrangements for foreign trade with the objective of incentivizing the American agriculture and manufacturing sectors to take the reins in developing and supplying the critical drugs needed for the delivery of medical care.

C. REVERSE OUR PHYSICIAN SHORTAGE

The Drain of DRexit

We cannot have quality medical care in the United States without an adequate supply of physicians.

Yet one in five physicians plans to leave medicine in the next two years,⁸⁶ deepening an already anticipated physician shortage.⁸⁷

In the United Kingdom, the same phenomenon in their National Health Service has been dubbed “DRexit.”

The COVID-19 pandemic has only strengthened the impulse of many physicians to get out of the field. Nearly 50% report “burnout;” that figure is 60% among those practicing emergency medicine.⁸⁸

Physicians Wendy Dean and Simon Talbot coined the term “moral injury”⁸⁹ to describe a physician’s sense of futility when working against a system that increasingly seeks to marginalize them and reduce them to clerical cogs in multiple ways.

What do physicians in the American system of health care identify as the sources of a discouragement so great that they feel moved to think of abandoning medicine?

At the top of most lists⁹⁰ are the administrative, bureaucratic, reporting, and informational chores that rob physicians of time with patients. Those chores are a constant reminder that somehow their vision of being independent, autonomous professionals has veered way off track. Instead, they are under the control of non-medical, regulatory and business interests—the “suits.”

What would help the situation?

Reducing the aforementioned chores would be helpful.

⁸⁶ <https://www.ama-assn.org/practice-management/physician-health/medicine-s-great-resignation-1-5-doctors-plan-exit-2-years>

⁸⁷ <https://www.aamc.org/news-insights/us-physician-shortage-growing>

⁸⁸ <https://www.cidrap.umn.edu/news-perspective/2022/05/emergency-medical-staff-report-high-levels-burnout-amid-covid-19>

⁸⁹ <https://www.statnews.com/2019/07/26/moral-injury-burnout-medicine-lessons-learned/>

⁹⁰ <https://aceaglobal.com/continuing-education-journal/medical-insights/the-link-between-administrative-burden-and-physician-burnout/>

C. REVERSE OUR PHYSICIAN SHORTAGE

The Drain of DRexit (*continued*)

Obviously, training more physicians is a good idea.

Incentivizing physicians to become or to remain *independent* would address a significant issue.

Getting the “suits” off their backs would be a *huge* relief.

But Section 6001 of the Affordable Care Act (ACA)⁹¹ actually enhances the power of the “suits” by preventing physicians from creating the very settings where the power of the “suits” would be severely limited.

Specifically, what does Section 6001 do?

Quite specifically, it bans physicians from owning any new hospitals that are established.

As in so many instances when law and regulation intrude on medical practice, we encounter a striking irony.

The data show⁹² that those hospitals owned by physicians:

- Provide care of higher quality than those hospitals owned by “suits.”
- Pay local, state, and federal taxes.
- Foster a competitive marketplace in health care.

Free2Care firmly believes that reversing the ACA’s ban on physician-owned hospitals is integral to restoring the practice of independent medicine, restoring confidence among physicians, and stanching the American version of DRexit.

The legislation exists on the House⁹³ and Senate⁹⁴ sides to get it done.

⁹¹ https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals

⁹² <https://www.mercatus.org/publications/healthcare/cost-and-quality-care-physician-owned-hospitals-systematic-review>

⁹³ <https://burgess.house.gov/blog/?postid=403056>

⁹⁴ <https://www.lankford.senate.gov/news/press-releases/lankford-colleagues-continue-to-push-for-more-options-in-quality-health-care-for-oklahomans>

C. REVERSE OUR PHYSICIAN SHORTAGE

The Drain of DRexit (*continued*)

Reform 9. Reverse the ban on physicians owning hospitals.

To accomplish this objective, *Free2Care* calls for the following.

Passage of H.R. 1330—the bipartisan Patient Access to Higher Quality Health Care Act of 2021, introduced by Rep. Dr. Michael Burgess (R-TX, 26th District) and Rep. Vincent Gonzales (D-TX, 15th District)—as reconciled with its Senate counterpart, introduced in May 2022.

C. REVERSE OUR PHYSICIAN SHORTAGE

Physicians' Legal Vulnerability as Employees and Due Process Rights

In 2000, more than half of America's physicians were independent. Today, that number is closer to one in three.⁹⁵

Over the last several decades, incessant increases in the regulatory burden on the practice of medicine have forced physicians to cede the running of their business operation to administrators. Hospitals, private equity, and even third-party payers have bought physicians' practices. **Optum**, an arm of the insurer United Health and one of the three leading PBMs, is now the largest employer of physicians—over 100,000—in the United States.⁹⁶

When a physician works for a corporation, that physician's allegiance is compelled to shift from the patients to the employer. When the physician is independent, there is no such conflict.

Private equity owns 25% of hospitals, a significant number of urgent care facilities, and the staffing groups that provide personnel for 30% of ERs in this country.⁹⁷ The leveraged buyout by private equity—once most prevalent in the inpatient fields of ER, anesthesia, radiology, and pathology—is rapidly moving into outpatient and specialty settings.⁹⁸

Private equity's focus is first on generating revenue, and then consolidation that eliminates competition or prevents it from developing.

This has led to calls for greater visibility into their activities, particularly when it comes to billing.

Physicians working for hospitals or groups owned by private equity have no idea how much their employers are billing and collecting for clinical work the physicians have performed. If the profit margin for the employer is above fair market value for the services, there is a risk of putting the physician into the position of a fee splitter (a payer of an illegal kickback to the employer for the right to see patients⁹⁹).

⁹⁵ <https://www.healthcarefinancenews.com/news/nearly-70-us-physicians-are-employed-hospitals-or-corporate-entities>

⁹⁶ <https://www.beckersasc.com/asc-transactions-and-valuation-issues/optum-has-50-000-employed-affiliated-physicians-and-a-vision-for-the-future.html>

⁹⁷ <https://hcp.hms.harvard.edu/news/private-equity-investments-health-care>

⁹⁸ <https://www.modernhealthcare.com/physicians/specialty-physician-groups-attracting-private-equity-investment>

⁹⁹ <https://aaem.org/resources/key-issues/fee-splitting#:~:text=Fee%2Dsplitting%20is%20a%20commo n,for%20management%20expenses%20and%20overhead>

C. REVERSE OUR PHYSICIAN SHORTAGE

Physicians' Legal Vulnerability as Employees and Due Process Rights (continued)

In increasing numbers, physicians work for Contract Management Groups (CMGs) owned by private equity.

The CMGs are not legally bound to honor “due process” rights because of an exception¹⁰⁰ to the precedent set by the Healthcare Quality Improvement Act of 1986. Therefore, physicians employed by CMGs have no due process protections when providing services in fields like emergency room services or anesthesiology. We saw a glaring example of this when a Washington physician employed by a CMG was fired for questioning corporate practices that affected patient safety.¹⁰¹

Rep. Raul Ruiz (D-CA, 36th District), and Rep. Roger Marshall—now Sen. Marshall (R-KS)—both physicians—introduced the “E.R. Hero and Patient Safety Act” in May 2020.¹⁰² This would give due process protections to all emergency physicians, regardless of employer.

Reform 10. Protect physicians employed by hospitals and private equity groups.

Reform 11. Restore the right of due process to our physicians.

To protect physicians from falling into the illegal act of fee splitting and to ensure their due process rights, *Free2Care* calls for the following.

The enhancement and subsequent reintroduction of H. R. 6910 to require that:

- ***A physician has access to the amounts an employer bills in the physician's name.***
- ***Physicians employed by any CMG have due process protections in the form of freedom from restrictions in non-compete agreements regarding geography and time, inter alia.***

¹⁰⁰ <https://www.emra.org/be-involved/be-an-advocate/working-for-you/2018-cms-due-process/>

¹⁰¹ <https://www.npr.org/sections/health-shots/2020/05/29/865042307/an-er-doctor-lost-his-job-after-criticizing-his-hospital-on-covid-19-now-hes-sui>

¹⁰² <https://www.aam.org/current-news/important-due-process-bill-update>

C. REVERSE OUR PHYSICIAN SHORTAGE

Knowing the Training of the Person Treating You

In 2010, the National Academy of Medicine (formerly the Institute of Medicine), funded by the Robert Wood Johnson Foundation (RWJF), provided to the writers of the Affordable Care Act a document that served as a roadmap toward fundamental change¹⁰³ in how health care would be delivered in the United States.

That document promoted non-physician professionals as “providers” of care.

RWJF and the AARP, via a joint initiative, Campaign for Action,¹⁰⁴ have worked to help corporatized medicine follow the roadmap to a system in which non-physicians and physicians have the same scope of practice and the same level of compensation. The following numbers illustrate how successful the Campaign for Action has been.

- In the period from 2010 to 2017, the number of Nurse Practitioners (NPs) in the United States more than doubled from approximately 91,000 to 190,000.¹⁰⁵
- In 2017, nearly 28,000 individuals graduated from NP programs, almost 250% higher than a decade earlier (8,248).¹⁰⁶
- As of 2022, there are 355,000 licensed NPs.¹⁰⁷

Newly trained nurses have either left or never even entered the field of bedside nursing, instead pursuing APRN degrees.

The result? BEFORE the pandemic hit, there were shortages of bedside nurses.

The United States now faces a staggering shortage of over a million bedside nurses.

That looks like another of those ironies that spring up when law and regulation intrude on medical practice.

¹⁰³ <https://nap.nationalacademies.org/read/12956/chapter/1>

¹⁰⁴ <https://campaignforaction.org/>

¹⁰⁵ <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2019.00686>

¹⁰⁶ <https://www.healthaffairs.org/doi/10.1377/forefront.20180524.993081/full/>

¹⁰⁷ <https://www.aanp.org/about/all-about-NPs/np-fact-sheet>

C. REVERSE OUR PHYSICIAN SHORTAGE

Knowing the Training of the Person Treating You *(continued)*

To date, over 26 states, Washington, DC, and the Veterans Administration, allow APRNs to care for patients in the same way that physicians have traditionally done.¹⁰⁸ There is little, if any, oversight by or collaboration with a physician.

State legislatures have also taken up the question of expanding the scope of practice for physician assistants (PAs). It has become a movement supported by the lobbying efforts of the American Academy of Physician Assistants.¹⁰⁹

We are witnessing a seismic shift in the training for the practice of medicine and in the quality of care received by patients. Enabling non-physicians to practice medicine *without* the benefit of extensive education in a highly structured medical school and *without* rigorous testing of competence is nothing short of a highly risky social experiment—both astonishing and, so far, scarcely monitored in its consequences.

Until a study emerged recently from the Hattiesburg Clinic in Mississippi, there has been no study comparing unsupervised non-physician providers of care with licensed physicians. The study reviewed a decade and the cases of 30,000 patients in a primary care setting.

The results?

In nine of 10 quality metrics, licensed physicians scored higher.

The use of emergency rooms and referrals to specialists were more frequent for patients cared for by non-physicians.

That tendency increased costs by about \$10.3 million *per year* for the 30,000 patients tracked in the study.

Consider, also, the skewing of the financial incentives. In states and venues where non-physician providers have been empowered by law to perform the same role as physicians, hospitals and other corporations are incentivized to replace employed physicians with non-physician providers. After all, a corporation can bill and collect the same fees, but pay a lower salary.

¹⁰⁸ <https://www.policymed.com/2022/06/more-states-adopt-full-practice-authority-for-nurse-practitioners.html>

<https://www.forbes.com/sites/brucejapsen/2022/04/15/kansas-lifts-hurdle-to-nurse-practitioners-becomes-26th-state-to-do-so/?sh=6018aacb793f>

¹⁰⁹ <https://www.aapa.org/advocacy-central/optimal-team-practice>

C. REVERSE OUR PHYSICIAN SHORTAGE

Knowing the Training of the Person Treating You *(continued)*

The patient is in the dark about all of this. They have no idea of the difference in the level of training between a physician—who can have anywhere from 12,000 to 16,000 hours of clinical training—and a nurse practitioner (NP) or PA. The latter categories may have experienced only 500 to 720 hours (for APRNs) of clinical training.¹¹⁰

If the public had a grasp of this seismic shift in the training of the healthcare professionals they encounter, who knows what could happen? There could even be a seismic shift in the composition of the United States Congress and state legislatures.

Free2Care supports being straight with the public, and that means requiring transparency about training.

Reform 12. Ensure transparency for the public regarding the training of clinicians.

To achieve this reform, *Free2Care* calls for the following.

The enhancement and subsequent reintroduction of H. R. 3928—the “Truth in Healthcare Marketing Act”—first proposed in 2017 by Rep. Larry Buchson, a physician (R-IN, 8th District). This Act, when enhanced, would forbid, inter alia, the misleading use of generic terms like “provider” in an insurance plan’s list of approved healthcare professionals and require disclosure of the licensure and levels of training associated with the different categories of professional.

¹¹⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7995928/>

C. REVERSE OUR PHYSICIAN SHORTAGE

Strangulation by Medical Certification Board

We now turn to the peculiar stranglehold some medical boards have on their own specialties.

Until 1989, after a physician passed an exam, a specialty board would grant lifetime board certification. Continued licensure was dependent upon continuing education *chosen by* the physician. After 1989, specialty boards began limiting the lifespan of the certificates. Eventually, those boards pressured physicians, along with the hospitals and insurers employing them, to subscribe to an expensive proprietary product, Maintenance of Certification (MOC®), for recertification.¹¹¹

Those certified before 1990 were “grandfathered” and did not have to recertify.

The mandate discriminated against younger physicians, a group increasingly made up of women and minorities, whose MOC® fees have netted a profit for the boards that demand them.

The top executives of these boards enjoy salaries *many times* that of physicians caring for patients.¹¹²

MOC® was enshrined in the Affordable Care Act as a “quality metric,” despite the absence of any evidence that it helped improve the quality of care given to patients or promoted their safety.

Furthermore, surveys have demonstrated that nearly all physicians believe that mandatory “maintenance of certification” contributes to burnout. One will hear the words “racket” and “scam” when they discuss the subject.

Consider the ABIM, ostensibly a non-profit organization. But on its own Form 990, Return of Organization Exempt from Income Tax, it acknowledges having “restricted contributors.”¹¹³ Now, who would be contributing from the dark shadows to an organization that is extracting more and more from the income of physicians, while simultaneously abetting their burnout?

The chart on the next page identifies some of the key players in the world of MOCery.

¹¹¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3716034/>

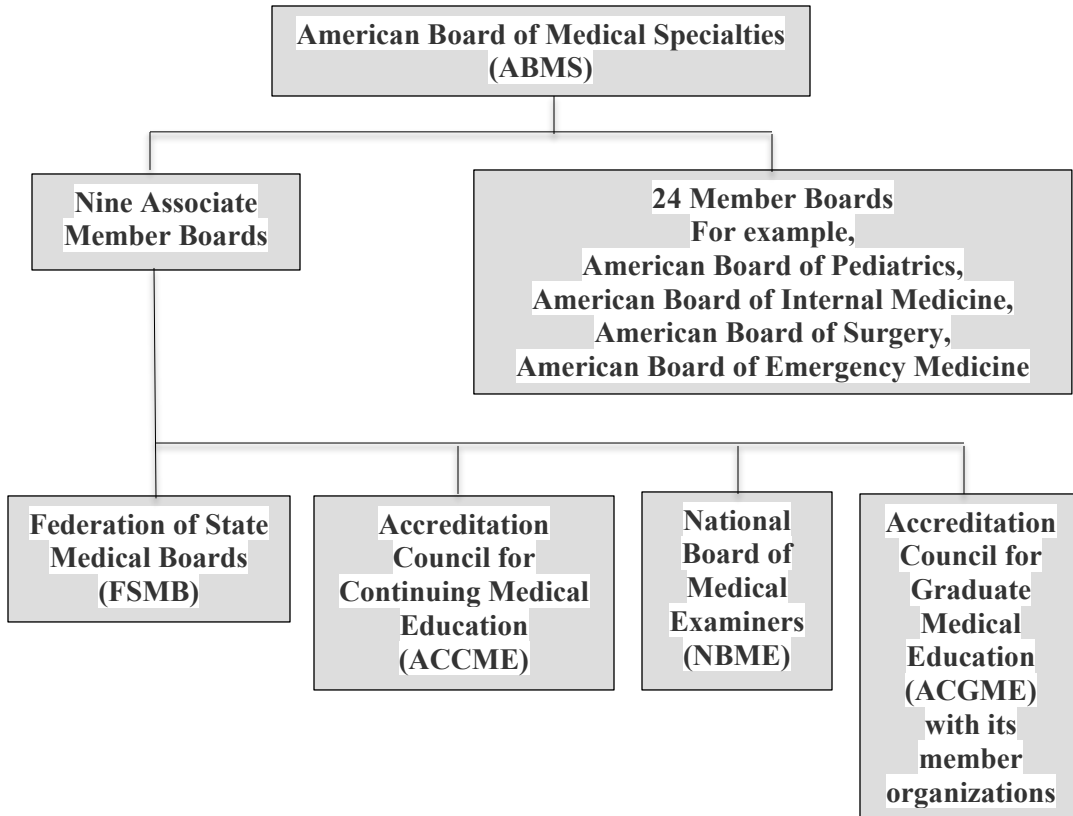
¹¹² <https://www.newsweek.com/2015/06/05/medical-mystery-making-sense-abims-financial-report-334772.html>

<http://drwes.blogspot.com/2020/10/the-unjust-enrichment-at-abim.html>

¹¹³ <http://drwes.blogspot.com/>

C. REVERSE OUR PHYSICIAN SHORTAGE

Strangulation by Medical Certification Board (*continued*)



Free2Care urges a reform to ease the burden MOC imposes.

Reform 13. Allow choice and competition in recertifying physicians

To achieve that result, *Free2Care* calls for the following.

- ***Remove from the ACA the authorization to use the proprietary product, MOC®, as a quality metric.***
- ***Order the IRS to perform a full forensic accounting of the ABIM and require all “restricted contributors” and the amounts of their respective contributions to be disclosed.***
- ***Publication in a prominent, easily accessible database all conflicts of interest (including stock options) of salaried board members in the ABMS and other boards under the ABMS umbrella.***

C. REVERSE OUR PHYSICIAN SHORTAGE

Level the Playing Field in Disputes Over Surprise Medical Bills

When Americans are wheeled into an emergency room, they expect and receive medical care, no questions asked.

Americans with insurance also expect that their insurance company will perform its expected duty and pay a reasonable bill for emergency care.

When circumstances demand that a physician, perhaps a specialist, who happens to be outside an insurer's network, attend to the patient, an uncovered surprise bill can enter the picture. With the enactment of the No Surprises Act (NSA), patients are now no longer on the hook for payment of this bill; an independent arbitrator between the insurer and the physician settles any dispute over payment.

A battle between insurers on one hand and physicians, hospitals, and patient advocates on the other accompanied the run-up to passage of the NSA in December 2020. The NSA aimed to protect patients from being stuck with uncovered medical expenses. It also sought to establish a fair process, known as independent dispute resolution (IDR), for resolving disputes between the insurer and physician.

But something went wrong, and the Act's implementation by the Departments of Health and Human Services (HHS), Labor, and Treasury strayed not only from the intent of Congress, but from the text of the statute itself.

After Congress passed the NSA, HHS gave the job of working out the regulatory details to the Centers for Medicare & Medicaid Services (CMS) and its Center for Consumer Information and Insurance Oversight (CCIIO).

Instead of requiring—as specifically spelled out in the NSA—the arbitrator to consider multiple factors equally, HHS and CMS instructed arbitrators to favor a “Qualifying Payment Amount” (QPA), a figure not only controlled by insurers, but of unknown origin and calculation, impossible to verify, and unrepresentative of what physicians are actually paid.

Predictably, less than a month after the NSA took effect, E.R. physicians received contracts from insurers with 20-to-40% cuts in rates.¹¹⁴ For the physicians to remain in the insurer's network, the cuts had to be accepted.

Insurers have already sent to physicians in other specialties contract proposals that impose similar cuts. Without question, insurers are exploiting the law, gaming it to exert continuing downward pressure in the IDR process.

¹¹⁴ <https://www.medpagetoday.com/special-reports/exclusives/97308>

C. REVERSE OUR PHYSICIAN SHORTAGE

Level the Playing Field in Disputes Over Surprise Medical Bills *(continued)*

While rates of payment from Medicare are stagnating or falling as part of an ongoing trend, ER visits are up for both Medicare and Medicaid patients.¹¹⁵

The reimbursement for Medicaid is 35% below Medicare rates, an unsustainable predicament for ER physicians, who see half of all Medicaid, acute-care visits.¹¹⁶ (NOTE: Medicaid patients still have low access to primary care providers).

Keep in mind that it is not just ER physicians who are affected, but every physician who staffs a hospital around the clock—surgeons, cardiologists, intensivists, anesthesiologists, pathologists and radiologists. We need those physicians to remove an appendix, insert a stent into our clogged arteries, and take care of our children with pneumonia.

The hastening of America’s DRexit and decreased access to care for patients are not hard to foresee.

On February 23, 2022, the U.S. District Court for the Eastern District of Texas vacated the undermining parts of the administration’s IDR regulations nationwide,¹¹⁷ while keeping the protection intact. In a suit, plaintiffs (the Texas Medical Association and Dr. Adam Corley) successfully challenged the rule’s so-called “rebuttable presumption,” which instructed certain entities in the IDR process to assume that the QPA is the appropriate out-of-network payment unless it could be proven—and the standard of proof was very high— that a higher payment was called for. The same court reached a near-identical decision on July 26, 2022, again favoring the plaintiffs over HHS.¹¹⁸

A bipartisan group of over 150 lawmakers is on the record in support of the District Court’s ruling.¹¹⁹

Make no mistake. Health insurance companies do not want an impartial Independent Dispute Resolution (IDR) process. They would like to prevail in every case. If that were to happen, a significant number of physicians would be forced to close their practices. Insurance networks would become narrower than ever. Patients would lose access to the treatment they need.

¹¹⁵ <https://www.healthleadersmedia.com/revenue-cycle/reasons-emergency-room-visits-vary-health-insurance>

¹¹⁶ https://www.cdc.gov/nchs/data/nhamcs/web_tables/2016_ed_web_tables.pdf

¹¹⁷ <https://ogletree.com/app/uploads/blog-assets/Texas-Med-Assn-v.-HHS.pdf>

¹¹⁸ <https://sites-polsinelli.vuturvx.com/112/3606/uploads/22-07-26-lifenet-op-and-order.pdf>

¹¹⁹ https://wenstrup.house.gov/uploadedfiles/2021.11.05_no_surprises_act_letter.pdf

C. REVERSE OUR PHYSICIAN SHORTAGE

Level the Playing Field in Disputes Over Surprise Medical Bills *(continued)*

The sensible way to implement the NSA is to construct an IDR process in which all factors listed in the law receive equal, unbiased consideration.

On August 19, 2022, HHS, CMS, and other federal regulators issued their final rule for the IDR process,¹²⁰ claiming that this satisfied the court's requirements. This was not the case. The regulators' new language still required the arbitrator to use the QPA as a "guidepost" for considering other factors in the dispute.

The regulators justified this "final rule" by saying that the QPA presumably already included other factors. Therefore, they reasoned, the arbitrators need not consider the other data that the Congress, in the NSA, had explicitly said should be considered. The "final rule" placed the burden on the physician to prove to the arbitrator that the physician's data was so exceptional that it was ***not*** already included in the QPA.

But the presumption that all relevant factors are included in the QPA is based on thin air. The NSA itself does not presume that to be the case. As said earlier, the QPA is a number of unknown origin and calculation, impossible to verify, and unrepresentative of what physicians are actually paid.

With its "final rule," HHS and CMS continue to favor health insurance companies and now skirt ***two*** decisions by the federal court.

Legal challenges are afoot in Georgia, Illinois, Washington, DC, and elsewhere. *Free2Care* supports them and calls for new lawsuits that focus on the current administration's continued favoritism toward a QPA controlled by the health insurance companies. We insist on an IDR process that follows the text of the NSA in requiring an arbitrator to weigh fairly ***all*** data presented by the disputants, and to decide, with an explanation, which of the two figures is a more-reasonable, out-of-network payment in the case.

Free2Care supports the intent of Congress in passing the NSA with its protections for patients and expectation of a truly fair IDR process for resolving disputes over surprise medical bills.

Reform 14. Enforce parity (stop favoring insurers) in the NSA's IDR process and conduct a fact-finding mission into why the current administration favors insurers.

¹²⁰ <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/ebbsa1210-ac00-and-1210ab99-idr-process-final-rule-dol816-final.pdf>

C. REVERSE OUR PHYSICIAN SHORTAGE

Level the Playing Field in Disputes Over Surprise Medical Bills *(continued)*

Free2Care calls for the following.

The Congress must drive HHS and CMS to fulfill their duty and ensure that the “No Surprises Act” is implemented fairly. The law’s IDR process must be free of bias and readily accessible. Specifically, the continued skewing of the IDR process toward favoring the QPA must end, as directed by the Texas court.

The Congress should continue to write bipartisan letters to HHS in support of a truly fair method of arbitration for resolving disputes over surprise medical bills.

The next Congress must investigate how and why the administration has continued to skew the NSA regulations to favor obviously the health insurance companies in direct defiance of what the NSA said.

C. REVERSE OUR PHYSICIAN SHORTAGE

What's to Be Done With the Surplus of Med School Grads?

Each year, between 4,000 and 5,000 people who graduate from medical school fail to match into residencies.

To train more physicians, we must increase the number of available residencies.

The proposed, bipartisan “Resident Physician Shortage Reduction Act of 2021”¹²¹ provides funding for an additional 2,000 residency positions per year for seven years—a total of 14,000 new spots by 2029.

As mentioned elsewhere, no one tracks how the money from Medicare that funds residencies is spent. Again, this is a matter of *opacity* trumping *transparency*—a defect that riddles the American system of health care, funded greatly by the taxpayer.

Providing transparency, as *Free2Care* has urged repeatedly in this document, may very well assist in re-allocating funding so that paying for the additional 2,000 residencies would be budget-neutral, or nearly so.

Free2Care urges...

Reform 15. Increase the number of residency positions.

To achieve that objective, *Free2Care* calls for the following.

Pass the bipartisan “Resident Physician Shortage Reduction Act of 2021” (S.834) introduced by Sen. Robert Menendez (D-NJ), and its companion bill in the House, H.R. 2256, proposed by Rep. Terri Sewell (D-LA, 7th District).

¹²¹ [https://www.congress.gov/bill/117th-congress/senate-bill/834#:~:text=Introduced%20in%20Senate%20\(03%2F18%2F2021\)&text=This%20bill%20increases%20the%20number,and%20health%20professional%20shortage%20areas](https://www.congress.gov/bill/117th-congress/senate-bill/834#:~:text=Introduced%20in%20Senate%20(03%2F18%2F2021)&text=This%20bill%20increases%20the%20number,and%20health%20professional%20shortage%20areas)

C. REVERSE OUR PHYSICIAN SHORTAGE

Make Med School Grads Useful as They Await Open Residencies

Missouri has been experimenting to solve the problem of having more medical school graduates than it has open spots for training them in residency programs.

The state’s “Assistant Physician (AP)” program has enabled these graduates, while they wait for a match, to be clinically active and useful by providing primary care in underserved areas.¹²²

The graduates in this novel program work under a physician’s direct supervision for the first 120 hours. After that, they can work within 50 geographical miles of the supervisor.

Missouri’s example has been instructive. So far, its AP program has produced 392 licensed APs.

Utah,¹²³ Arkansas,¹²⁴ Kansas,¹²⁵ and Arizona¹²⁶ have developed similar programs. Several other states are working on legislation to support licensing programs for these individuals waiting to be matched.

With the help of physicians and institutions engaged in training resident physicians, programs like the one in Missouri can be refined in other states to create more opportunities for paid work, standardized training, and credits toward residency experience.

Free2Care commends Missouri and other states that have found a socially beneficial way to use medical school graduates who are waiting to be matched into residency programs.

Reform 16. Increase “Assistant Physician” positions in the United States.

Free2Care urges the following.

The Centers for Medicare & Medicaid Services should be instructed to innovate with pilot projects that deploy supervised “assistant physicians” to all medically underserved areas of the country, urban or rural.

¹²² <https://www.aafp.org/dam/AAFP/documents/advocacy/workforce/scope/BKG-Scope-AssistantPhysicians.pdf>

¹²³ <https://le.utah.gov/~2017/bills/static/HB0396.html>

¹²⁴ <https://www.armedicalboard.org/Professionals/pdf/REGULATION%2037%20%2010-5-15.pdf>

¹²⁵ http://www.kslegislature.org/li_2016/b2015_16/measures/documents/hb2225_enrolled.pdf

¹²⁶ <https://www.azleg.gov/legtext/55leg/1R/laws/0354.htm>

C. REVERSE OUR PHYSICIAN SHORTAGE

Where Does the Money that Funds Residencies Really Go?

The federal government dispenses funds out of the Medicare and Medicaid programs to large hospital systems for the training of medical residents.

While the average salary per medical resident is \$63,000,¹²⁷ some hospital programs receive as much as \$180,000 annually for the resident's training.¹²⁸

Part of that money must go toward malpractice insurance; none goes toward housing.

The medical resident pays for housing out of the resident's salary.

The difference between what Medicare pays to the large hospital system and how much the medical resident benefits from, apart from salary, is neither tracked nor known.

Even with known limits on the hours a resident can work, the amount of money billed in a resident's name—an amount that the hospital itself collects—is unknown.

Knowing the way things really operate, *Free2Care* doubts that lifting up the rock to see what's happening underneath will reveal only beautiful things.

Reform 17. Account fully for how taxpayer funding is used for medical residents.

Free2Care urges the following.

The Centers for Medicare & Medicaid Services, under guidance from the GME Policy Council, must define comprehensive data collection and reporting requirements for entities receiving Medicare GME funds.

¹²⁷ <https://www.ziprecruiter.com/Salaries/Medical-Residency-Salary>

¹²⁸ <https://www.fiercehealthcare.com/practices/study-suggests-medicare-overpaying-1-28b-annually-to-support-residency-programs>

C. REVERSE OUR PHYSICIAN SHORTAGE

A Prescription to Prevent the Pain of “Prior Authorization”

As the decades have passed since regulatory bodies, third-party payers, and medical boards first established an invisible presence in examination rooms all over America, physicians have been forced to spend less and less time with their patients.¹²⁹

Instead, the time spent on administrivia has gone up markedly.¹³⁰ To meet the expectations of corporate “suits” about the volume of daily business, it has become necessary also to hustle one patient out the door while hustling the next one in.

Patients and physicians have complained about the trend. They know it’s unhealthy.¹³¹

“Prior Authorization” is the process by which insurers require physicians and other providers to check in with the insurer first to obtain approval to use certain drugs, conduct tests and studies, and perform surgery. Of greatest concern is delay in a situation where delay is dangerous—as when access to a life-saving medication such as insulin is involved.

Prior Authorization is at the top of the list as a bureaucratic headache in the practice of medicine, costing physicians an estimated 13 hours *per week*—13 hours that could have been spent on patient care.¹³² About 34% of physicians report that confusion or delay related to prior authorization has led to a serious adverse event.

This staggering misallocation of the precious resource of time in providing medical care is a monstrosity and wonder of the American system of health care. Those who create the administrative burdens, but are without experience in carrying them—having never lifted a finger to do so—are oblivious to the consequences of their requirements.

Free2Care finds it impossible to condemn strongly enough the tendency of the most-recent decades.

¹²⁹ <https://www.acpjournals.org/doi/full/10.7326/M16-0961>

¹³⁰ <https://www.annfammed.org/content/15/5/419>

¹³¹ <https://nytimes.com/2017/11/14/well/live/the-patients-vs-paperwork-problem-for-doctors.html>

¹³² <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>

C. REVERSE OUR PHYSICIAN SHORTAGE

A Prescription to Prevent the Pain of “Prior Authorization” (*continued*)

Reform 18. Prevent Prior Authorization from impeding patient-care and increasing the administrative burden on physicians’ offices.

To reverse this trend, *Free2Care* calls for the following.

Passage of H.R. 3173, the “Improving Seniors’ Timely Access to Care Act of 2021.”

Passage of H.R. 7995, the “Gold Card Act of 2022.”

NOTE: *Free2Care* calls for the timely access envisioned by these acts¹³³ to be extended eventually to ALL ages in ALL contexts involving a third-party payer, public or private, in a time-sensitive medical decision.

¹³³ <https://www.congress.gov/bill/117th-congress/house-bill/3173/text>
<https://www.congress.gov/bill/117th-congress/house-bill/7995/text>

C. REVERSE OUR PHYSICIAN SHORTAGE

Get Out of the Way of the Direct Primary Care (DPC) Movement

Despite regulatory barriers, primary-care physicians are leading a grassroots movement in the United States to provide patients with care that is affordable, accessible, personal, and portable.

The movement is based on an economic model¹³⁴ called Direct Primary Care (DPC), which cuts third-party payers and other corporate middlemen **OUT OF** the relationship between the physician and patient.

As insurance networks have narrowed, Direct Specialty Care (DSC) has also started to emerge¹³⁵ as an alternative to in-network referrals. With DSC, there is no insurance requirement or restriction. Access to specialists improves, especially where they are in short supply. DSC is available also on price-per-visit basis without subscription. This creates greater choice for patients and encourages them to seek good value, using Health Savings Accounts to do so.

DPC demonstrates how medical care—which should *never* be confused with insurance coverage—can be both accessible and affordable for patients, while helping physicians get out from under much of the regulatory burden that contributes to burnout.¹³⁶

For employers, also, DPC and DSC models are integral to self-funded health plans and medical cost-sharing groups.

DPC is not concierge medicine.¹³⁷ It is an affordable membership model with an average cost of \$75 per month.

Under DPC, patients benefit from:

- Increased personal attention;
- Full, same-day access;
- No cap on visits;
- Coordination in their care;
- Transparent costs.

¹³⁴ <https://www.medicaleconomics.com/view/direct-primary-care-three-key-consequences->

¹³⁵ <https://www.kevinmd.com/2021/09/the-emergence-of-direct-specialty-care.html>

¹³⁶ <https://www.medicaleconomics.com/view/reasonable-defense-direct-primary-care>

¹³⁷ <https://dpcalliance.org/DPCU-Understanding-DPC>

C. REVERSE OUR PHYSICIAN SHORTAGE

Get Out of the Way of the Direct Primary Care (DPC) Movement (*continued*)

It is advisable to maintain insurance coverage for expensive, catastrophic illness, and for essential follow-up care, such as procedures, cancer therapy, or advanced imaging. Such coverage entails lower premiums because of the high deductible. Again, a third-party payer, such as commercial insurer, plays no part in the DPC relationship, and decreased use leads to lower overall spending.

Physicians providing care under the DPC model do the following:

- Negotiate substantial discounts with labs and imaging services;
- Dispense generic medications at near-wholesale cost directly from the office;
- Provide primary care to patients with pre-existing medical conditions

DPC works well for patients who need frequent visits with their physicians, medications, lab tests, and studies.

The use of telemedicine, without interference from insurers, has become integral to the relationship between DPC physicians and patients.

By converting to the DPC model, Desoto Memorial Hospital in Florida has saved \$1.2 million per year, ***over half*** their healthcare costs. Clinical outcomes have improved also.¹³⁸

K&N Management in Austin, Texas, spent \$1.2 million on health benefits in 2018 and reduced annual healthcare costs by 30% to 50%¹³⁹ by adopting the DPC model.

Smart legislation will foster reliance on the DPC model rather than obstructing it.

Legislative guardrails would ***NOT*** define DPC as a form of insurance, but as a medical service that is payable like other medical services.

Perhaps one the most telling arguments for DPC is who criticizes it and why. As indicated earlier, DPC is an economic model that cuts third-party payers and other corporate middlemen ***OUT OF*** the relationship between the physician and patient. Without claims, insurers have less access to patient data. (Data gathering and personal patient information have become sources of revenue for third parties who share it with other companies.) The argument ***for*** DPC is as simple as the arithmetic—with DPC, patients and physicians fare better in multiple ways and ***at lower, transparent cost.***

¹³⁸ <https://www.physicianoutlook.com/articles/desoto-memorial-hospital>

¹³⁹ <https://www.healthgram.com/insight/how-direct-primary-care-reduces-health-insurance-costs/>

C. REVERSE OUR PHYSICIAN SHORTAGE

Get Out of the Way of the Direct Primary Care (DPC) Movement *(continued)*

Free2Care calls upon legislators at the federal and state levels to do the following.

Reform 19. Foster unobstructed expansion of Direct Patient Care in its pure form.

To clear the way, *Free2Care* supports essential clarifications in the tax code related to health care, **SUCH AS THE ONES FOUND IN THE COMPANION BILLS OF H.R. 725 AND S.153 OF 2021 AND 2022. THESE BILLS EFFECTIVELY DECOUPLE HEALTH SAVINGS ACCOUNTS FROM HIGH DEDUCTIBLE HEALTH PLANS AND MAKE DIRECT PRIMARY CARE DISTINCT FROM INSURANCE.**

We call for:

Passage of H.R 725 and S.153, both titled Personalized Care Act of 2021

C. REVERSE OUR PHYSICIAN SHORTAGE

Ban Non-Compete Agreements for Medical Professionals

Used for centuries by employers, Non-Compete Agreements (NCAs) are an instrument to prevent an employee from using specialized training and confidential information as a competitor after leaving the employer's service.

When applied to the medical profession—especially in these times of increased consolidation in health care—NCAs are potentially harmful. They can restrict patients' access to care, interrupt continuity of care, and even lead to a shortage of medical care within a geographical footprint.

Despite longstanding opposition to NCAs, they are enforceable in most states, although to varying degrees. This patchwork of inconsistent policies has stimulated interest at the federal level. When applied to physicians rather than to the general labor market, the argument that NCAs are needed to protect an employer's legitimate business interest does not have much support.

Nonetheless, bills introduced in Congress¹⁴⁰ to address NCAs have made no progress toward passage.

An executive order issued by President Biden in July 2021¹⁴¹ suggested that the Federal Trade Commission should assess the applicability of NCAs in general. However, the order did not definitively address the issue of NCAs in medicine.

Free2Care opposes generally the restrictions that NCAs impose on workers, most especially those that restrict the freedoms imposed of medical professionals to use their education and experience.

Free2Care calls upon legislators at the federal level to do the following.

Reform 20. Ban non-compete agreements for medical professionals.

To achieve this result, *Free2Care* urges:

Passage of S.483, the Workforce Mobility Act of 2021.

¹⁴⁰ <https://www.congress.gov/bill/117th-congress/senate-bill/483/text?r=1&s=1>

¹⁴¹ <https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/>

D. STRENGTHEN ACCESS TO CARE FOR ALL

Radical Rethinking of How and Where Taxpayer Money Flows

The United States must ensure to the greatest extent possible access to medical care of high quality and sustainability for the most economically vulnerable, whether in urban or less-populated, rural areas.

Free2Care has already discussed Direct Primary Care (DPC) arrangements.

For many covered by Medicare and Medicaid, their funding could easily cover Direct Primary Care (DPC) and specialty direct care arrangements. This part of the population would experience increased choice and access with full transparency of costs.

In DPC, patients pay physicians a subscription fee (often less than the cost of a cell phone bill) that covers most primary and acute care.

Innovative technology—such as HIPAA-compliant smartphone apps and other tools—has allowed patients to build trusting relationships with DPC physicians and specialists. Patients and physicians report that more-robust relationships with patients make it easier to treat chronic, long-term conditions, such as diabetes, depression, and heart disease. Access to specialists is faster. When patients have more choices and know the cost on the way in, the care is affordable and has greater value to them.

A shifted paradigm from being reactive to proactive has the potential to change our sick-care system into a system with a stronger focus on maintaining good health.

When combined with guaranteed-coverage pools for those with high-cost medical needs, such a change can lead to measurable improvement in American health and wellbeing.

Free2Care urges radical rethinking of how and where taxpayer money flows into meeting medical needs in this country.

Reform 21. Allow use of Medicare and Medicaid funds for direct payment for medical care.

To serve this objective, *Free2Care* calls for the following.

Development and passage of legislation enabling Medicare and Medicaid patients to use funding as vouchers for the purchase of DPC services. Medicare beneficiaries should have the choice to opt out of Medicare Part A without fear of losing Social Security benefits.

D. STRENGTHEN ACCESS TO CARE FOR ALL

Closing the Gaps in Care

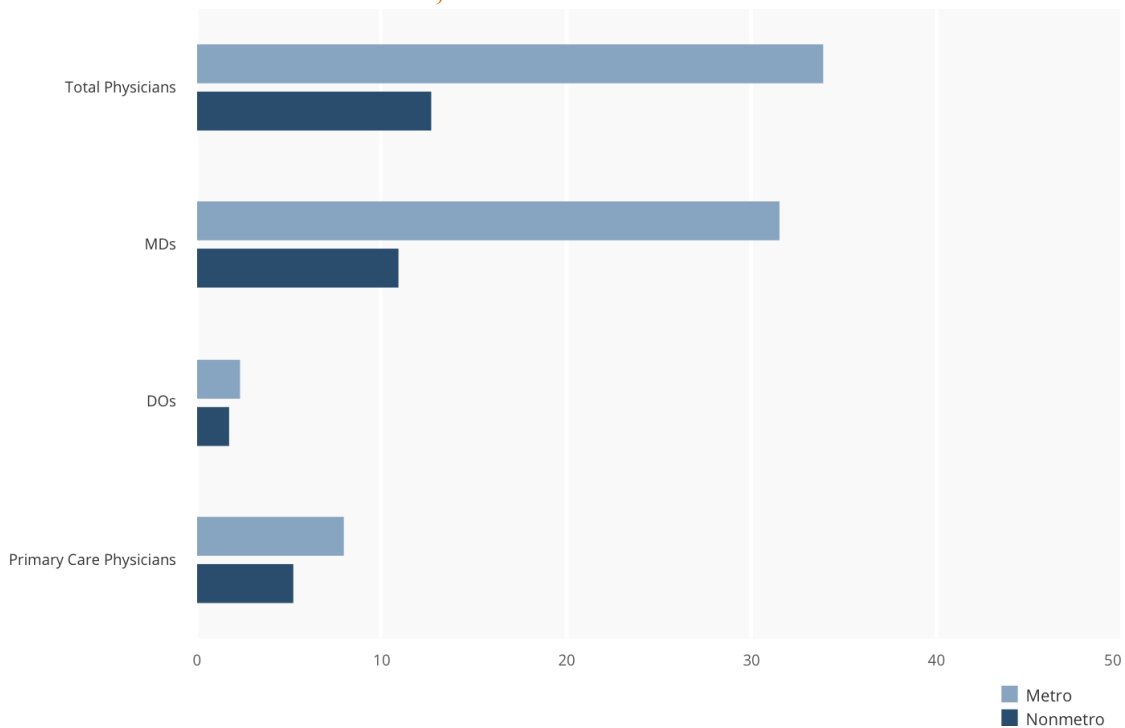
There are fewer physicians per capita in rural areas than in urban settings (see the chart below).

Pre-pandemic, 40% of all rural hospitals in the United States were at immediate or high risk of closure.¹⁴²

Hospitals in rural settings have experienced a merger binge.¹⁴³ Following a merger, rural hospitals usually cut services and staff.¹⁴⁴

Obviously, access to healthcare in rural areas is in decline.

Physicians per 10,000 people Metro and nonmetro counties, 2019



Source: Rural Health Info¹⁴⁵

¹⁴² https://chqpr.org/downloads/Rural_Hospitals_at_Risk_of_Closing.pdf

¹⁴³ <https://www.shepscenter.unc.edu/wp-content/uploads/2014/08/MergersAcquisitionsAugust2014.pdf>

¹⁴⁴ <https://www.benefitspro.com/2021/10/13/rural-hospital-mergers-reduce-access-to-specialty-care/?amp=1>

¹⁴⁵ <https://www.ruralhealthinfo.org/charts/109>

D. STRENGTHEN ACCESS TO CARE FOR ALL

Closing the Gaps in Care (*continued*)

In view of all that, it is no surprise that those who live in rural areas are more likely to die earlier from one or more of the leading causes of death in the United States.¹⁴⁶ Even worse, it costs more for the privilege.¹⁴⁷

Some of the reforms *Free2Care* called for in Section C—such as Missouri’s program for licensing “Assistant Physicians”—will go some distance toward alleviating the shortage of physicians.

There are other reforms, also, that would be helpful, specifically, in addressing the shortage in rural parts of the country. Here are a few reforms worth considering as the subject of incentivizing legislation.

- Tax deductions for providing pro-bono care are an excellent way to do this, and are the subject of Rep. Daniel Webster’s (R-FL, 11th District) H.R. 7831, “The Helping Everyone Access Long Term Healthcare Act.”¹⁴⁸ The Association of Mature American Citizens describes¹⁴⁹ details how this bill improves access to medical and dental care, and saves billions for taxpayers and Medicaid outlays.
- Vouchers for paying for DPC and other arrangements of direct care.
- Increased reliance on telehealth, billable at a rate of at least 80% of the rate for an in-person visit.
- Setting aside a percentage of residencies for students who want to practice medicine in their home communities, provided that those communities are underserved.
- Incentivizing medical schools through grant programs to allow students early exposure to rural communities.
- Speeding up pursuit of the target of 99.9% of Americans having access to broadband Internet services.

¹⁴⁶ <https://cdc.gov/chronicdisease/resources/publications/factsheets/rural-health.htm#:~:text=People%20who%20live%20in%20rural,lower%20respiratory%20disease%2C%20and%20stroke>

¹⁴⁷ <https://ncbi.nlm.nih.gov/pmc/articles/PMC7370548/>

¹⁴⁸ <https://www.congress.gov/bill/117th-congress/house-bill/7831?s=1&r=3>

¹⁴⁹ <https://www.amac.us/hr-7831/>

D. STRENGTHEN ACCESS TO CARE FOR ALL

Closing the Gaps in Care *(continued)*

The Potential of Telehealth with Real Physician Involvement

Physicians, whether independent or employed, should be able to deliver medical services through telehealth. *Free2Care* encourages rethinking of existing regulation that is a barrier to communication between physicians and patients across rural/urban divides and state lines.

A POINTED RESERVATION: Certain restrictions regulating the practice of telehealth that were loosened during the pandemic must be tightened again. It should be impossible to repeat a case like that of *Cerebral*,¹⁵⁰ a telehealth company that relied disproportionately on non-physician providers. *Cerebral*'s over-prescription of controlled substances such as Adderall¹⁵¹ and Ritalin, without attention to intervals between in-person appointments, was plainly irresponsible.

With any future expansion in the use of telehealth, responsible, ethical physicians must be in the forefront of patient care; they must lead that care and oversee it. Online prescription of controlled substances is wholly unacceptable. **No other model will work.**

Free2Care recognizes also that funding for mental health counseling via telehealth in rural and underprivileged areas must increase. The number of practitioners must grow—perhaps through the states mutually recognizing each other's training and licensing. Access to the services of practitioners must expand. And it is essential to give greater attention to military veterans—including support for relocation to settings of lower stress, if the veteran desires it.

Free2Care is pleased to recognize the passage of H.R. 7666¹⁵²—introduced by Rep. Frank Pallone (D-NJ, 6th District) and Rep. Cathy McMorris Rogers (R-WA, 5th District)—and its overwhelming bipartisan support. The bill promotes the use of telehealth in pediatric mental health care with built-in guardrails to prevent practitioners unknown to the patient from taking over a case from an existing primary care physician who knows the patient. The next step is passage of the Senate's counterpart of the House bill without alteration that frustrates the intent of the House.

¹⁵⁰ <https://www.wsj.com/articles/cerebral-receives-subpoena-from-federal-prosecutors-11651950307>

¹⁵¹ <https://www.wsj.com/amp/articles/cerebral-adderall-adhd-prescribe-11654705250>

¹⁵² <https://republicans-energycommerce.house.gov/wp-content/uploads/2022/05/Restoring-Hope-for-Mental-Health-and-Well-Being-Act-of-2022-5.6.2022.pdf>

D. STRENGTHEN ACCESS TO CARE FOR ALL

Closing the Gaps in Care *(continued)*

Reform 22. Incentivize physicians in rural areas to stay there.

To mount that response and base it on sound principles of expanding choices while lowering costs, *Free2Care* urges the following.

Increasing the number of residencies in rural areas so that graduates of medical school may become inclined to stay there.

Allowing greater tax deductions by medical professionals who provide pro-bono care.

Tailoring generous terms for repaying medical school loans for medical professionals who choose to practice full time in rural settings.

Reform 23. Remove barriers to the practice of telehealth.

Development and passage of legislation that removes barriers to the use of telehealth in which physicians provide and supervise patient care.

Prevail upon the Federation of State Licensing Boards and Interstate Medical Licensure Commission to modify the “Interstate Medical Licensure Compact (IMLC)” to require the leadership of physicians in providing and supervising patient care.

Passage of the bipartisan “Telehealth Extension and Evaluation Act” (S.3593), introduced by Sen. Catherine Cortez Masto (D-NV) and Sen. Todd Young (R-IN), to maintain pandemic-era access to telehealth through 2024 and ensure that physicians lead in providing and supervising patient care.

Passage in the Senate of H.R. 7666.

E. Money Moves in Mysterious Ways.

How Did We Get Here?

Inadequate foresight by legislators, followed by indifferent oversight and listless hindsight.

Opportunistic profiteers preying on patients' needs by maneuvering over, under, around, and through law and regulation.

As a consequence of the foregoing, the American system of health care is riddled with conflicts of interest.^{153, 154, 155}

In their totality, those conflicts are a modern Gordian Knot. Alexander the Great could have been forgiven for turning around and going home at the sight of it,

Nor is there is any maneuvering around the uncomfortable fact that some organizations of physicians are themselves enmeshed in conflicts of interest. For example, as physicians themselves have acknowledged, money flows from health insurance companies to large organizations for physician advocacy.¹⁵⁶

Sometimes these same organizations are part of a larger coalition, other elements of which also support policies that are detrimental to both patients and practicing physicians

It would be an understatement to call things a convoluted mess.

Consider the current model of physician training. It has long since morphed into a confused jumble of controlling, handsomely salaried, fee-collecting, affiliated regulatory boards, some of whom seem to have a mission of creatively expanding their revenue streams. The granddaddy of them all is the Accreditation Council for Graduate Medical Education (ACGME).

Formed in 1981, ACGME shapes the current and future practice of medicine through accreditation of the residency programs that are required of medical school graduates (physicians) prior to being licensed to practice and to bill patients independently and without supervision. ACGME decides (1) how a physician is educated and trained in residency, and (2) where residencies are available—in other words, which hospitals and sites are authorized to offer residencies.

¹⁵³ <https://www.investopedia.com/terms/c/conflict-of-interest.asp>

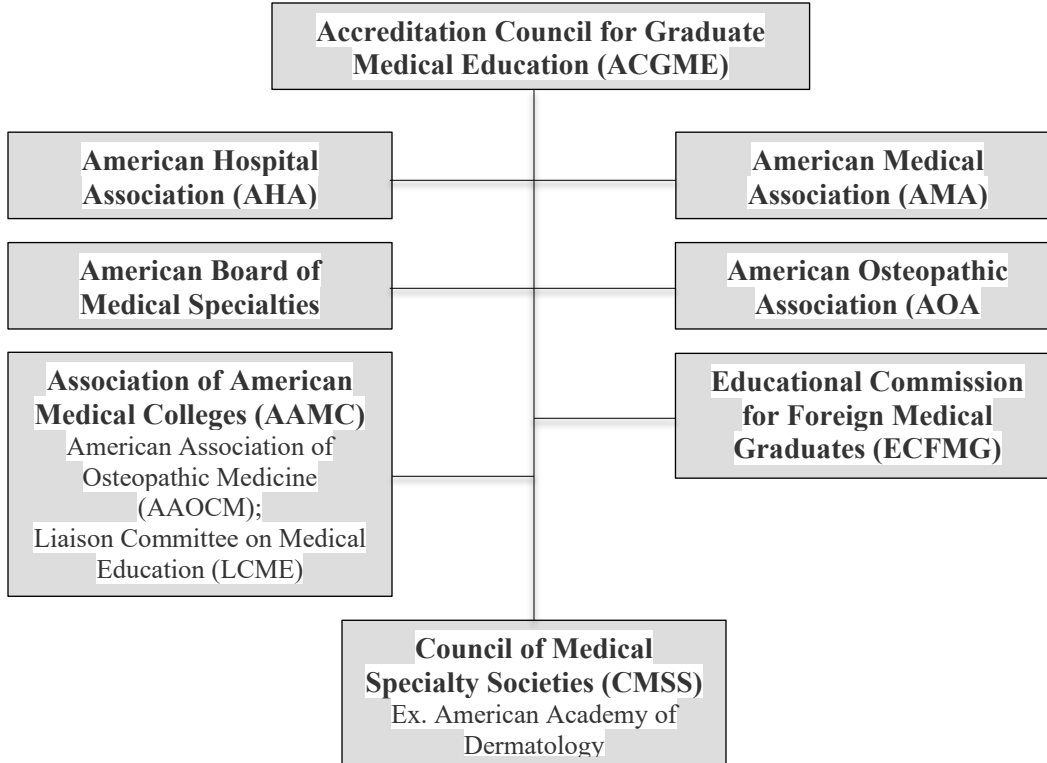
¹⁵⁴ <https://www.healthstream.com/resource/blog/specific-healthcare-conflict-of-interest-examples-and-how-to-prevent-them>

¹⁵⁵ <https://washingtonmonthly.com/2022/06/20/the-amas-little-known-committee-that-sets-physician-service-prices/>

¹⁵⁶ <https://www.healthleadersmedia.com/strategy/sermo-wars-ama-over-cpt-codes>

E. Money Moves in Mysterious Ways.

How Did We Get Here? *(continued)*



Because members of the ACGME have their own agendas and methods of maneuvering, practicing physicians and patients have not always been favorably disposed toward them. For example, the American Board of Medical Specialties (ABMS) has had a hand in the money flowing this way and that in health care via the monopolized Maintenance of Certification (MOC®) process discussed earlier on pages 57-58 of this document. Another example has been the American Hospital Association's suit to overturn the law requiring that they post prices for the services they provide.¹⁵⁷ What a moment of glory for the heirs to the mantle of Hippocrates!

To borrow a phrase from the world of infomercials—but wait, there's more!

Inherent conflicts of interest also feed numerous other, lesser-known streams of revenue.

Data on physicians and their prescribing behavior are a saleable commodity.

Who knew?

¹⁵⁷ <https://www.healthcarediver.com/news/hospitals-lose-another-attempt-to-stave-off-price-transparency/589592/>

E. Money Moves in Mysterious Ways.

How Did We Get Here? (continued)

The AMA, which is part of ACGME, maintains a “master file” that identifies every physician who graduates from medical school, even if those physicians never become AMA members (under 12% of physicians are members).¹⁵⁸

Through that “master file,” the AMA can sell information to data mining companies that can then extract from the data physicians’ patterns in prescribing medication. This enables the data mining companies to turn around and then sell what they have learned to pharmaceutical companies so that they can be more effective in marketing their products to physicians who may not be prescribing them.¹⁵⁹ Overhead on the system, much?

The ABMS MOC® process, adherence to which most hospitals require of physicians, enables the member boards of the ABMS to share a physician’s personal and practice data with an unlimited number of third parties through a HIPAA Business Agreement.¹⁶⁰

Conceivably, that data can be used to access data from a physician’s individual patients, although the names of the patients are not part of this process. Information about patients generally is highly valuable.

One of those third parties is—wait for it—the GPO, Premier, Inc.¹⁶¹

Recent estimates put the market for all of this data at \$22 billion in 2021, with anticipated growth to \$85 billion by 2030.¹⁶²

Free2Care would like to see patients and physicians control their own data. If the data are to be sold, it should be up to the physicians and patients to sell the data. It is not within the scope of this paper to prescribe a path from where we are to where we would prefer to be, but the burden on the system attributable to this form of trafficking needs very close study by independent experts and those who shape policy impartially.

¹⁵⁸ Mark Lopatin, M.D., *Rheum for Improvement: The Evolution of a Health-Care Advocate* (United States, Universal Publishers, Inc., 2022), <https://www.universal-publishers.com/m/book.php?method=ISBN&book=1627343768>

¹⁵⁹ <https://jamanetwork.com/journals/jama/article-abstract/1356001>

¹⁶⁰ <https://www.abim.org/~media/ABIM%20Public/Files/pdf/hipaa/hipaa-privacy-and-security.pdf>

¹⁶¹ <http://drwes.blogspot.com/2017/10/what-is-moc-why-is-this-important.html>

¹⁶² https://www.einnews.com/pr_news/588251950/global-big-data-in-healthcare-market-worth-84-5-billion-by-2030-exclusive-report-by-insightace-analytic

E. Money Moves in Mysterious Ways.

How Did We Get Here? (continued)

For a flicker of hope in this rather dismal discussion, we can cite the CMS Open Payments Database¹⁶³ as an instrument of transparency with at least some promise of reinforcing (or obliterating, to the patient's advantage) a bond of trust among patients, physicians and healthcare institutions. Through that database, anyone can search for a physician, nurse practitioner, physician assistant, or teaching hospital and discover whether they receive payments from a manufacturer of pharmaceutical products or medical devices. Inquisitive and informed patients can then know whether they are using certain medications or medical devices recommended by a physician whose judgment very probably influenced by payments from the manufacturer.

Oh, Hippocrates!

Free2Care fully supports this transparency, but believes that we must go further.

Why?

Because money moves in mysterious ways.

Take, for example, the reporting of the legislative debate over the Surprise Medical Bills (SMB), described on pages 59 through 62 earlier in this document. It was reported¹⁶⁴ that United Healthcare had influenced the writing of study findings from Yale University that ended up the New England Journal of Medicine (NEJM). The version of the study that went to the NEJM somehow neglected to mention the role of the health insurance industry in the SMB mess. Internal emails made it clear that United Healthcare had been involved in editing the study's findings.

The story reached the New York Times and Wall Street Journal, which, in turn, reported on the Yale findings, but without mention of United Healthcare's role in framing those findings. The reporting itself was bound to influence the legislative process.

Given the larger Gordian Knot that our American system of health care has become, one can easily understand that the conflicts of interest were not something the news media were aware of. Like too much of our system of health care, those conflicts operate in shadow and outright darkness.

¹⁶³ <https://openpaymentsdata.cms.gov/search>

¹⁶⁴ <https://theintercept.com/2021/08/10/unitedhealthcare-yale-surprise-billing-study/>

E. Money Moves in Mysterious Ways.

How Did We Get Here? (continued)

From time to time, however, the news media are on the take.¹⁶⁵ Instead of good, old-fashioned muckraking, we find buckraking instead. (What?! You were hoping for some relief?)

Ask yourself—when was the last time you saw or heard sustained, forceful reports by any major news outlet dealing with the matters that this document has brought to light?

Conflicts of interest are now firmly embedded not only in our American system of health care, but too often in the reporting that describes that system, telling us what we should think about it and who the “good guys” and “bad guys” are. The Gordian Knot is massive and tight. Again, its complex pathology works in shadow and outright darkness.

If there is to be a cure, it will come only through **transparency and light**.

Free2Care believes that if we open the books and make all of the players in the American healthcare system play by the same rules, we will see a renaissance. Physicians will be in a position to provide the highest quality of medical care to patients at the lowest possible cost. We will enter a new era of robust competition that allows patients to choose the personalized care they need.

It is in the national interest that a comprehensive “Sunshine for ALL Act” lead to the documentation and exposure of the conflicts of interest—past and present—in the American system of health care.

¹⁶⁵ <https://mattstoller.substack.com/p/buckraking-did-a-medical-monopolist>

E. Money Moves in Mysterious Ways.

How Did We Get Here? *(continued)*

Therefore, *Free2Care* urges the United States Congress to do the following.

Reform 24. Adopt a strong “Sunshine for ALL Act.”

To achieve fully the aims of such legislation, it should have the features described below.

Development and passage of legislation—an historic “Sunshine for ALL Act”—requiring documentation in a database of streams of funding between and among all of the following going back ten years:

- ***Drug and medical device manufacturers.***
- ***Hospitals.***
- ***Hospital systems.***
- ***Pharmacy and device channel companies (the PBMs and GPOs).***
- ***Distribution companies (such as AmerisourceBergen, Cardinal Health, and McKesson).***
- ***Professional societies of providers of medical care.***
- ***Advocacy organizations for both patients and physicians.***
- ***Educational organizations for patients.***
- ***Providers of continuing education.***
- ***Co-pay assistance organizations.***
- ***Healthcare data-collection entities, private and public.***
- ***Think tanks.***
- ***Corporate media, including (but not limited to) newspapers, television networks, and social media.***

The database should also document total payments in excess of \$10,000 to non-physician providers during the ten preceding years.

APPENDIX A

Repeal the Safe Harbor for GPO/PBM Kickbacks: Save Billions, Save Lives

PROPOSED LANGUAGE

ENSURING COMPETITION IN HEALTHCARE PURCHASING ACT

To amend title XI of the Social Security Act to repeal a safe harbor with respect to vendors in order to ensure full and free competition in the medical device and hospital supply industries.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. ENSURING COMPETITION IN HEALTHCARE PURCHASING ACT.

This Act may be cited as the “Ensuring Competition in Healthcare Purchasing Act”.

SECTION 2. ENSURING FULL AND FREE COMPETITION.

(a) IN GENERAL—Section 1128B(b)(3) of the Social Security Act (42 U.S.C. 1320a–7b(b)(3)) is amended—

- (1) by striking subparagraph (C); and
- (2) by redesignating subparagraphs (D) through (J) as subparagraphs (C) through (I), respectively.

(b) CONFORMING AMENDMENT—Section 1860D–31(g)(4)(A) of the Social Security Act (42 U.S.C. 1395w–141(g)(4)(A)) is amended by striking “section 1128B(b)(3)(G)” and inserting “section 1128B(b)(3)(F)”.

(c) EFFECTIVE DATE—The amendments made by this section shall take effect one (1) year after the date of enactment of this Act.

APPENDIX B

AUTHORS



Marion Mass, M.D., graduated from Duke University Medical School and trained in pediatrics at Northwestern University.

She has practiced in suburban Philadelphia for about 20 years in outpatient and urgent care settings. She is the co-founder of PRACTICING PHYSICIANS OF AMERICA and serves on the board of the Bucks County Health Improvement Partnership, and the editorial board of the *Bucks County Courier Times* and *Doylestown Intelligencer*. She is also a delegate to the Pennsylvania Medical Society.



David Balat is the Director of the Right on Healthcare initiative with the Texas Public Policy Foundation.

He has a broad base of experience throughout the healthcare spectrum in leadership and executive management positions, with special expertise in healthcare finance

He has also led the revitalization of complex facilities that were in financial distress. His expertise and success have made him a respected thought leader on problems in the American system of healthcare—a leader whose opinion is sought by legislators at the state and national levels. He has written numerous op-ed pieces and is active as a speaker and commentator on matters of health policy.

He is a former congressional candidate in Texas (2nd District).

APPENDIX C

CONTRIBUTORS



John M. Chamberlain, M.H.A., LFACHE, is the chairman of the board of Citizen Health, a healthcare cooperative owned by patients and physicians.

With more than 48 years of healthcare experience, John has been a champion for patients and physicians, believing that patients and their families, and the physicians who care for them are the most important part of health care.

He has served at a number of hospitals and other healthcare organizations in senior executive roles and as a CEO and COO.

His focus has been on the delivery at an affordable price the quality medical care that patients and their families should expect. He has also worked at improving relationships with physicians and with other caregivers.

He is a native of Little Rock, Arkansas, and resides in Austin, Texas, with his wife, Debby. They have two children, Jason and Frankie. Jason and his wife, Jen, live in New Orleans, Louisiana, with their son, Johnny, and daughter, Zoe. Frankie and her husband, Chris, live in Austin, Texas



Kimberly Legg-Corba, M.D., is a board-certified family physician and the owner of Green Hills Direct Family Care. In 2016, her family practice became the first Direct Primary Care (DPC) office to open in Pennsylvania's Lehigh Valley.

She is an early innovator, champion, and national leader for independent DPC practices. Her articles about DPC have appeared in local, state, and national publications.

Dr. Corba has been a national speaker and testified publicly on behalf of DPC in 2017 before the Pennsylvania Senate Banking and Insurance Committee.

Along with other members of the Board of Directors of DPC Action (<https://dpcaction.com/>), she has participated in numerous meetings about healthcare reform with bipartisan groups of legislators in the United States House and Senate. She has met also with the leaders in the Executive Branch—including the White House National Economic Council, the Department of Health and Human Services, Department of the Treasury, Centers for Medicare & Medicaid Services, Veterans Administration, and Small Business Administration.

CONTRIBUTORS

(continued)



Christina Dewey, M.D. is a board-certified pediatrician, published author, speaker, entrepreneur, and the founder and CEO of PedsMamaDoc. LLC. She is also a mom, an RA warrior, a believer in science and evidence-based medicine, and a fierce advocate for patients, physicians, mental health, children, and vaccines.

Dr. Dewey graduated with a B.S. in Biology from the University of Michigan in 1992, received her medical doctorate degree from Loyola University Stritch School of Medicine in 1996, completed her intern year in general surgery at Wayne State University/Detroit Medical Center, and then followed up with two years of Pediatric Surgery Research at ColumbusChildren's Hospital. She then switched her focus and completed Pediatric Residency at the University of Minnesota.

She has been a practicing pediatrician in the Twin Cities Metro Area for over two decades.

She has personally experienced the loss of physician autonomy and the transformation by corporate cartel of our once-sacred profession of medicine into for-profit, money-driven, health care.

Determined to bring back medicine, physician autonomy, and the trusted patient-physician relationship, Dr. Dewey is an active member of multiple, grassroots, physician-advocacy groups, with the focused intent of connecting physicians so that they can collaborate and create needed change. She shares her thoughts on her blog (<https://drchristinadeweymd.com/about-me/>) and can be followed on social media @PedsMamaDoc.




Caren E. Gallaher, M.D., is a retired surgeon in Knoxville, Tennessee.


After completing a combined BA/MD degree and surgical residency at the University of Missouri Kansas City, and a liver transplant fellowship at Baylor University in Dallas, Texas, Dr. Gallaher joined the academic faculty at Baylor University Medical Center as an assistant professor, and ultimately became the Trauma Medical Director for the John Peter Smith Hospital in Fort Worth, Texas.

Dr. Gallaher is a co-founder of the not-for-profit group, PHYSICIANS FOR PATIENTS, which works to educate physicians, patients, and legislators about the significance of medical training and how education can affect the level of care available to patients.

CONTRIBUTORS

(continued)

	<p>Leah Houston, M.D., practiced medicine across the United States for nearly ten years before founding HPEC—Humanitarian Physicians Empowerment Community (https://www.hpec.io/)—a decentralized digital identity solution for practicing physicians.</p> <p>HPEC developed <i>Evercred</i>, a credential-issuing system that automates the processes of issuing credentials and verifying them. <i>Evercred</i> is available (https://www.evercred.com) for pilot projects with credential issuing, as well as verifying and maintaining entities</p>
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	<p>Nicole “Nikki” Johnson, M.D., NBPAS lives in Cleveland, Ohio, and specializes in pediatric procedural sedation.</p> <p>She received her undergraduate degree from Case Western Reserve University and her medical degree from Case Western Reserve University School of Medicine. Dr. Johnson is certified in both General Pediatrics and Pediatric Critical Care Medicine.</p> <p>Dr. Johnson hosts Free2Care the Podcast, and is the co-founder and past president of PHYSICIANS FOR PATIENTS, an organization that champions physician-led medical care and transparent medical practice. She is an active member of Urgency of Normal, which works to restore the life for of our youth to pre-pandemic conditions.</p> <p>She is passionate about restoring the physician-patient relationship, making sure that all Americans have access to their choice of affordable medical care, increasing the physician workforce lowering the cost of medical care, and ending mandatory Maintenance of Certification®.</p>
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CONTRIBUTORS

(continued)



Faarina Khan, M.D., is a Chicago native in residency training at Roseburg Family Medicine Residency Program in Roseburg, Oregon.

She graduated from Dow International Medical College in 2015, and is completing a master's degree in public health at the University of Kansas School of Medicine in Wichita, Kansas.

She serves on the boards of several non-profits, as well as the National Association of Assistant/Associate Physicians and the American Society of Physicians.

She is dedicated to empowering international medical school graduates and addressing the physician shortage.



David Levien, M.D, M.B.A., F.A.C.S., is president, CEO, and board chairman of the American College of Healthcare Trustees.

He has practiced clinical surgery for 34 years—20 of which were as chairman of surgery, and 12 as program director of a surgical residency.

He has served as a member of the Board of Directors of the College of Physicians of Philadelphia; the Philadelphia County Medical Society; Meals on Wheels and Senior Outreach Services of Walnut Creek, California; the Chamber of Commerce of Pleasant Hill, California; and the Shore Acres Point Corporation of Mamaroneck, New York.

He has been president of the Baltimore Academy of Surgery and the Pennsylvania Society of Colon and Rectal Surgery. He has been vice president of the Academy of Surgery of Philadelphia and vice president of the American Society of Colon and Rectal Surgeons.

He has patented a medical device, published three surgical books and multiple papers, and achieved the faculty rank of Clinical Professor of Surgery, Jefferson Medical College, and Professor of Clinical Surgery, New York Medical College.

He received his B.A. from Johns Hopkins, his M.D. from Georgetown (cum laude), and his MBA from the University of Massachusetts Isenberg School of Management.

He has been board-certified in both general and colorectal surgery, and has held a certificate of special qualification in surgical critical care.

He is also a certified physician executive (CPE).

CONTRIBUTORS

(continued)



Mark Lopatin, M.D., is a rheumatologist who recently retired after 28 years in independent practice.

He is the author of the book, “Rheum for Improvement – The Evolution of a Health-care Advocate,” which addresses how corporate medicine is removing the humanity from health care.

He is active in organized medicine, having served as president and chairman of the Montgomery County Medical Society. He has served also as chair of the Montgomery County Medical Legal Committee and the Montgomery County Task Force on Mediation.

He is on the Board of Trustees for both the Pennsylvania Medical Society and their Political Action Committee, and is an active member of multiple grassroots advocacy groups.

He has lectured and written numerous op-eds and articles on a multitude of health-care issues to educate patients and physicians how healthcare policies affect the care that patients receive.

He is passionate about preserving the patient- physician relationship and is outspoken against those who seek to destroy that relationship to control the healthcare dollar.



Andy Mangione served as Association of Mature Citizens’ (AMAC’s) point person on Capitol Hill from 2012 through 2014.

In 2013, he created and led a national grassroots outreach platform, the AMAC Action Delegate Program, establishing the foundation, structure, and procedures for the program that today features hundreds of volunteer advocates throughout the United States.

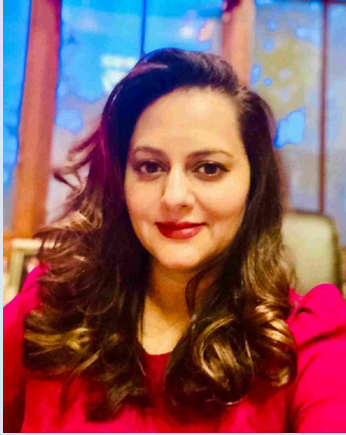
As senior vice president for AMAC’s advocacy arm— AMAC Action—Andy leads outreach activity across the country and also represents the interests of the Association’s membership in Washington, DC.

He is very involved in charting the policy course for AMAC Action and the subsequent execution of legislative strategies.

He also represents AMAC as a national spokesperson, frequently writes for all AMAC media, and contributes to national online publications and other media.

CONTRIBUTORS

(continue)



Saba Rizvi, M.D., is a graduate of the University of South Alabama College of Medicine. She did her residency in Emergency Medicine at the University of Alabama, Birmingham.

She has been a practicing Board Certified Emergency Physician for 12 years, holding licenses in both Colorado and Texas.

She has worked in a variety of practice settings, including Level 1 trauma centers and rural community hospitals in places like Delta, Colorado.

Dr. Rizvi also served as an ER Medical Director for three years in Austin, Texas.

Dr. Rizvi is keenly interested in the intersection of clinical medicine and healthcare policy. During her undergraduate training, she was awarded dual diplomas, attaining both a B.Sc. and a B.A. in Philosophy.

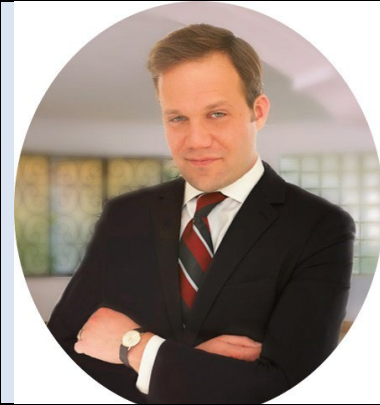
In her spare time, Dr. Rizvi likes to write and advocate for physicians. She believes in the rights of autonomous practice for physicians, and freedom from the conflicting interests of hospital monopolies, insurers, and mostly private-equity ownership.

She is a member of the American Academy of Emergency Physicians.

Dr. Rizvi lives in Texas. You can find her on Twitter @sabarizvimd.

CONTRIBUTORS

(continued)



Christopher Sheeron is founder and president of Action for Health, a national non-profit patient advocacy organization working to ensure fair outcomes for critical healthcare issues.

He is also chief executive officer of Grayson & Co., a strategic public affairs and advisory firm focused on policy, business, and reputations for clients worldwide.

Additionally, he serves as a communications advisor to ndp | analytics, an advisor to the Institute for Regulatory Analysis and Engagement, and an advisor to a London-based technology company.



Roy B. Stoller, D.O., received his medical degree from the New York College of Osteopathic Medicine/New York Institute of Technology.

He completed his residency in Otolaryngology/Facial Plastic Surgery at the University Hospitals of the Philadelphia College of Osteopathic Medicine.

Following his residency, he served as the medical director of a United States Air Force field hospital. He held a clinical faculty appointment at Walter Reed Army Hospital also where he instructed resident physicians, medical students, and physician assistant students.

In private practice, Dr. Stoller has been politically active. President George W. Bush consulted with him regarding the ongoing medical malpractice crisis. Most recently, he was one of four plaintiffs who prevailed in a suit against the American Osteopathic Association. The verdict severed mandatory membership in the AOA to maintain board certification.

Dr. Stoller is a contributor and examiner for the written and oral exams for board certification in his specialty.

He is a requested international speaker in his subspecialty interest of hair restoration science and medicine.

He is currently a Board Member of Physicians for Patient Protection, an organization that promotes physician led care. He is a newly appointed Board Member of Practicing Physicians of America fighting for transparency in the delivery of health care.

CONTRIBUTORS

(continued)

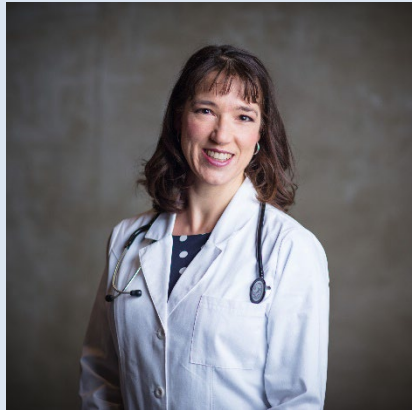


Judith L. Thompson, M.D., F.A.C.S., PCEO, is a solo and independent general and breast surgeon in New Braunfels, Texas.

She has been a participant in the advocacy movement since 2014, being one of four physicians who founded **United Physicians and Surgeons of America**, the organizer and sponsor of “The Summit at the Summit: A National Town Hall on the State of Medicine in America.

She later became the chairperson of the Board for Practicing Physicians of America

She is a 2018 graduate of Physician CEO (<https://physician-ceo.com/>), and is now the chief of staff for the local division of an international hospital system to which she brings a fresh perspective on the traditional role of physician leader.



Mary Tipton, M.D., F.A.A.P., F.A.C.P., graduated from the University of Utah Medical School. Her residency for Internal Medicine and Pediatrics was at Wright State University in Dayton, Ohio.

Since 2006, she has been the owner of and a fulltime physician at CopperView Medical Center, a private primary care practice in South Jordan, Utah.

Her experience as a mother of four children, business owner, employer, primary care physician and spouse of an Air Force Master Sergeant makes her an expert in providing, consuming and financing healthcare for all ages.

Mary is passionate about getting government out of her exam room, fixing the problem of high drug prices, advancing physician-led care, and squashing the middlemen.

CONTRIBUTORS

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Terry Wilcox, the co-founder and executive director of Patients Rising, helps patients find their voice and become outspoken advocates for their health care. She is the visionary behind the organization's programs—Patients Rising University (education), Patients Rising Concierge (support), Institute for Patient Access & Affordability Project (research)—and its policy and advocacy work of through Patients Rising Now.

She has built coalitions among patients, caregivers, and medical professionals. As a regular opinion writer on health policy and its effect on patients, she has been published in the *Boston Globe*, *The Hill*, *Morning Consult*, *Crain's New York Business*, *Real Clear Health*, the *American Thinker*, and more.

Selma Schimmel inspired Terry's career in patient advocacy. Regarded as the "original" young adult survivor advocate, Schimmel was Terry's mentor.

As executive director, Terry advanced Selma's legacy at the nonprofit cancer communication, education, and advocacy organization, Vital Options International

(<http://www.businesswire.com/news/home/20150528005588/en/Vital-Options-International-Presents-Programs-ASCO-Cancer>),.

Terry lives in the Washington, D.C., area with her husband, Jonathan, and twin boys, Jackson and James.



Marlene J. Wüst-Smith, M.D., is a board-certified pediatrician who has spent the last decade and a half living in rural Pennsylvania.

Born of Latino immigrant parents in New York City, she first learned to speak English when she started elementary school.

Dr. Wüst-Smith received her undergraduate degree from Cornell University in Ithaca, New York, in 1985, and her Medical Doctorate from Cornell University Medical College in New York City in 1989. She completed her residency in Pediatrics in 1992, and has been practicing medicine for the last 30 years in a variety of settings.

She is the physician at a small, rural, private university near her home for nine months of the year. During her summers, weekends, and holidays, she practices telemedicine and works as a traveling pediatrician throughout the country.

She has had the privilege of caring for patients across the socioeconomic spectrum.

She is passionate about physicians being able to practice independently and autonomously so that they can best meet the needs of their patients.

Dr. Wüst-Smith is the publisher and founder of *Physician Outlook*, a national print and online magazine, which uses art and storytelling to advocate for quality medical care for ALL patients.