ELIZABETH WARREN
MASSACHUSETTS

COMMITTEES:
BANKING, HOUSING, AND URBAN AFFAIRS
ARMED SERVICES
FINANCE
SPECIAL COMMITTEE ON AGING

United States Senate

UNITED STATES SENATE
WASHINGTON, DC 20510–2105
P: 202–224–4543

2400 JFK FEDERAL BUILDING
15 NEW SUDBURY STREET
BOSTON, MA 02203
P: 617–565–3170

1550 MAIN STREET
SUITE 406
SPRINGFIELD, MA 01103
P: 413–788–2690

www.warren.senate.gov

June 5, 2024

The Honorable Lina M. Khan
Chair
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, D.C. 20580

The Honorable Jonathan Kanter
Assistant Attorney General Antitrust Division
United States Department of Justice
950 Pennsylvania Avenue, NW
Washington, D.C. 20530

The Honorable Xavier Becerra
Secretary Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Chair Khan, Secretary Becerra, and Assistant Attorney General Kanter:

I write regarding the cross-government inquiry from the Federal Trade Commission (FTC), Department of Justice (DOJ), and Department of Health and Human Services (HHS) into the impacts of corporate greed in health care, and to respond to the agencies' March 5 Request for Information (RFI).[1] I commend your agencies' efforts to address the corporatization of health care, including DOJ's reported antitrust investigation into UnitedHealth,[2] FTC's suit against U.S. Anesthesia Partners and its private equity parent company over alleged anticompetitive practices[3] and its recently finalized rule banning noncompete provisions in contracts,[4] and HHS's appointment of a Chief Competition Officer and rules reining in abusive prior authorization and marketing practices in Medicare Advantage (MA) and requiring greater ownership transparency for long-term care facilities.[5] As you move forward with your inquiry, I urge you to continue to

[1] Federal Trade Commission, "Federal Trade Commission, the Department of Justice and the Department of Health and Human Services Launch Cross-Government Inquiry on Impact of Corporate Greed in Health Care," press release, March 5, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/03/federal-trade-commission-department-justice-department-health-human-services-launch-cross-government.
[2] Wall Street Journal, "U.S. Opens UnitedHealth Antitrust Probe," Anna Wilde Mathews and Dave Michaels, press release, February 27, 2024, https://www.wsj.com/health/healthcare/u-s-launches-antitrust-investigation-of-healthcare-giant-unitedhealth-ff5a00d2.
[3] Federal Trade Commission, "FTC Challenges Private Equity Firm's Scheme to Suppress Competition in Anesthesiology Practices Across Texas," press release, September 21, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-challenges-private-equity-firms-scheme-suppress-competition-anesthesiology-practices-across.
[4] Federal Trade Commission, "FTC Announces Rule Banning Noncompetes," press release, April 23, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-announces-rule-banning-noncompetes.
[5] U.S. Department of Health and Human Services, "Secretary Becerra Names Chief Competition Officer to Help Identify Areas to Promote Competition in Health Care," press release, January 8, 2024,

closely scrutinize, promulgate regulations regarding, and take appropriate enforcement actions against vertically integrated insurers, private equity firms, and pharmaceutical companies that are driving health care consolidation — a trend that has enriched corporate actors at the expense of patients' health and financial security, taxpayer dollars, and health care providers' clinical autonomy.

Vertical integration helps companies game the system to boost corporate profits

Today, the U.S. health care system — 70 percent of which is funded with taxpayer dollars — is dominated by giant corporate actors that control every link in the health care payment and delivery chain.[6] For example, the largest insurers in the country also own their own pharmacies, pharmacy benefit managers (PBMs), physician groups, home health providers, claims processors, and more.[7] These arrangements allow giant conglomerates, such as UnitedHealth Group (UnitedHealth) and CVS, to operate on both sides of health care transactions: as the providers of health care services *and* the entities responsible for paying, or reimbursing, for those services. Using this structure, giant corporations can effectively shift profits from the insurance arm of the business to various provider subsidiaries to evade federal requirements capping insurers' profits and administrative expenses,[8] all while raising prices and disadvantaging competitors.[9] Picking up on this strategy, private equity companies have aggressively purchased provider groups across the country, often with the sole intention of exiting these transactions by selling out to large health care conglomerates after a few years.[10] There is extensive evidence that these tactics lead to higher prices for patients,[11] worse health care outcomes,[12] and financial distress for independent health providers.[13]

Capitation-based financing and Corporate Practice of Medicine

Alarmingly, these trends have been fueled, in part, by federal health care payment policy and the shift away from fee-for-service and toward "capitation-based financing," such as Medicare

https://www.hhs.gov/about/news/2024/01/08/secretary-becerra-names-chief-competition-officer-to-help-identify-areas-to-promote-competition-in-health-care.html.

[6] American Economic Liberties Project, "Medicare Advantage and Vertical Consolidation in Health Care," Hayden Rooke-Ley, April 2024, p. 33, https://www.economicliberties.us/wp-content/uploads/2024/04/Medicare-Advantage-AELP.pdf.

[7] *Id.* p. 20.

[8] *Id.* pp. 28-29.

[9] *Id.* p. 20.

[10] *Id.*

[11] Letter from Senator Elizabeth Warren to HHS Office of Inspector General Christi Grimm, November 21, 2023, https://www.warren.senate.gov/imo/media/doc/2023.11.21%20Letter%20to%20HHS%20OIG%20regarding%20MLR%20evasion.pdf; Ohio Capital Journal, "Contractor for WV public employees system pays itself way more for some drugs than necessary," Marty Schladen, February 6, 2024, https://ohiocapitaljournal.com/2024/02/06/contractor-for-w-va-public-employees-system-pays-itself-way-more-for-some-drugs-than-necessary/#:~:text=Express%20Scripts%2C%20the%20company%20that,by%20the%20Ohio%20Capital%20Journal.

[12] CNN, "Private equity ownership of hospitals made care riskier for patients, a new study finds," Brenda Goodman, December 27, 2023, https://www.cnn.com/2023/12/26/health/private-equity-hospitals-riskier-health-care/index.html#:~:text=The%20study%20found%20that%20rates,purchased%20by%20private%20equity%20firms.

[13] The American Prospect, "UnitedHealth Exploits an 'Emergency' It Created," Maureen Tkacik, March 10, 2024, https://prospect.org/health/2024-03-10-unitedhealth-exploits-emergency-change-ransomware-oregon/.

Advantage and accountable care organizations (ACOs). [14] Under capitation, insurers and providers receive lump sum payments — adjusted depending on the health of the patient population — to deliver care.[15] If the insurer or provider can keep costs under that amount, they can keep the balance.[16] Insurers and private equity companies have identified ways to exploit the system, including by acquiring entities that are eligible for, or can influence the size of, these capitated payments.[17] Once in control, corporate actors game patients' medical records and billing practices to secure higher government payments, aggressively deny care to pad profits, and exert control over providers' business *and* clinical decisions.[18]

Lax enforcement of state prohibitions on the corporate practice of medicine (CPOM) has further greased the wheels for the corporatization of health care. These laws, many of which were enacted in the 19th century, were intended to insulate health care providers from outside forces that might seek to influence their clinical decision-making, prohibiting non-physicians, or lay entities, from owning provider practices.[19] But today, state CPOM laws are largely unenforced and marred with loopholes, leaving provider practices vulnerable to corporate takeover.[20] For example, to circumvent state CPOM laws, private equity firms and insurers, including UnitedHealth's subsidiary Optum, form management services organizations (MSOs) that contract with a physician practice to manage its billing and administration.[21] Although the practice's clinical operations remain nominally owned by a licensed physician, the practice is often completely managed and operated by the MSO. As a result, providers are often forced — through restrictive and punitive employment contracts — to put corporate profits over the interests of their patients.[22]

Medical Loss Ratio (MLR) evasion

Vertically integrated companies can take advantage of their size to engage in anticompetitive practices that increase their profits. By steering patients towards provider subsidiaries,[23] large conglomerates can effectively evade the MLR – a federal requirement that insurers spend 85 percent of premium dollars on medical claims – while keeping only 15 percent for administrative

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[14] American Economic Liberties Project, "Medicare Advantage and Vertical Consolidation in Health Care," Hayden Rooke-Ley, April 2024, p. 4, https://www.economicliberties.us/wp-content/uploads/2024/04/Medicare-Advantage-AELP.pdf.
[15] Centers for Medicare & Medicaid Services, "Capitation and Pre-payment," https://www.cms.gov/priorities/innovation/key-concepts/capitation-and-pre-payment.
[16] Physicians For a National Health Program, "Our Payments Their Profits," October 4, 2023, p. 2, https://pnhp.org/system/assets/uploads/2023/09/MAOverpaymentReport_Final.pdf.
[17] American Economic Liberties Project, "Medicare Advantage and Vertical Consolidation in Health Care," Hayden Rooke-Ley, April 2024, p. 19, https://www.economicliberties.us/wp-content/uploads/2024/04/Medicare-Advantage-AELP.pdf.
[18] *Id.*
[19] The New England Journal of Medicine, "A Doctrine in Name Only — Strengthening Prohibitions against the Corporate Practice of Medicine," Jane M. Zhu, Hayden Rooke-Ley, and Erin Fuse Brown, September 9, 2023, https://www.nejm.org/doi/full/10.1056/NEJMp2306904.
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] American Economic Liberties Project, "Medicare Advantage and Vertical Consolidation in Health Care," Hayden Rooke-Ley, April 2024, p. 29, https://www.economicliberties.us/wp-content/uploads/2024/04/Medicare-Advantage-AELP.pdf.

costs and profit.[24] The strategy is simple: the insurance branch of the business sends inflated payments to its provider subsidiary. Then, by realizing those payments on the provider side, or the side that charges for care, the insurance line of the business appears to be in compliance with MLR requirements. As a result, the parent company walks away with increased profits while the company remains nominally in compliance with federal requirements.[25]

Insurers can effectively use any of their providers – whether home-health, pharmacies, physician practices, or ambulatory surgery centers – to game the MLR. For example, UnitedHealth's physician group, Optum, received 62 percent of its *total* revenue from UnitedHealth's insurance branch, meaning well over half of its revenue came from its parent company.[26] Zooming out, UnitedHealth sent $138 billion, or 25 percent of its revenue, to its own subsidiaries in 2023.[27] CVS, similarly, sent 13 percent of its total revenue to its subsidiaries in 2019.[28]

To illustrate one egregious example, I wrote to the HHS Office of Inspector General last year after a *Wall Street Journal* (WSJ) report revealed significant markups of generic drugs at specialty pharmacies owned by CVS, Cigna, and UnitedHealth.[29] In all three cases, the WSJ found that the companies charged 27.4, 24.2, and 3.5 times more, respectively, at their vertically integrated pharmacies compared to Cost Plus, an independent pharmacy the WSJ used as a baseline. Indeed, these companies, in addition to owning their own insurers and pharmacies, each own the three largest PBMs in the country, which set prices at and pay pharmacies for prescription drugs. In other words, this vertical structure allowed the three companies to set prices and pay themselves: According to the WSJ, "PBMs try to pay as little as possible for drugs distributed through independent retail pharmacies. But when their own pharmacies dispense prescriptions, PBMs profit from the higher prices."[30]

Medicare Advantage is rife with corporate greed

The federal program in which these tactics have been used most aggressively, and where the impact of corporatization is clearest, is Medicare Advantage (MA), the program that allows

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[24] Brookings, "Medicare Advantage spending, medical loss ratios, and related businesses: An initial investigation," Richard G. Frank and Conrad Milhaupt, March 24, 2023, https://www.brookings.edu/articles/medicare-advantage-spending-medical-loss-ratios-and-related-businesses-an-initial-investigation/.

[25] Letter from Senator Elizabeth Warren to HHS OIG Inspector Christi Grimm, November 21, 2023, https://www.warren.senate.gov/imo/media/doc/2023.11.21%20Letter%20to%20HHS%20OIG%20regarding%20MLR%20evasion.pdf.

[26] Gist Healthcare, "The model vertically integrated payer," March 15, 2024, https://gisthealthcare.com/the-model-vertically-integrated-payer/.

[27] Letter from Senator Elizabeth Warren to FTC Chair Lina Khan and DOJ Assistant Attorney General Jonathan Kanter, April 5, 2024, https://www.warren.senate.gov/imo/media/doc/letter_to_ftc_and_doj_on_optum-stewardship_merger.pdf.

[28] The Lever, "Obamacare Created Big Medicine," Matt Stoller, January 29, 2024, https://www.levernews.com/how-obamacare-created-big-medicine/.

[29] Letter from Senator Elizabeth Warren to HHS OIG Inspector Christi Grimm, November 21, 2023, https://www.warren.senate.gov/imo/media/doc/2023.11.21%20Letter%20to%20HHS%20OIG%20regarding%20MLR%20evasion.pdf.

[30] *Id.*

private insurers to administer Medicare benefits for over half of all Medicare beneficiaries.[31] While MA was enacted on the premise that private insurance companies could administer Medicare coverage more cost-effectively than the federal government, the MA program has failed to deliver savings to taxpayers in any year since its inception.[32] In fact, the non-partisan Medicare Payment Advisory Committee (MedPAC) projects that the Centers for Medicare and Medicaid Services (CMS) will overpay private insurers in MA by $88 billion in 2024 alone, while the Physicians for a National Health Program estimates overpayments to be as high as $140 billion per year.[33]

In MA, the federal government sends private insurers risk-adjusted capitated payments each month to cover an enrollee's anticipated health care costs. If these private insurers can keep patients' costs under that amount, they realize the savings.[34] As a result, private insurers in MA, often leveraging their own subsidiaries, routinely make their enrollees appear sicker than they actually are to secure higher payments, deny care to boost profits, and funnel the money to their own subsidiaries.[35]

Upcoding

The main driver of overpayments to private insurers in MA is upcoding, the process by which private insurers exaggerate the medical diagnoses of their enrollees to influence patient risk scores, and by extension, secure higher payments from CMS.[36] According to MedPAC, upcoding accounts for $54 billion of the estimated $88 billion in annual overpayments to MA plans.[37] Adjusting capitated payments based on risk score was intended to prevent insurers from choosing not to cover sicker patients. However, lax program oversight has invited insurers in MA to manipulate the system to boost profits using their vertically integrated subsidiaries.[38]

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[31] Letter from Senator Elizabeth Warren to CMS Administrator Chiquita Brooks-LaSure, January 25, 2024, https://www.warren.senate.gov/imo/media/doc/2024.01.25%20Letter%20to%20CMS%20on%20Medicare%20Advantage%20overpayments.pdf.
[32] Medicare Payment Advisory Commission, "Report to the Congress: Medicare Payment Policy," March 2023, p. 13, https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_v2_SEC.pdf.
[33] Committee for a Responsible Federal Budget, "New Evidence Suggests Even Larger Medicare Advantage Overpayments," July 17, 2023, https://www.crfb.org/blogs/new-evidence-suggests-even-larger-medicare-advantage-overpayments; Physicians For a National Health Program, "Our Payments Their Profits," October 4, 2023, https://pnhp.org/system/assets/uploads/2023/09/MAOverpaymentReport_Final.pdf.
[34] Letter from Senator Elizabeth Warren to CMS Administrator Chiquita Brooks-LaSure, January 25, https://www.warren.senate.gov/imo/media/doc/2024.01.25%20Letter%20to%20CMS%20on%20Medicare%20Advantage%20overpayments.pdf.
[35] *Id;* Health Care un-covered, "UnitedHealth's self-dealing is accelerating," Sara Sirota and Krista Brown, January 12, 2024, https://wendellpotter.substack.com/p/unitedhealths-self-dealing-is-accelerating.
[36] Letter from Senator Elizabeth Warren to CMS Administrator Chiquita Brooks-LaSure, January 25, https://www.warren.senate.gov/imo/media/doc/2024.01.25%20Letter%20to%20CMS%20on%20Medicare%20Advantage%20overpayments.pdf.
[37] MedPAC, "The Medicare Advantage program: Status report," Stuart Hammond, Andy Johnson, and Luis Serna, January 12, 2024, https://www.medpac.gov/wp-content/uploads/2023/10/MedPAC-MA-status-report-Jan-2024.pdf.
[38] *Id.*; Letter from Senator Elizabeth Warren to CMS Administrator Chiquita Brooks-LaSure, January 25, 2024, https://www.warren.senate.gov/imo/media/doc/2024.01.25%20Letter%20to%20CMS%20on%20Medicare%20Advantage%20overpayments.pdf.

For example, UnitedHealth, the nation's largest insurer, is also the nation's largest employer of physicians through its subsidiary, Optum, which employs or is affiliated with 90,000 physicians, or 10 percent of all physicians in the United States.[39] By employing physicians directly, UnitedHealth can pressure their physicians to add diagnosis codes to their patients' medical charts – including by pre-populating patients' medical records with suggested codes before their visits even begin[40] – as a way to increase Medicare payments.[41] Private insurers in MA, including UnitedHealth, also own or use health risk assessment (HRA) and chart review companies, which help upcode their enrollees. While private insurers send third-party vendors to patients' homes to conduct HRAs, often with the sole intention of collecting diagnosis codes, chart review companies add diagnosis codes based on reviews of patients' medical records.[42] To illustrate the scope of this scheme, using both tactics, UnitedHealth squeezed taxpayers out of $3.7 billion in 2017 alone.[43] CVS[44] and Humana,[45] two of the largest private insurers in MA, also own HRA or chart review companies, and have both overbilled CMS to cover MA enrollees, according to Inspectors General.[46]

Care denials

Despite raking in $88 billion in overpayments — including $54 billion from upcoding alone — private insurers in MA still routinely deny medically necessary care to their enrollees, even though federal law requires them to cover all Medicare Part A and Part B services.[47] For example, a 2022 investigation by the HHS Office of the Inspector General (OIG) found that, among all requests MA plans denied, 13 percent of prior authorization denials and 18 percent of payment denials met Medicare coverage rules, meaning the MA plans unlawfully delayed or denied services that would have been approved in traditional Medicare (TM).[48]

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[39] STAT, "UnitedHealth Group now employs or is affiliated with 10% of all physicians in the U.S.," Bob Herman, November 29, 2023, https://www.statnews.com/2023/11/29/unitedhealth-doctors-workforce/.
[40] American Economic Liberties Project, "Medicare Advantage and Vertical Consolidation in Health Care," Hayden Rooke-Ley, April 2024, p. 26, https://www.economicliberties.us/wp-content/uploads/2024/04/Medicare-Advantage-AELP.pdf.
[41] The Examiner News, "Whistleblower Releases Audio, Files Complaint: Cites Medical Billing Plot at Optum," Adam Stone, March 18, 2024, https://www.theexaminernews.com/whistleblower-releases-audio-files-complaint-cites-medical-billing-plot-at-optum/.
[42] Letter from Senator Elizabeth Warren to CMS Administrator Chiquita Brooks-LaSure, January 25, 2024, https://www.warren.senate.gov/imo/media/doc/2024.01.25%20Letter%20to%20CMS%20on%20Medicare%20Advantage%20overpayments.pdf.
[43] *Id.*
[44] Signify Health, "In-Home Health Evaluations," https://www.signifyhealth.com/in-home-health-evaluations.
[45] American Economic Liberties Project, "Medicare Advantage and Vertical Consolidation in Health Care," Hayden Rooke-Ley, April 2024, p. 21, https://www.economicliberties.us/wp-content/uploads/2024/04/Medicare-Advantage-AELP.pdf.
[46] The New York Times, "'The Cash Monster Was Insatiable': How insurers Exploited Medicare for Billions," Reed Abelson and Margot Sanger-Katz, October 8, 2022, https://www.nytimes.com/2022/10/08/upshot/medicare-advantage-fraud-allegations.html.
[47] MedPAC, "The Medicare Advantage program: Status report," Stuart Hammond, Andy Johnson, and Luis Serna, January 12, 2024, https://www.medpac.gov/wp-content/uploads/2023/10/MedPAC-MA-status-report-Jan-2024.pdf.
[48] HHS OIG, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care," April 27, 2022, https://oig.hhs.gov/documents/evaluation/3150/OEI-09-18-00260-Complete%20Report.pdf.

These care denials allow vertically integrated insurers to disadvantage competitors. A STAT investigation last year found that UnitedHealth pressured its employees to follow an unregulated artificial intelligence algorithm that systematically cut down stays for their enrollees who needed care at nursing homes following hospitalization, even if the prediction went against the judgement of the patients' doctors.[49] According to documents reviewed by STAT, some of the decisions "had little or no basis in clinical evidence," forcing patients with "open wounds" and "broken bones" to lose out on care that they were entitled to, likely in violation of Medicare rules.[50] In addition to disadvantaging competitors at the expense of patients,[51] the denials at nursing facilities allowed UnitedHealth to steer patients to its own home health providers, helping keep revenue in-house.[52] Unsurprisingly, the company that developed the algorithm, NaviHealth, had recently been acquired by UnitedHealth, and has since changed its name following these allegations.[53]

Health care and private equity companies design serial roll-ups to avoid antitrust scrutiny

Private equity companies and insurers often engage in a series of small acquisitions to fly under the radar of antitrust scrutiny. Taken individually, these acquisitions may not reach the reporting threshold under the Hart-Scott-Rodino Act of 1976, which requires parties to report certain large transactions to FTC and DOJ. Yet, taken together, serial roll-ups can significantly increase a company's market share.[54] Last year, I wrote to the CEO of U.S. Anesthesia Partners (USAP) following an investigation that found that USAP and its private equity backers had systematically bought up anesthesiology practices in the Denver area, "rolling up" companies to form a group that could leverage monopoly power to raise patient costs and force physicians to prioritize profits over patients.[55] By 2019, USAP was the largest provider of anesthesiology services to Medicare beneficiaries in the Denver market, controlling approximately 30% of the anesthesiology market in the state of Colorado.[56] A lawsuit by FTC against USAP for similar practices in Texas is ongoing.[57]

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[49] STAT, "UnitedHealth used secret rules to restrict rehab care for seriously ill Medicare Advantage patients," Bob Herman and Casey Ross, December 28, 2023, https://www.statnews.com/2023/12/28/medicare-advantage-united-health-navihealth-rehab-care-restrictions/.
[50] *Id.*
[51] American Economic Liberties Project, "Medicare Advantage and Vertical Consolidation in Health Care," Hayden Rooke-Ley, April 2024, p. 30, https://www.economicliberties.us/wp-content/uploads/2024/04/Medicare-Advantage-AELP.pdf.
[52] *Id.*
[53] STAT, "UnitedHealth discontinues a controversial brand amid scrutiny of algorithmic care denials," Bob Herman and Casey Ross, October 23, 2023, https://www.statnews.com/2023/10/23/unitedhealth-optum-navihealth-rebranding-algorithm/.
[54] Letter from Senator Elizabeth Warren to U.S. Anesthesia Partners CEO Robert Coward, November 26, 2023, https://www.warren.senate.gov/imo/media/doc/2023.11.22%20Letter%20to%20USAP%20on%20Anti-Competitive%20Tactics1.pdf.
[55] *Id;* Washington Post, "Financiers bought up anesthesia practices, then raised prices," Peter Whoriskey, June 29, 2023, https://www.washingtonpost.com/business/2023/06/29/private-equity-medical-practices-raise-prices/.
[56] Wall Street Journal, "FTC Probes Market Power of One of Country's Biggest Anesthesia Providers," Dave Michaels, October 1, 2022, https://www.wsj.com/articles/ftc-probes-market-power-of-one-of-countrys-biggestanesthesia-providers-11664644401.
[57] Federal Trade Commission, "FTC Challenges Private Equity Firm's Scheme to Suppress Competition in Anesthesiology Practices Across Texas," September 21, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-challenges-private-equity-firms-scheme-suppress-competition-anesthesiology-practices-across.

FTC and DOJ, in recognition of the dangers posed by serial roll-ups, updated the agencies' merger review guidelines to clarify that antitrust law allows agencies to examine "the whole series" of mergers by a company to determine the cumulative effect of multiple transactions that are part of an overall pattern or strategy.[58] As Congress noted in adopting the 1950 amendments to the Clayton Act, "[a]cquisitions of stock or assets have a cumulative effect, and control of the market sufficient to constitute a violation of the Sherman Act may be achieved not in a single acquisition but as the result of a series of acquisitions."[59] Similarly, the Supreme Court has affirmed that serial acquisitions can "convert an industry from one of intense competition among many enterprises to one in which three or four large [companies] produce the entire supply."[60]

Serial roll-ups have become pervasive in the health care industry, and have resulted in market dominance leading to higher prices, particularly when private equity has been involved.[61] It is important that your agencies consider this trend in health care acquisitions and take a holistic view of market dominance in order to prevent harms to competition and patients.

Pharmaceutical companies abuse the drug patent listing system to crush competition

Last year, I wrote to eight pharmaceutical companies who received warnings from the FTC about improper listing of patents, requesting that companies voluntarily remove from the Orange Book patent listings that did not comply with applicable laws and regulations.[62] As I noted, pharmaceutical companies employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from generic and biosimilar competition, and keep prices artificially high. Companies may be incentivized to improperly list patents in the Orange Book in order to hold off competition from generics, increasing drug and health care costs for patients and driving up insurance premiums. The FTC highlighted these practices in warning letters to major pharmaceutical companies, promising scrutiny of patent practices for violations of Section 5 of the Federal Trade Commission Act.[63] These tactics, together with other practices used to stifle competition, have a devastating effect on American consumers. In 2019, U.S. patients and payers spent an additional $40.07 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry."[64] We urge your agencies to continue to crack down on abusive and anticompetitive patent practices in the health care space in order to foster competition and bring down drug prices.

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[58] U.S. Department of Justice and Federal Trade Commission, "Merger Guidelines," https://www.ftc.gov/system/files/ftc_gov/pdf/p859910draftmergerguidelines2023.pdf, p. 22, Guideline 9.
[59] House Judiciary Committee Report, 11300 H.rp.1191, p. 8.
[60] Brown Shoe Co. v. United States, 370 U.S. 334 (1962).
[61] Antitrust Institute, "Monetizing Medicine: Private Equity and Competition in Physician Practice Markets," Richard Scheffler et al., July 10, 2023, p. 32, https://www.antitrustinstitute.org/wp-content/uploads/2023/07/AAIUCB-EG_Private-Equity-I-Physician-Practice-Report_FINAL.pdf.
[62] Letter from Senator Elizabeth Warren to AbbVie CEO Richard A. Gonzalez, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf.
[63] Federal Trade Commission, "Warning Letters by Press Release," https://www.ftc.gov/legal-library/browse/warning-letters/81927.
[64] American Economic Liberties Project and Initiative for Medicines, Access, and Knowledge (I-MAK), "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

Conclusion

Given the serious threats that consolidation and anticompetitive practices pose to health care quality and costs, I urge you to focus your efforts on the following actions:

1. **Scrutinize serial roll-ups:** Consistent with the FTC's and DOJ's merger guidelines, I urge your agencies to consider a company's entire history of transactions to detect serial roll-ups and fully inform antitrust enforcement decisions.
2. **Analyze intercompany elimination/related-party transactions:** CMS should collect better ownership data of MA plans and providers to determine whether insurers are engaging in profit-shifting schemes to evade MLR requirements. As I detailed in my May 29, 2024 letter to CMS Administrator Brooks-LaSure,[65] CMS should collect the Taxpayer Identification Number (TIN) for each parent company, the corresponding TIN for each health care provider that the parents company own or controls, and the parent company's ownership share of each health care provider. CMS should require insurers to identify payments to related parties and the profit margins those entities realize. And CMS should establish benchmarks for common health care services to compare transfer prices.
3. **Crack down on overpayments in MA:** MedPAC projects that CMS will overpay private insurers in MA by $88 billion in 2024 alone. To limit these overpayments, CMS should pursue changes to the MA risk adjustment model, increase the recoupment of overpayments, raise the standard for the Quality Bonus Program, and terminate contracts with private insurers in MA who unlawfully deny medically necessary care, as described in my January 25, 2024 letter to CMS Administrator Brooks-LaSure.[66]
4. **Big PhRMA patent abuses:** Pharmaceutical companies, especially brand-name companies, have routinely abused the Orange Book system by improperly listing patents to block the introduction of lower-cost generics. In addition to FTC's critical work urging pharmaceutical companies to de-list sham patents, the FDA should release clarifying Orange Book guidance, work with the USPTO to develop a review and validation system for patents listed in the Orange Book, revise policies regarding 'suitability petitions,' and share key information provided by drug manufacturers in applications for investigational New Drugs with the USPTO, as outlined in my August 28, 2023 letter to FDA Commissioner Califf.[67]
5. **Support state CPOM laws:** Strong and well-enforced CPOM laws will protect fair competition, allowing truly independent physician and provider groups to remain viable without the threat of interference from private equity companies that turn quick profits by squeezing providers and patients. Consistent with the Administration's efforts to end corporate greed in health care, HHS, DOJ, and FTC should support state and federal efforts to strengthen CPOM laws.

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[65] Letter from Senator Elizabeth Warren to CMS Administrator Chiquita Brooks-LaSure, May 29, 2024, https://www.warren.senate.gov/imo/media/doc/final_-_warren_letter_to_cms_on_ma_data_rfi_on_intercompany_transfers.pdf.

[66] Letter from Senator Elizabeth Warren to CMS Administrator Chiquita Brooks-LaSure, January 25, 2024, https://www.warren.senate.gov/imo/media/doc/2024.01.25%20Letter%20to%20CMS%20on%20Medicare%20Advantage%20overpayments.pdf.

[67] Letter from Senator Warren to FDA Commissioner Robert Califf, August 28, 2023, https://www.warren.senate.gov/imo/media/doc/2023.08.28%20Letter%20to%20FDA%20re%20drug%20patents.pdf.

6. **Undo mergers that are harming competition:** Your agencies should use all the authorities at your disposal to examine the competitive effects of consolidation in the health care industry, and take decisive action to enforce structural separation of companies that use their vertically integrated structure to illegally crush competition.

Sincerely,

Elizabeth Warren
United States Senator