
THE COLUMBIA
SCIENCE & TECHNOLOGY
LAW REVIEW

VOLUME XXIII

STLR.ORG

FALL 2021

ARTICLE

PRIVACY AS THE PRICE OF DRUG ACCESS

Laura Karas*

In response to the recent increase in FDA-approved specialty drugs and escalating specialty drug prices, drug companies now offer patient support programs (“PSPs”) for eligible patients prescribed a particular pharmaceutical drug. Such programs encompass both financial assistance for the purchase of a specialty drug and behavioral services, including nursing support and injection training, intended to improve drug adherence. Although ostensibly gratuitous, these programs have a steep and underappreciated cost: disclosure of protected health information. In effect, patient support programs compel patients to trade protected health information for drug access. This Article provides the first in-depth examination of the legal and ethical concerns associated with patient support programs. Enrollment in a drug company’s patient support program furnishes the company with linked patient- and prescriber- identifying information for each enrollee, data which may enable drug companies to target marketing to patients and healthcare providers with an otherwise unattainable degree of precision. Moreover, once a drug company acquires an enrollee’s protected health information pursuant to a valid Health Insurance Portability and Accountability Act (HIPAA) authorization, a drug company faces few limits on downstream uses of those data. This Article illuminates a possible role for patient support program-mediated data collection in two unlawful drug company practices: (1) kickback schemes in coordination with foundations that cover pharmaceutical drug copays,

* J.D. candidate, Harvard Law School, class of 2022. A special thank you to the team at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, including Faculty Director Professor I. Glenn Cohen, Executive Director Carmel Shachar, Laura Chong, and Chloe Reichel, for their tireless efforts in guiding the Petrie-Flom Student-Fellows. Also, I am grateful to Professor Oren Bar-Gill and Professor Gerard Anderson for thoughtful comments on portions of this paper. Finally, my gratitude to Dena Katz and the editors of the *Columbia Science and Technology Law Review* for their diligent editing.

and (2) “product hopping” to a new brand-name drug formulation after patent expiration of an older formulation. The current regime for health data privacy in the United States lacks adequate safeguards to prevent drug companies from exploiting patient support program-derived data to the detriment of patients. The Article ends by proposing practical modifications to the HIPAA Privacy Rule to modernize HIPAA’s protections vis-à-vis health data transferred from covered entities to noncovered entities such as drug companies.

I.	INTRODUCTION	52
II.	THE RISE OF SPECIALTY PHARMACEUTICALS AND SPECIALTY DRUG SPENDING	54
III.	A BRIEF SKETCH OF THE SPECIALTY DRUG LANDSCAPE	59
	A. <i>Specialty Pharmacies</i>	60
	B. <i>Drug Coupons, Copay Assistance Programs, and Patient Assistance Programs</i>	62
	C. <i>Patient Support Programs</i>	65
IV.	A DISSECTION OF PATIENT SUPPORT PROGRAM ENROLLMENT FORMS AND THEIR LEGAL UNDERPINNINGS	69
V.	PATIENT SUPPORT PROGRAM HIPAA AUTHORIZATIONS: ETHICAL AND LEGAL CONCERNS	73
	A. <i>The Privacy Calculus of Information Sharing</i>	77
	B. <i>Do HIPAA Authorizations Subject Patients to Economic Duress?</i>	83
	C. <i>Is the Patient Support Program Bargain a Threat or Merely an Offer?</i>	88
VI.	REFORMING HIPAA IN THE 21ST CENTURY	92
	A. <i>Patient Support Programs Illuminate the Shortfalls of HIPAA</i>	92
	1. <i>The Role of PHI in Foundation-Related Kickback Schemes</i>	93
	2. <i>Patient Support Program Data Collection as a Means to Targeted Marketing and Product Hopping</i>	95
	B. <i>Limits on the Disclosure, Use, and Sale of PHI</i>	100
	C. <i>Reforming HIPAA: The Path Forward</i>	106
VII.	CONCLUSION.....	112

I. INTRODUCTION

High prices for specialty drugs,¹ in conjunction with high levels of patient cost-sharing, have fostered a curious relationship between drug companies and the patients who utilize their products: one of mutual dependence, but also one of unequal bargaining power. Drug companies depend on patients afflicted by rare diseases and other chronic illnesses to serve as ongoing consumers of the investment-intensive drugs they develop. By the same token, patients often depend on pharmaceutical therapies to relieve the unrelenting symptoms that accompany lifelong, incurable diseases. Yet, high manufacturer-imposed prices make specialty drugs unaffordable for most patients. In response to the profit-driven incongruity between patient populations in genuine need of pharmaceutical drugs and inaccessibility of those very therapies due to price, most drug companies now offer copay support and various forms of financial assistance. Increasingly, drug companies couple financial assistance with patient-directed, disease-related support services in what are termed patient support programs (“PSPs”), gratuitous programs designed and administered by drug companies.

At first blush, patient support programs appear to achieve a “win-win” outcome for patients and drug companies alike. Patients benefit from greater access to expensive specialty drugs, while behavioral components of patient support programs, such as disease education, adverse event monitoring, and nursing support, facilitate adherence to therapies that are often challenging to administer. Drug companies, in turn, utilize patient support program copay and reimbursement support to ensure that patients utilize—and insurers cover—specialty drugs, despite unaffordable drug prices. Moreover, behavioral and education-related services increase drug utilization and a drug company’s bottom line.

Patient support programs may indeed expand drug access, enable short-term affordability, and improve medication adherence. However, these programs come with a steep and underappreciated cost: disclosure of protected health information (PHI). A patient must disclose PHI—including name, address, prescriber’s identity, precise diagnosis, and prescription information—in order to qualify for patient support program services. Patient support program enrollment also enables a drug company to acquire each enrollee’s insurance information and pharmacy fill data.

Disclosure of PHI to drug companies through patient support programs is not inconsequential. On the contrary, PHI is incredibly valuable to drug makers. In the normal course of drug prescribing and prescription fills, a drug company typically plays no role beyond direct-to-consumer advertising and detailing visits to healthcare providers. Patient support programs, however, give a drug company

¹ For background on specialty drugs and the enduring problem of high specialty drug prices, see Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 860–64 (2016); and Robert Penington & Jo Ann Stubbings, *Evaluation of Specialty Drug Price Trends Using Data from Retrospective Pharmacy Sales Transactions*, 22 J. MANAGED CARE SPECIALTY PHARMACY 1010, 1010–11 (2016).

entryway into the stages downstream of pharmaceutical drug marketing and sales, including insurance coverage, drug utilization, and monitoring. These programs also place the PHI of each patient support program enrollee squarely in the hands of the drug company that administers the program.

In effect, patient support programs compel patients to trade PHI for drug access. Conceptualized in this way, patient support programs take on new meaning, and they become ethically and morally problematic. It is true that businesses frequently place the modern-day consumer in a position to voluntarily trade personally identifiable information for access to knowledge, goods, and services via the Internet. Pharmaceutical drugs, however, are different. They are medically necessary—sometimes curative, sometimes lifesaving, and often the sole treatment option on the market when a health condition is serious and rare. High prices for specialty drugs afford few patients the luxury of declining a drug company's offer of patient support program-mediated financial support, even if it comes at the cost of their privacy. Patients, in essence, are left with an offer they cannot refuse. In this way, the patient support program bargain has become a modern archetype of economic duress in the healthcare setting.

This Article contends that the current regime for health data privacy in the United States lacks adequate safeguards to prevent drug companies from exploiting patient support program-related data to the detriment of patients. Drug companies acquire PHI via Health Insurance Portability and Accountability Act ("HIPAA") authorizations obtained during patient support program enrollment. Once enrollees consent to share data pursuant to a valid HIPAA authorization, drug companies face few limits on downstream uses of those data. Moreover, patient support program enrollment furnishes drug companies with a granular *patient-provider linkage* for every patient utilizing a particular drug; that is, a drug company gains knowledge of each named patient who attempts to enroll in a patient support program and that patient's prescriber. This stands in contrast to aggregated data that drug companies may purchase for marketing purposes, which typically contain only prescribers' data without patient-identifying information.

Linked patient- and prescriber- identifying information may enable drug companies to target marketing to patients and healthcare providers with an otherwise unattainable degree of precision. Targeted marketing, in turn, may enable companies to more effectively block newly approved alternative drugs—whether brand-name drugs, generics, or biosimilars—from gaining market share, thereby extending periods of monopoly power, prolonging supracompetitive drug prices, and causing financial injury to patients and payers.

This Article provides the first in-depth examination of the legal and ethical concerns associated with drug companies' acquisition of PHI through patient support programs. Parts II and III describe the growing problem of high specialty drug prices and present a brief overview of the specialty drug landscape. Part IV examines the content of HIPAA authorizations in patient support program enrollment forms as a prelude to later discussion of the dangers of downstream data uses after patients authorize sharing of PHI during enrollment. Part V considers the ethical dimensions of patient support program-mediated PHI transfer viewed

through the lens of information sharing in the healthcare context and its attendant privacy risks. Drawing on contract law, this Part contends that the patient support program bargain subjects patients to economic duress. Part VI posits a possible role for patient support program-mediated PHI collection in two unlawful practices by pharmaceutical manufacturers: (1) kickback schemes in coordination with purportedly independent patient foundations that cover specialty drug copays; and (2) “product hopping” to a new brand-name drug formulation after patent expiration of an older formulation. Part VI ends by proposing practical modifications to HIPAA to better protect data shared during patient support program enrollment from unintended and unlawful uses. Ultimately, this Article casts serious doubt on whether an exchange of PHI for patient support program services is worth the bargain. Finally, it argues that elimination of patient support program-mediated financial assistance could have the salutary effect of inducing drug makers to voluntarily lower drug prices.

II. THE RISE OF SPECIALTY PHARMACEUTICALS AND SPECIALTY DRUG SPENDING

Driven by advancements in science and technology, drug development has attained an unprecedented pace and scope in recent years.² The U.S. Food and Drug Administration (“FDA”) approves numerous new biologic therapies for rare and serious disorders on an annual basis.³ For example, in 2002, the FDA approved the tumor necrosis factor (“TNF”) antagonist Humira,⁴ which has since become the world’s top-selling drug, catapulting its drug maker, AbbVie, to financial success.⁵

² See U.S. FOOD & DRUG ADMIN., ADVANCING HEALTH THROUGH INNOVATION: NEW DRUG THERAPY APPROVALS 2019 (2020); Jonathan J. Darrow et al., *FDA Approval and Regulation of Pharmaceuticals, 1983–2018*, 323 JAMA 164, 171 (2020) (noting, for example, a doubling of the number of biologic drugs approved by the FDA from the ten-year period 1986–1996 to 1997–2007, and again from 1997–2007 to 2008–2018); Kathleen L. Miller & Michael Lanthier, *Investigating the Landscape of U.S. Orphan Product Approvals*, 13 ORPHANET J. RARE DISEASES 1, 4 (2018) (finding a substantial increase in the number of new oncology products approved, particularly during the period from 2013–2017); Murray Aitken et al., ORPHAN DRUGS IN THE UNITED STATES: RARE DISEASE INNOVATION AND COST TRENDS THROUGH 2019 8 (IQVIA Inst. for Hum. Data Sci. ed., 2020) (“Of all orphan designated drugs receiving marketing approval, half have been approved since 2013 . . .”).

³ See *Biological Approvals by Year*, U.S. FOOD & DRUG ADMIN. (Feb. 22, 2021), <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biological-approvals-year> [<https://perma.cc/LXU5-M9GG>].

⁴ See *Drug Approval Package: HUMIRA (adalimumab)*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/125057_toc.cfm [<https://perma.cc/ZKN4-H7HH>].

⁵ See Eric Sagonowsky, *The Top 20 Drugs by Worldwide Sales in 2020*, FIERCE PHARMA (May 3, 2021, 3:00 AM), <https://www.fiercepharma.com/special-report/top-20-drugs-by-2020-sales> [<https://perma.cc/XR49-Y7NY>]; Rick Claypool & Zain Rizvi, PUB. CITIZEN, UNITED WE SPEND: FOR 20 TOP-SELLING DRUGS WORLDWIDE, BIG PHARMA REVENUE FROM U.S. SALES COMBINED EXCEEDED REVENUE FROM THE REST OF THE WORLD 4 (2021). Humira had an annual net revenue in the United States of \$14.864 billion in 2019. See Press Release, AbbVie, AbbVie Reports Full-Year and Fourth-Quarter 2019 Financial Results (Feb. 7, 2020), <https://investors.abbvie.com/news-releases/news-release-details/abbvie-reports-full-year-and-fourth-quarter-2019-financial> [<https://perma.cc/JJ3M-LT4N>]. Humira’s net revenue in the United States increased to \$16.112 billion by the end of 2020. See Press Release, AbbVie, AbbVie Reports Full-Year and Fourth-

But specialty drugs are not merely profit generators; they are transformative therapies in the lives of the patients who consume them. Humira itself has more than a dozen indications to treat inflammatory conditions ranging from plaque psoriasis and rheumatoid arthritis to adult and pediatric Crohn's disease.⁶ It can help quell difficult-to-manage autoimmune conditions, many of which severely impair quality of life⁷ and impose a significant resource burden at an individual and societal level.⁸

In addition to Humira, a slew of other recent therapeutic advancements indelibly altered the treatment regimens for serious diseases. Sovaldi (sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Epclusa (sofosbuvir/velpatasvir) and their successors transformed hepatitis C virus from a deadly blood-borne illness causing substantial morbidity and mortality into a treatable condition with a near-100% cure rate.⁹ The biologic drug Keytruda (pembrolizumab), predicted to become the world's top-selling drug in the near future, treats a wide array of cancers.¹⁰ Patients with multiple sclerosis ("MS") and rheumatoid arthritis—serious, chronic inflammatory conditions with substantial morbidity—no longer need to settle for symptom management alone. Patients can now choose from a multitude of disease-

Quarter 2020 Financial Results (Feb. 3, 2021), <https://investors.abbvie.com/news-releases/news-release-details/abbvie-reports-full-year-and-fourth-quarter-2020-financial> [<https://perma.cc/8GRS-ERKD>].

⁶ *Humira*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125057s417lbl.pdf [<https://perma.cc/ZC5Z-FSGN>]. A drug is indicated to "treat[], prevent[], mitigat[e], cure, or diagnos[e] . . . a recognized disease or condition." 21 C.F.R. 201.57(c)(2). The indication also includes the age group for which FDA has deemed the drug safe and effective (such as adults or children of a certain age). *See id.* In addition, it may include other identifiers of the target patient population, such as individuals with a particular subtype of a disease or who have a particular genetic mutation, and it may specify if the drug is an adjunct to another therapy. *See id.*

⁷ *See, e.g.,* R.G.B. Langley et al., *Psoriasis: Epidemiology, Clinical Features, and Quality of Life*, 64 ANNALS RHEUMATOLOGIC DISEASES ii18, ii20–21 (2005); Emily K. Wright & Michael A. Kamm, *Impact of Drug Therapy and Surgery on Quality of Life in Crohn's Disease: A Systematic Review*, 21 INFLAMMATORY BOWEL DISEASE 1187 (2015).

⁸ *See, e.g.,* Gary R. Lichtenstein et al., *Lifetime Economic Burden of Crohn's Disease and Ulcerative Colitis by Age at Diagnosis*, 18 CLINICAL GASTROENTEROLOGY & HEPATOLOGY 889, 895 (2020) (calculating, for example, incremental lifetime healthcare costs exceeding \$700,000 per pediatric Crohn's patient with a diagnosis of Crohn's disease between birth and age 11).

⁹ *See* Troyen Brennan & William Shrank, Opinion, *New Expensive Treatments for Hepatitis C Infection*, 312 JAMA 593, 593–94 (2014); *FDA Approves Epclusa for Treatment of Chronic Hepatitis C Virus Infection*, U.S. FOOD & DRUG ADMIN. (June 28, 2016), <https://www.fda.gov/news-events/press-announcements/fda-approves-epclusa-treatment-chronic-hepatitis-c-virus-infection> [<https://perma.cc/W6WE-UHGJ>] (noting that, twelve weeks after completing treatment with Epclusa, 95% to 99% of patients had no detectable hepatitis C virus); Omar Massoud, *Hepatitis C: Looking into the Future*, 14 EXPERT REV. GASTROENTEROLOGY & HEPATOLOGY 367 (2020).

¹⁰ *See* Eric Sagonowsky, *Move Aside, Humira. Merck's Keytruda Will Capture Industry's Top Sales Spot in 2024: Report*, FIERCE PHARMA (June 5, 2019, 10:44 AM), <https://www.fiercepharma.com/pharma/move-aside-humira-merck-s-keytruda-will-capture-industry-s-top-sales-ranking-2024-report> [<https://perma.cc/7U4A-SLB7>].

modifying therapies¹¹ such as Ocrevus (ocrelizumab) and Kesimpta (ofatumumab), anti-CD 20 monoclonal antibodies; Lemtrada (alemtuzumab), a CD 52-directed monoclonal antibody; and JAK inhibitors such as Xeljanz (tofacitinib), Olumiant (baricitinib), and Rinvoq (upadacitinib), to name but a few.

Each of the aforementioned drugs can be considered a specialty drug, a category that encompasses the broad and growing group of high-priced drugs, including biologics, used to treat rare diseases and other serious medical conditions. Specialty drugs tend to be characterized by drug manufacturing, handling, and administration of higher-than-average complexity.¹² For example, a specialty drug may be administered by injection or infusion in a doctor's office rather than self-administered at home. It may require cold-chain distribution to maintain the drug within certain temperature bounds,¹³ or it may carry certain risks that compel FDA Risk Evaluation and Mitigation Strategies (REMS) or closer monitoring.¹⁴

Despite the variety among specialty drugs, the primary distinguishing feature of a specialty drug is a high price.¹⁵ In 2015, the average annual cost of a specialty drug was more than nine times greater than the average annual cost of a nonspecialty branded prescription drug.¹⁶ A recent study by the AARP Public Policy Institute found that more than 80% of 180 specialty drugs examined had retail price increases at or above the rate of inflation.¹⁷ The average annual retail

¹¹ See, e.g., Daniel Aletaha & Josef S. Smolen, *Diagnosis and Management of Rheumatoid Arthritis: A Review*, 320 JAMA 1360, 1364–67 (2018); Lisa Batcheller & David Baker, *Cost of Disease Modifying Therapies for Multiple Sclerosis: Is Front-Loading the Answer?*, 404 J. NEUROLOGICAL SCI. 19, 19–22 (2019).

¹² See Ian Spatz & Nancy McGee, *Specialty Pharmaceuticals*, HEALTH AFFS. 1, 1–2 (Troyen A. Brennan et al. eds., 2013); see also *What Is a Specialty Drug?*, PHARM. CARE MGMT. ASS'N, <https://www.pcmnet.org/pcma-cardstack/what-is-a-specialty-drug/> [<https://perma.cc/5WPV-BXUU>].

¹³ See, e.g., *AllianceRx Walgreens Prime Is the Only Specialty Pharmacy to Use a Patented Process for Shipping Temperature-Sensitive Medicine*, ALLIANCERX WALGREENS PRIME (Aug. 6, 2020), <https://www.alliancerxwp.com/contents/press-releases/alliancerx-walgreens-prime-is-th.html> [<https://perma.cc/TY8U-UP9X>].

¹⁴ See Sean D. Sullivan, *The Promise of Specialty Pharmaceuticals: Are They Worth the Price?*, 14 J. MANAGED CARE PHARMACY S3, S4 (2008).

¹⁵ See Alan M. Lotvin et al., *Specialty Medications: Traditional and Novel Tools Can Address Rising Spending on These Costly Drugs*, 33 HEALTH AFFS. 1736, 1737 (2014). Orphan drugs, which can be thought of as a subset of specialty drugs, are among the highest priced. In 2019, nearly 40% of orphan drugs had an annual cost in excess of \$100,000. See Aitken et al., *supra* note 2, at 14.

¹⁶ See STEPHEN W. SCHONDELMAYER & LEIGH PURVIS, TRENDS IN RETAIL PRICES OF SPECIALTY PRESCRIPTION DRUGS WIDELY USED BY OLDER AMERICANS: 2006 TO 2015 8 (AARP Pub. Pol'y Inst., 2017) <https://www.aarp.org/content/dam/aarp/ppi/2017/11/full-report-trends-in-retail-prices-of-specialty-prescription-drugs-widely-used-by-older-americans.pdf> [<https://perma.cc/K4MG-465N>]; see also Penington & Stubbings, *supra* note 1, at 1014–15.

¹⁷ See STEPHEN W. SCHONDELMAYER & LEIGH PURVIS, TRENDS IN RETAIL PRICES OF SPECIALTY PRESCRIPTION DRUGS WIDELY USED BY OLDER AMERICANS: 2006 TO 2020 13 (AARP Pub. Pol'y Inst., 2021) <https://www.aarp.org/content/dam/aarp/ppi/2021/09/trends-retail-prices-specialty-drugs.doi.10.26419-2Fppi.00073.006.pdf> [<https://perma.cc/K4XW-45LJ>].

cost of specialty drug treatment has marched steadily upward, increasing from \$16,703 in 2006 to \$84,442 in 2020.¹⁸

High specialty drug prices result in high copays, which in turn force many patients to forego necessary treatment¹⁹ and, in some cases, may contribute to medical bankruptcy.²⁰ Similarly, specialty drug prices also place an onerous burden on public payers and private insurers, which each face expenditures growing at an unsustainable rate. A recent report by the Congressional Budget Office found that Medicaid spending on specialty drugs more than doubled between 2010 and 2015, increasing from \$4.8 billion to \$9.9 billion,²¹ and Medicare Part D spending on specialty drugs increased nearly four-fold, from \$8.7 billion in 2010 to \$32.8 billion in 2015.²² A study of commercial plan fills for specialty versus nonspecialty drugs reported that spending on specialty drugs increased from 11% of total prescription spending in 2003 to 43.2% of prescription spending in 2014, even though specialty drug fills comprised less than 2% of all prescription fills during that period.²³

The absence of generic and biosimilar treatment alternatives for many specialty drugs due to government-granted periods of exclusivity and patent protection exacerbates the financial burden of specialty drugs.²⁴ In response, insurers often impose prior authorization requirements and other utilization-management strategies, such as specialty tiers with high levels of patient cost-sharing.²⁵ Recently, rising out-of-pocket healthcare spending has most affected patients with

¹⁸ *Id.* at 8. Inclusion of five “outlier” specialty drugs with very high prices or unusually large price increases would have brought the average annual cost of a specialty drug in 2020 to \$136,401. *Id.*

¹⁹ See Liz Szabo, *As Drug Costs Soar, People Delay or Skip Cancer Treatments*, NPR (Mar. 15, 2017, 5:00 AM), <https://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments> [<https://perma.cc/Q53B-R9ME>].

²⁰ See David U. Himmelstein, Deborah Thorne, Elizabeth Warren & Steffie Woolhandler, *Medical Bankruptcy in the United States, 2007: Results of a National Study*, 128 AM. J. MED. 741, 743–44 (2009) (finding that “[i]llness or medical bills contributed to 62.1% of all bankruptcies in 2007,” *id.* at 743, and the proportion of all bankruptcies that can be attributed to medical problems increased nearly 50% from 2001 to 2007, *id.* at 744); David U. Himmelstein et al., *Medical Bankruptcy: Still Common Despite the Affordable Care Act*, 109 AM. J. PUB. HEALTH 431, 432 (2019).

²¹ CONG. BUDGET OFF., PRICES FOR AND SPENDING ON SPECIALTY DRUGS IN MEDICARE PART D AND MEDICAID 6 (2019), https://www.cbo.gov/system/files/2019-03/54964-Specialty_Drugs.pdf [<https://perma.cc/F35K-JQXP>].

²² *Id.* at 6–7.

²³ Stacie B. Dusetzina, *Share of Specialty Drugs in Commercial Plans Nearly Quadrupled, 2003–14*, 35 HEALTH AFFS. 1241, 1245 (2016). Here, specialty drugs were defined as those drugs for which a 30-day supply was reimbursed at least \$600. See *id.* at 1242.

²⁴ See Spatz & McGee, *supra* note 12, at 2.

²⁵ See *Specialty Tiers*, HEMOPHILIA FED’N OF AM., <https://www.hemophiliafed.org/our-role-and-programs/assisting-and-advocating/policy-priorities/specialty-tiers> [<https://perma.cc/9PAY-EUHB>]; Juliette Cubansky et al., *The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019*, KAISER FAM. FOUND. (Feb. 1, 2019), <https://www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019> [<https://perma.cc/A6BK-DPGC>].

employer-sponsored health insurance and incomes of at least 400% of the federal poverty level.²⁶ The Affordable Care Act (“ACA”) and certain states have placed maximum limits on patients’ out-of-pocket spending,²⁷ but drug affordability remains a high-priority issue among policymakers that continues to fuel vigorous state and federal efforts to lower drug prices.²⁸ Despite these efforts, the problem of high drug prices has continued largely unabated.

²⁶ Sherry A. Glied & Benjamin Zhu, *Catastrophic Out-of-Pocket Health Care Costs: A Problem Mainly for Middle-Income Americans with Employer Coverage*, COMMONWEALTH FUND (Apr. 17, 2020), <https://www.commonwealthfund.org/publications/issue-briefs/2020/apr/catastrophic-out-of-pocket-costs-problem-middle-income> [<https://perma.cc/5N5P-A2V3>] (“Policy changes have afforded much more risk protection to low-income groups but have increased out-of-pocket risk for higher-income groups.”).

²⁷ See Kai Yeung et al., *Patient and Plan Spending After State Specialty-Drug Out-of-Pocket Spending Caps*, 383 NEW ENG. J. MED. 558, 559 (2020); *Affordable Care Act Implementation FAQs – Set 18*, CTFS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18#:~:text=Section (noting that “[s]ection 1302(c)(1) [of the ACA] limits out-of-pocket costs and, for small group market plans, section 1302(c)(2) limits deductibles”) [<https://perma.cc/C7AC-M355>].

²⁸ Drug pricing seems to be a perennial issue on the agenda of both Congress and the executive branch. See, e.g., Juliette Cubansky et al., *A Status Report on Prescription Drug Policies and Proposals at the Start of the Biden Administration*, KAISER FAM. FOUND. (Feb. 11, 2021), <https://www.kff.org/medicare/issue-brief/a-status-report-on-prescription-drug-policies-and-proposals-at-the-start-of-the-biden-administration> [<https://perma.cc/6NH5-DZEH>]; Billy Wynne & Alyssa Llamas, *New Legislation to Control Drug Prices: How Do House and Senate Bills Compare? An Update*, COMMONWEALTH FUND (Jan. 9, 2020), <https://www.commonwealthfund.org/blog/2020/new-legislation-control-drug-prices-how-do-house-and-senate-bills-compare-update> [<https://perma.cc/M72U-BTPR>].

The Trump Administration issued an Executive Order in September 2020 granting the Secretary of Health and Human Services authority to test a payment model that would lower Part B drug prices to the “Most Favored Nation” (“MFN”) price, meaning the lowest price paid for a drug in a member OECD nation with a comparable per-capita GDP. Lowering Drug Prices by Putting America First, Exec. Order No. 13,948, 85 Fed. Reg. 59,649, 59,649 (Sept. 13, 2020). In November 2020, CMS issued an interim final rule to implement the MFN model, outlining that MFN would be a mandatory model encompassing fifty high-expenditure, single-source drugs and biologics. See Most Favored Nation (MFN) Model, 85 Fed. Reg. 76,180, 76,181, 76,189 (Nov. 27, 2020) (to be codified at 42 C.F.R. pt. 513). But implementation was preliminarily enjoined due to inadequacies in the notice-and-comment process. See Order Granting Motion for Preliminary Injunction, Cal. Life Scis. Ass’n v. Ctr. for Medicare & Medicaid Servs., No. 20-cv-08603 (N.D. Cal. Dec. 28, 2020).

Recently, the Biden Administration announced a plan to allow Medicare to negotiate drug prices. Press Release, The White House, President Biden Announces Prescription Drug Pricing Plan in Build Back Better Framework (Nov. 2, 2021), <https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/02/president-biden-announces-prescription-drug-pricing-plan-in-build-back-better-framework> [<https://perma.cc/BMK6-ZRC4>]. Compromise terms for Medicare drug price negotiation won Senate support for inclusion in a reconciliation bill before Congress. Tami Luhby, *Senate Democrats Reach Agreement on Prescription Drug Prices*, CNN (Nov. 2, 2021, 8:56 PM), <https://www.cnn.com/2021/11/02/politics/drug-price-negotiation-democrats-deal/index.html> [<https://perma.cc/9QW8-YU3S>]. Negotiating power, however, would initially apply only to a limited set of “negotiation-eligible” drugs, with expansion over time. Lowering Prices Through Drug Price Negotiation, H.R. 5376, 117th Cong. § 139001 (2021), <https://rules.house.gov/sites/democrats.rules.house.gov/files/BILLS-117HR5376RH-RCP117-18.pdf> [<https://perma.cc/93TK-G4FK>].

III. A BRIEF SKETCH OF THE SPECIALTY DRUG LANDSCAPE

The pressing need for effective treatments for serious chronic illnesses stands at odds with the unaffordable price of specialty drugs for the average American. High prices force some patients to forego treatment, skip doses, or prematurely terminate a therapeutic course.²⁹ High prices thus also offset a drug company's ability to maximize patient access to a drug. As the out-of-pocket cost for a drug rises, the willingness of patients to purchase the drug falls, exerting a dampening effect on a drug maker's sales. This effect is compounded by the fact that many specialty drugs treat uncommon chronic illnesses or rare diseases, which are defined by statute as affecting fewer than 200,000 individuals in the United States.³⁰

States, too, have been active in attempting drug pricing reforms. One notable achievement at the state level was the passage of legislation in Maryland in 2019 that established a prescription drug affordability board with authority to promulgate criteria for "upper payment limits" on drugs. See Jane Horvath, *Maryland Passes Nation's First Prescription Drug Affordability Board Legislation*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Apr. 15, 2019), <https://www.nashp.org/maryland-passes-nations-first-prescription-drug-affordability-board-legislation> [<https://perma.cc/M2BQ-36PY>]; Jared S. Hopkins, *Maryland Takes Step Toward Capping Drug Prices*, WALL ST. J. (Apr. 30, 2019, 4:33 PM), <https://www.wsj.com/articles/maryland-takes-step-toward-capping-drug-prices-11556616600> [<https://perma.cc/3KBR-Q479>]. A number of states have introduced bills or passed legislation in recent years to regulate pharmacy benefit managers (PBMs), middlemen in the pharmaceutical supply chain that negotiate between drug makers, insurers, and pharmacies over drug rebates, discounts, and the formulary status of drugs. For a discussion of PBMs, see Cole Werble, *Pharmacy Benefit Managers*, HEALTH AFFS. (2017), https://www.healthaffairs.org/doi/10.1377/hpb20171409.000178/full/healthpolicybrief_178.pdf [<https://perma.cc/E9KG-UR7K>]. For a state-by-state summary of recent drug pricing-related legislation, see *2021 State Legislative Action to Lower Pharmaceutical Costs*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Oct. 14, 2021), <https://www.nashp.org/rx-legislative-tracker> [<https://perma.cc/32JY-JSWT>].

²⁹ Unaffordable prices are a deterrent to medication initiation and adherence. A study of medication abandonment (defined as "never actually taking possession" of a prescribed medication) for MS drugs found an odds ratio of abandonment of 6.1 to 7.3 when out-of-pocket expenses were greater than \$200. See Patrick P. Gleason et al., *Association of Prescription Abandonment with Cost Share for High-Cost Specialty Pharmacy Medications*, 15 J. MANAGED CARE PHARMACY 648, 651 (2009). A study of diabetes medications found that adherence was significantly reduced above a diabetes-related, out-of-pocket pharmacy cost of \$51 to \$75, and adherence was significantly reduced for a total out-of-pocket pharmacy cost of \$91 to \$150. Wendy S. Bibeau et al., *Impact of Out-of-Pocket Pharmacy Costs on Branded Medication Adherence Among Patients with Type 2 Diabetes*, 22 J. MANAGED CARE SPECIALTY PHARMACY 1338, 1343 (2016). For additional studies examining the relationship between patient out-of-pocket costs and medication adherence, see Parvaneh Heidari et al., *Do Out-of-Pocket Costs Affect Medication Adherence in Adults with Rheumatoid Arthritis? A Systematic Review*, 48 SEMINARS IN ARTHRITIS & RHEUMATISM 12 (2018); and Evan L. Reynolds et al., *Association of Out-of-Pocket Costs on Adherence to Common Neurologic Medications*, 94 NEUROLOGY e1415 (2020).

³⁰ 21 U.S.C. § 360bb(a)(2) ("[T]he term 'rare disease or condition' means any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug.").

Maximizing utilization of expensive therapies among small target populations without dramatically lowering drug prices presents a dilemma for drug makers. Yet it has also fostered a business opportunity: provision of *partial* financial assistance for drugs—enough to offset patients’ out-of-pocket costs—can help ensure that a public or private payer³¹ foots the remainder of an otherwise outrageous bill. In effect, drug makers provide financial assistance to expand market access in lieu of lowering drug prices. In so doing, they achieve higher demand for their drugs than would be possible in the absence of financial assistance.

Escalating specialty drug prices have led to a burgeoning ecosystem of financial and nonfinancial support services, including (1) services provided by specialty pharmacies; (2) drug company-derived forms of financial assistance such as drug coupon cards, copay assistance programs, and patient assistance programs; and (3) manufacturer-sponsored patient support programs. Each will be discussed in turn.

A. Specialty Pharmacies

A relatively small number of pharmacies dominates the specialty pharmacy market. The leading specialty pharmacies operate as subsidiaries of vertically integrated insurer-PBM or pharmacy-PBM corporate alliances.³² Originating in the 1980s,³³ specialty pharmacies supply high-cost, “high-touch” specialty drugs³⁴ and offer a flourishing line of patient-directed services. Those services include 24/7

³¹ Public payers refer to federal or state government payers, including Medicare, Medicaid, and the State Children’s Health Insurance Program (SCHIP). For a breakdown of U.S. healthcare spending by payer type, see Joseph L. Dieleman et al., *US Health Care Spending by Payer and Health Condition, 1996–2016*, 323 JAMA 863 (2020).

³² See Adam J. Fein, *The Top 15 Specialty Pharmacies of 2019: PBMs Stay on Top*, DRUG CHANNELS (Apr. 28, 2020), <https://www.drugchannels.net/2020/04/the-top-15-specialty-pharmacies-of-2019.html> [<https://perma.cc/NY64-QPP9>] [hereinafter Fein, *The Top 15 Specialty Pharmacies*]; Adam J. Fein, *The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation*, DRUG CHANNELS (Apr. 6, 2021), <https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html> [<https://perma.cc/2RD5-BFZU>]. The four largest specialty pharmacies by specialty drug revenue in 2019 were: (1) CVS Specialty, a subsidiary of CVS Health; (2) Accredo, a subsidiary of insurer Cigna; (3) AllianceRx Walgreens Prime, a subsidiary of Walgreens Boots Alliance; and (4) OptumRx, a subsidiary of UnitedHealth Group. See Fein, *The Top 15 Specialty Pharmacies*.

³³ See Kevin Colgan & Robert Beacher, *Importance of Specialty Pharmacy to Your Health System*, 72 AM. J. HEALTH-SYSTEM PHARMACY 753, 753 (2015); see also Gordon J. Vanscoy, *The Emergence of Specialty Pharmacy*, 6 J. MANAGED CARE PHARMACY 280, 280 (2000) (noting the emergence of specialty pharmacy as a concept in the 1980s, naming several specialty pharmacy providers at that time, including Stadtlanders, CVS Procure, Chronimed, and Priority Healthcare, and explaining that the early specialty pharmacies functioned to lower the costs of managing patients with “catastrophic” illnesses, such as organ transplant patients and HIV-AIDS patients).

³⁴ See *Specialty Pharmacy Drug List*, MAGELLANRX, https://magellanrx.com/member/external/commercial/common/doc/en-us/MRx_Formulary_Specialty.pdf [<https://perma.cc/V25S-5FN4>] (describing features of specialty drugs, including “high cost,” “high complexity,” and “high touch”).

nursing or pharmacist support;³⁵ counseling and disease education;³⁶ adherence and side effect management;³⁷ logistical support for drug refills, shipping, and tracking;³⁸ and “financial resource assistance teams,” which function as intermediaries between drug makers, foundations, and insurance companies³⁹ and provide services such as confirming eligibility for insurance benefits and mediating the prior authorization process.⁴⁰ Touting the alluring promise of “personalized care and guidance,”⁴¹ the specialty pharmacy business model has burgeoned to fill a niche created by complex, expensive specialty drugs, and PBM ownership of the largest specialty pharmacies has further entrenched PBMs in the pharmaceutical drug distribution and reimbursement landscape. PBMs position their specialty pharmacy services in opposition to those of drug manufacturers,⁴² and they aggressively promote specialty pharmacy, highlighting cost savings for payers and optimized patient outcomes as the principal benefits.⁴³

³⁵ See *Accredo Specialty Pharmacy Explained*, EXPRESS SCRIPTS, <https://www.express-scripts.com/corporate/articles/accredo-specialty-pharmacy-explained> [https://perma.cc/FA6Z-2V4Z].

³⁶ *Specialty Pharmacy*, CVSHEALTH, <https://cvshealth.com/about/our-offerings/cvs-specialty> [https://perma.cc/6WTF-FS57].

³⁷ *Id.* (“Dedicated teams of specialists called CareTeams . . . help patients manage side effects, communicate with doctors, and coordinate with other care providers. They are available 24 hours a day, 7 days a week to answer questions about conditions and treatments.”). Accredo, the specialty pharmacy of Express Scripts/Cigna, advertises that its specialty pharmacy services have increased the likelihood of medication adherence for those with diabetes, hypertension, and high cholesterol and have lowered hospitalizations and emergency room visits, as compared to outcomes for patients who use retail pharmacies. *Express Scripts Pharmacy Increases Adherence and Savings*, EXPRESS SCRIPTS, <https://www.express-scripts.com/corporate/articles/express-scripts-pharmacy-increases-adherence-and-savings> [https://perma.cc/R593-GYLG].

³⁸ See *Specialty Pharmacy*, *supra* note 36.

³⁹ See *Accredo Specialty Pharmacy Explained*, *supra* note 35.

⁴⁰ See *Specialty Pharmacy*, *supra* note 36 (“We work with providers to streamline prior authorization for prescriptions, and with insurance companies to verify benefits coverage.”).

⁴¹ See, e.g., *He’s More than a Patient. He’s a PB&J Chef. A Tee-Ball Coach. A Little Boy’s Hero. And Our Focus.*, ACCREDO, <https://www.accredo.com/> [https://perma.cc/4G9C-4UBQ].

⁴² Citing the example of unsavory practices by Valeant’s specialty pharmacy, a recent report on specialty pharmacy from the Pharmaceutical Care Management Association (“PCMA”), the U.S. trade association for PBMs, questioned the motives of “manufacturer-aligned” pharmacies: “Not all pharmacies serve in the best interest of patients. Manufacturer-aligned pharmacies frequently market themselves as specialty pharmacies, but in reality they prioritize the needs of pharmaceutical companies over those of patients, healthcare providers, and payers.” *PBM Specialty Pharmacies Improve Patient Outcomes and Reduce Costs*, PHARM. CARE MGMT. ASS’N 1, 4 (2017), https://www.pcmanet.org/wp-content/uploads/2017/04/PBM-Specialty-Pharmacies-Improve-Patient-Outcomes-and-Reduced-Costs_whitepaper_final.pdf [https://perma.cc/82UB-AAJQ] [hereinafter *PBM Specialty Pharmacies*].

⁴³ See *id.* at 6, 9; see also *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers*, VISANTE (prepared for PCMA) 1, 4 (Feb. 2016), <https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf> [https://perma.cc/HAS9-EMBS] (claiming, without citing, an estimated \$257 billion in savings to Medicare Part D over the next ten years as a result of “[c]ontinued use of PBM tools at their current levels,” *id.* at 8). Published studies in the literature have also demonstrated improved clinical outcomes from specialty pharmacy care, with positive effects likely mediated by improved

B. Drug Coupons, Copay Assistance Programs, and Patient Assistance Programs

Although PBMs have gained a foothold in the domain of specialty pharmacy, drug makers, too, provide specialty pharmacy-related services. Drug makers facilitate patient access to high-priced therapies and promote brand loyalty by offering coupon cards and copay assistance programs,⁴⁴ both controversial offerings that may ultimately increase individual- and population-level costs by enabling patients to remain on more expensive brand drugs for longer periods of time than necessary.⁴⁵ For example, Gilead promises that “[e]ligible patients may pay as little as a \$0 co-pay with no monthly limit” through its Advancing Access® Copay Coupon Card.⁴⁶ Bearing catchy names such as Amgen FIRST STEP™⁴⁷ and the CIMplicity® Savings Program,⁴⁸ coupons and copay assistance programs exist for nearly all specialty drugs. Drug makers often provide specialty drugs at

medication adherence. See, e.g., Jun Tang et al., *Effects of Specialty Pharmacy Care on Health Outcomes in Multiple Sclerosis*, 9 AM. HEALTH & DRUG BENEFITS 420, 424 (2016) (demonstrating that specialty pharmacy care is associated with a lower risk of first relapse in patients with MS, for example, and a longer time period without relapse); H. Tan et al., *Clinical and Economic Impact of a Specialty Care Management Program Among Patients with Multiple Sclerosis: A Cohort Study*, 16 MULTIPLE SCLEROSIS 956, 958 (2010) (reporting a statistically significant improvement in treatment adherence and persistence among MS patients who participated in a specialty care management program as compared to nonparticipants, but with concomitant increases in pharmacy expenditures). After finding that medical cost reductions could not offset increased pharmacy expenditures among those using specialty care management, the latter study conceded that “it is unlikely that a long-term cost saving will be seen in MS-related total cost for participants, unless there is a significant drop in medication costs in the future.” Tan et al., *supra*, at 961.

⁴⁴ See, e.g., *Affordability Options for STELARA*, JANSEN CAREPATH, <https://www.janssencarepath.com/sites/www.janssencarepath-v1.com/files/stelara-patient-affordability-chart.pdf> [<https://perma.cc/LE5R-CUQR>]; *Once-Daily AUBAGIO (teriflunomide)*, SANOFI GENZYME, <https://www.aubagio.com/cost> [<https://perma.cc/7BAR-X8HA>]; *Advancing Access: Welcome to the Gilead Advancing Access Co-pay Program*, GILEAD, <https://www.gileadadvancingaccess.com/copay-coupon-card> [<https://perma.cc/75Q4-E29T>]; *Ocrevus (ocrelizumab)*, GENZYME, <https://www.ocrevuscopay.com> [<https://perma.cc/T4QY-8ET6>].

⁴⁵ See David Grande, *The Cost of Drug Coupons*, 307 JAMA 2375, 2375 (2012) (“Drug coupons raise two primary financial concerns. First, coupons can increase out-of-pocket spending for the coupon user in either the short or long term because copays may still be higher compared with therapeutic alternatives (ie, direct costs). Second, coupons can increase health care spending for coupon users and non-users by increasing aggregate health spending and thus health insurance premiums (ie, indirect costs).”); Joseph X. Ross & Aaron S. Kesselheim, *Prescription-Drug Coupons — No Such Thing as a Free Lunch*, 369 NEW ENG. J. MED. 1188, 1188–89 (2013) (noting that most drug coupons do not provide a discount for more than one year, leaving patients with high copays after the eligibility period for the drug coupon ends, and also noting that drug coupons tend to undercut insurer utilization-management tools like higher cost-sharing tiers for specialty drugs, thereby frustrating insurers’ efforts to control specialty pharmacy spending).

⁴⁶ *Advancing Access*, BIKTARVY, <https://www.biktarvyhcp.com/support/cost-assistance#> [<https://perma.cc/PK4K-RPSA>].

⁴⁷ *We’re Here to Help*, AMGEN ASSIST 360, <https://www.amgenassist360.com/patient/mvasi-cost-assistance/> [<https://perma.cc/9UUK-WS7C>].

⁴⁸ *You Have Support Every Step of the Way*, CIMZIA (CERTOLIZUMAB PEGOL), <https://www.cimzia.com/cimply-program> [<https://perma.cc/7JDT-E74N>].

little or no cost to eligible uninsured and underinsured patients meeting certain income requirements through patient assistance programs.⁴⁹ Patient assistance programs sometimes operate through foundations that are distinct legal entities from drug makers themselves but may receive drug company donations.⁵⁰ Patients covered by federal healthcare programs, however, are not eligible for drug coupons or manufacturer-sponsored patient assistance programs due to the constraints of the Anti-Kickback Statute (“AKS”).⁵¹

Although drug coupons lower patients’ out-of-pocket costs, they typically do not affect the amount a public or private payer pays for a drug.⁵² By permitting patients to shoulder a lower cost and therefore become less price-sensitive,⁵³ drug company-sponsored forms of financial assistance may indirectly increase insurance premiums⁵⁴ and drug prices.⁵⁵ Drug coupons remain a controversial feature of modern pharmaceutical drug financing that has prompted state and federal

⁴⁹ See, e.g., *Tablets and Other Dosage Forms: Patient Assistance Program (PAP)*, VIIVCONNECT, <https://www.viivconnect.com/patient-assistance-program/> [<https://perma.cc/8M6X-3LTV>]; see also Niteesh K. Choudhry et al., *Drug Company-Sponsored Patient-Assistance Programs: A Viable Safety Net?*, 28 HEALTH AFFS. 827, 827–28 (2009); CONG. RSCH. SERV., *PRESCRIPTION DRUG DISCOUNT COUPONS AND PATIENT ASSISTANCE PROGRAMS (PAPS)* 14–17 (2017) [hereinafter CONG. RSCH. SERV., PAPS].

⁵⁰ See, e.g., *Pfizer Hemophilia Connect*, PFIZER (June 2021), <https://www.pfizerhemophiliasupport.com/hemophilia-connect> [<https://perma.cc/8MCH-CGPR>] (“Eligible patients may receive their factor product at no charge or at a discount.”). In fine print, the website notes that “[t]he Pfizer Patient Assistance Program is a joint program of Pfizer Inc. and the Pfizer Patient Assistance Foundation. The Pfizer Patient Assistance Foundation is a separate legal entity from Pfizer Inc., with distinct legal restrictions.” *Id.*; see also So-Yeon Kang et al., *Financial Eligibility Criteria and Medication Coverage for Independent Charity Patient Assistance Programs*, 322 JAMA 422, 423 (2019); David H. Howard, *Drug Companies’ Patient-Assistance Programs – Helping Patients or Profits?*, 371 NEW ENG. J. MED. 97, 98 (2014) (“Private foundations are allowed to provide assistance subject to certain restrictions. For example, foundations cannot define their target population so narrowly that they effectively devote all their funds to one manufacturer’s product. Manufacturers are permitted to contribute to and steer patients to foundations that provide assistance, and many do so.”).

⁵¹ CONG. RSCH. SERV., PAPS, *supra* note 49, at 12, 17 (“Co-payment coupons cannot be used in conjunction with federal health benefits, including Medicare, Medicaid, TRICARE military insurance, and Veterans Health Administration programs. . . . Pharmaceutical companies may be liable under the [A]nti-[K]ickback [S]tatute if they offer coupons to induce the purchase of drugs paid for by federal health care programs.” *Id.* at 12.); see also Katherine Kraschel & Gregory Curfman, *Opinion, Patient Assistance Programs and Anti-Kickback Laws*, 322 JAMA 405, 405 (2019) (noting, with respect to Medicare, that “funds from the pharmaceutical industry provided to Medicare beneficiaries to assist those patients in acquiring Medicare Part D drugs are exactly what the federal Anti-Kickback Statute is designed to prohibit”).

⁵² See CONG. RSCH. SERV., PAPS, *supra* note 49, at 2.

⁵³ See Grande, *supra* note 45, at 2375 (explaining that copays, as a form of cost-sharing, lose effectiveness as a utilization-management tool when coupons decouple patient copays from drug prices).

⁵⁴ See *id.*

⁵⁵ See Howard, *supra* note 50, at 98.

scrutiny,⁵⁶ insurer countermeasures such as copay accumulator programs,⁵⁷ and legal challenges. Recently, several major pharmaceutical companies entered into settlements with the Department of Justice (“DOJ”) over allegations that they engaged in kickback schemes.⁵⁸ The schemes involved charitable foundations that covered the cost of Medicare beneficiaries’ copays for the companies’ drugs.⁵⁹ Drug makers allegedly directed funds to the charitable foundations, while in some cases simultaneously imposing drug price increases.⁶⁰ The coordination of funding to specific charitable foundations and the concurrent funneling of Medicare patients in need of copay assistance to those very foundations ran afoul of the False Claims

⁵⁶ See COMMONWEALTH OF MASS. HEALTH POL’Y COMM’N, PRESCRIPTION DRUG COUPON STUDY: REPORT TO THE MASSACHUSETTS LEGISLATURE (2020), <https://www.mass.gov/doc/prescription-drug-coupon-study/download> [https://perma.cc/67NS-875C]; see generally CONG. RSCH. SRV., PAPS, *supra* note 49.

⁵⁷ See Oliver Kim, *Feds and States Diverge on Patients’ Use of Drug Coupons*, COUNCIL OF STATE GOV’TS E. REG’L CONF. (May 14, 2019), <https://csg-erc.org/feds-and-states-diverge-on-patients-use-of-drug-coupons> [https://perma.cc/L739-5ECB]; see also Adam J. Fein, *Copay Accumulators: Costly Consequences of a New Cost-Shifting Pharmacy Benefit*, DRUG CHANNELS (Jan. 3, 2018), <https://www.drugchannels.net/2018/01/copay-accumulators-costly-consequences.html> [https://perma.cc/TSQ7-RX7F] (explaining that copay accumulators decline to count a drug company’s financial assistance in the form of coupons or other copay assistance toward a patient’s insurance deductible or out-of-pocket maximum, and predicting an ensuing reduction in patient adherence to and utilization of specialty drugs); Adam J. Fein, *Copay Accumulators and Maximizer Update: Adoption Accelerating as Pushback Grows*, DRUG CHANNELS (Nov. 17, 2020), <https://www.drugchannels.net/2020/11/copay-accumulator-and-maximizer-update.html> [https://perma.cc/D9UT-TPRC].

⁵⁸ See *infra* notes 59-60; see also Kraschel & Curfman, *supra* note 51, at 405-06.

⁵⁹ See, e.g., Press Release, Dep’t of Just. U.S. Att’y’s Off., Dist. of Mass., Pfizer Agrees to Pay \$23.85 Million to Resolve Allegations that It Paid Kickbacks Through a Co-Pay Assistance Foundation (May 24, 2018), <https://www.justice.gov/usao-ma/pr/pfizer-agrees-pay-2385-million-resolve-allegations-it-paid-kickbacks-through-co-pay> [https://perma.cc/22E9-L7QJ] [hereinafter Press Release, Pfizer]; Press Release, Dep’t of Just. U.S. Att’y’s Off., Dist. of Mass., Novartis Agrees to Pay over \$51 Million to Resolve Allegations that It Paid Kickbacks Through Co-Pay Foundations (July 1, 2020), <https://www.justice.gov/usao-ma/pr/novartis-agrees-pay-over-51-million-resolve-allegations-it-paid-kickbacks-through-co-pay> [https://perma.cc/MWC5-KFH8] [hereinafter Press Release, Novartis] (describing other variants on the illegal schemes, such as restrictions on foundation fund eligibility to confine eligibility to those taking a drug maker’s brand drugs, and subsequent drug company financing of the fund); Press Release, Dep’t of Just. U.S. Att’y’s Off., Dist. of Mass., Sanofi Agrees to Pay \$11.85 Million to Resolve Allegations that It Paid Kickbacks Through a Co-Pay Assistance Foundation (Feb. 28, 2020), <https://www.justice.gov/usao-ma/pr/sanofi-agrees-pay-1185-million-resolve-allegations-it-paid-kickbacks-through-co-pay> [https://perma.cc/7KKJ-A3KF] [hereinafter Press Release, Sanofi].

⁶⁰ See, e.g., Press Release, Pfizer, *supra* note 59 (“With respect to Tikosyn, Pfizer raised the wholesale acquisition cost of a package of forty 0.125 mg capsules of the drug by 44 percent during the last three months of 2015. Knowing the price increase would increase Medicare beneficiaries’ copay obligations for Tikosyn, which could result in more Medicare patients needing financial assistance to fill their Tikosyn prescriptions, Pfizer allegedly worked with the foundation to create and finance a fund for Medicare patients being treated for arrhythmia with atrial fibrillation or atrial flutter. . . . Pfizer coordinated the timing of the opening of the fund for these patients with the implementation of a Tikosyn price increase, and Pfizer then began referring to the foundation any Medicare patients who needed financial assistance to meet their newly-increased copays for the drug. For the next nine months, Tikosyn patients accounted for virtually all of the beneficiaries of the fund.”).

Act (“FCA”) and AKS, which prohibit direct or indirect remuneration to induce the purchase of goods or services covered by federal healthcare programs.⁶¹ Part VI of this Article considers the role that patient support program-mediated PHI may have played in drug makers’ schemes involving charitable foundations.

C. Patient Support Programs

Patient support programs provide “optional services . . . [that] aim at directly educating patient beliefs and behaviors to increase [drug] adherence.”⁶² Support services can be roughly divided into financial services and nonfinancial services, both available to eligible patients who have been prescribed a specialty drug and choose to enroll in the program. Financial services increase patients’ access to a therapy by lowering out-of-pocket costs. These services commonly include an assessment of enrollees’ eligibility for copay assistance, the drug manufacturer’s patient assistance program,⁶³ and foundation support.⁶⁴ Nonfinancial services, which are designed to improve medication adherence, include services such as personalized nursing support, injection training, and medication reminders, all of which are available free of charge to patients.⁶⁵

Drug manufacturers sponsor patient support programs, just as they do drug coupons and patient assistance programs.⁶⁶ Patient assistance programs and patient support programs, however, are not synonymous; instead, patient assistance programs are subsumed under the financial support prong of patient support

⁶¹ See sources cited *supra* note 59.

⁶² Florian Lenz & Lutz Harms, *The Impact of Patient Support Programs on Adherence to Disease-Modifying Therapies of Patients with Relapsing-Remitting Multiple Sclerosis in Germany: A Non-Interventional, Prospective Study*, 37 *ADVANCED THERAPEUTICS* 2999, 3001 (2020).

⁶³ Patient assistance programs, most but not all of which are sponsored by drug companies, provide pathways to access brand-name pharmaceutical drugs. See, e.g., *For Patients, Pfizer Patient Assistance Program*, PFIZER RXPATHWAYS, <https://www.pfizerRxpathways.com/resources/patients> [<https://perma.cc/TU9G-FW5X>]; Choudhry, *supra* note 49, at 829–31 (surveying and describing characteristics of patient assistance programs). In a 2009 study, Choudhry and colleagues evaluated 165 drug company-sponsored patient assistance programs and found variability in the benefits they offered and the eligibility criteria for the programs. *Id.* at 829.

⁶⁴ Foundation support refers to financial assistance provided to patients by nonprofit organizations, typically organized as 501(c)(3) nonprofits, that help cover patients’ out-of-pocket costs for pharmaceutical drugs. A notable example is the Patient Access Network (PAN) Foundation. See PAN FOUNDATION, <https://www.panfoundation.org> [<https://perma.cc/ZS6N-L4KE>]. Patients ineligible for a patient assistance program may qualify for foundation support. See Nancy J. Egerton, *In-Office Dispensing of Oral Oncolytics: A Continuity of Care and Cost Mitigation Model for Cancer Patients*, 22 *AM. J. MANAGED CARE* S99, S102 (2016).

⁶⁵ See Diana Brixner et al., *Patient Support Program Increased Medication Adherence with Lower Total Health Care Costs Despite Increased Drug Spending*, 25 *J. MANAGED CARE & SPECIALTY PHARMACY* 770, 771 (2019) (noting “no fee associated with program enrollment” in the Humira patient support program).

⁶⁶ See, e.g., Neeraj Narula et al., *Impact of Adalimumab Patient Support Program’s Care Coach Calls on Clinical Outcomes in Patients with Crohn’s Disease in Canada: An Observational Retrospective Cohort Study*, 1 *J. CANADIAN ASS’N OF GASTROENTEROLOGY* 191, 192 (2018) (noting that “AbbVie created the [AbbVie Care Patient Support Program] to facilitate access to and appropriate use of adalimumab and to improve patients’ experience on adalimumab therapy”).

programs. Put differently, after a patient enrolls in a patient support program, a drug manufacturer will assess an enrollee's eligibility for various forms of financial assistance, including patient assistance programs. To the author's knowledge, the degree of patient participation in patient support programs has not been comprehensively studied and likely varies by drug, by program, and by country.⁶⁷

Consider, for example, Mallinckrodt's patient support program for its drug Acthar gel (repository corticotropin injection).⁶⁸ Mallinckrodt promises that "[a] Nurse Navigator and a Case Manager will be your partners throughout your treatment journey,"⁶⁹ providing "free, one-on-one injection training"⁷⁰ and direct-to-home shipping of refrigerated Acthar gel from a specialty pharmacy, among other things.⁷¹ With respect to financial services, Mallinckrodt provides guidance navigating "potential financial assistance options and programs that may be available to [patients prescribed Acthar gel] and that [they] may qualify for."⁷²

Consider another example: Sanofi administers *MS One to One*, a patient support program for its MS drug Lemtrada (alemtuzumab), a therapy administered annually by infusion.⁷³ *MS One to One* provides patients with a designated "case manager who is available 24/7 to help them understand the risks and benefits of LEMTRADA, answer questions about MS, access financial support resources,

⁶⁷ See Lenz & Harms, *supra* note 62, at 3003 (noting low participation rates in patient support programs). A study from 2019 indicated that AbbVie's patient support program for Humira—HUMIRA Complete—had enrolled 300,000 patients since 2015. See Brixner et al., *supra* note 65.

⁶⁸ Acthar gel is FDA approved to treat MS and infantile spasms, a form of epilepsy in young children. See *Labeling-Package Insert, Acthar Gel*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/008372s0711bl.pdf.

⁶⁹ *If You Have Been Prescribed Acthar Gel, Your Support Starts Here*, ACTHAR GEL, <https://acthar.com/acthar-patient-support/#starting-treatment> [hereinafter *Acthar Gel Patient Support*] [<https://perma.cc/N6F4-FSGU>].

⁷⁰ ACTHAR GEL PATIENT SUPPORT, YOUR ACTHAR GEL TREATMENT JOURNAL 4 https://acthar.com/Static/pdf/US-2001308_PSR%20Treatment%20Journal-%20Digital%20Download.pdf [<https://perma.cc/A9X5-GD7T>].

⁷¹ *Acthar Gel Patient Support*, *supra* note 69.

⁷² *Id.* It is worth noting here that Mallinckrodt faced lawsuits for antitrust violations, racketeering, and other fraud charges after increasing the price of the drug from \$40 per vial in 2001 to roughly \$40,000 per vial by 2019. See Michael Gibney, *H.P. Acthar Gel – Questcor/Mallinckrodt*, FIERCE PHARMA (Oct. 14, 2014, 8:00 AM), <https://www.fiercepharma.com/special-report/h-p-acthar-gel-questcor-mallinckrodt> [<https://perma.cc/6F6Z-WW35>]; see also Press Release, Fed. Trade Comm'n, Mallinckrodt Will Pay \$100 Million to Settle FTC, State Charges It Illegally Maintained its Monopoly of Specialty Drug Used to Treat Infants (Jan. 18, 2017), <https://www.ftc.gov/news-events/press-releases/2017/01/mallinckrodt-will-pay-100-million-settle-ftc-state-charges-it> [<https://perma.cc/FTG2-Q5XM>]; Nate Raymond, *Mallinckrodt Shares Drop After U.S. Joins Case over Expensive Drug*, REUTERS (Apr. 30, 2019, 12:48 PM), <https://www.reuters.com/article/us-mallinckrodt-lawsuit/mallinckrodt-shares-drop-after-u-s-joins-cases-over-expensive-drug-idUSKCN1S623P> [<https://perma.cc/82WQ-KUSQ>].

⁷³ *Making a Choice: Lemtrada Stories*, LEMTRADA (ALEMTUZUMAB), <https://www.lemtrada.com/stories/choice-articles/questions-for-nurse> [<https://perma.cc/4J2P-7DFS>] (describing the Lemtrada infusion process and the role of the MS One to One Case Manager).

prepare the infusion process, and remember required monthly monitoring.”⁷⁴ Financial support included as part of Sanofi’s patient support program includes benefits verification and information on financial assistance programs, including the LEMTRADA Co-Pay Program.⁷⁵ An enrollee’s designated case manager “can assist with insurance investigation and verification, claims management and appeals, and provide prior authorization assistance.”⁷⁶

A body of published literature on patient support programs has begun to emerge, with a striking increase in the number of patient support program-related publications in academic journals since 2017.⁷⁷ Notably, this literature is almost exclusively authored and funded by major, multinational pharmaceutical companies.⁷⁸ At least twenty-seven published studies from across the globe have assessed patient support programs for specialty drugs, eight of which were funded by AbbVie and analyzed outcomes for Humira-related patient support programs, and ten of which analyzed outcomes for MS therapy-related patient support programs.⁷⁹ Many of these studies show a statistically significant increase in treatment persistence and adherence, or alternatively a lower likelihood of treatment abandonment, in patient support program participants as compared to nonparticipants.⁸⁰ Couched in positive, patient-centered language, these publications convey a decidedly favorable picture of patient support programs and their effects on patient experience and behavior. One such study describes a patient support program as a self-management program purportedly “designed to improve the overall patient experience” by “provid[ing] a broad range of resources to support patients throughout their treatment [courses].”⁸¹

The recent proliferation of drug company-sponsored, published studies establishing the benefits of patient support programs begs the question: Why do drug makers increasingly feel the need to sponsor these publications in academic journals? What do they stand to gain from documenting the clinical benefits of rather mundane offerings such as injection training and nursing support? One

⁷⁴ *Support Services for Your Lemtrada Patients*, LEMTRADA (ALEMTUZUMAB), <https://www.lemtradahcp.com/support> [<https://perma.cc/63LX-6VTB>].

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *See infra* Appendix I. Appendix I attempts to provide an exhaustive review of the literature on drug company-sponsored patient support programs as of January 2021. While this Article does not undertake a meta-analysis of patient support program-related studies, such an analysis could be an avenue for future empirical research. The purpose of this Table is to derive high-level takeaways, including the frequency of patient support program-related studies in the literature, the recency of publication of such studies, the drugs for which patient support program studies are most common, and the predominance of drug company sponsorship of these studies.

⁷⁸ *See id.*

⁷⁹ *See id.*

⁸⁰ *See* sources cited in Appendix I.

⁸¹ David T. Rubin et al., *Impact of a Patient Support Program on Patient Adherence to Adalimumab and Direct Medical Costs in Crohn’s Disease, Ulcerative Colitis, Rheumatoid Arthritis, Psoriasis, Psoriatic Arthritis, and Ankylosing Spondylitis*, 23 J. MANAGED CARE & SPECIALTY PHARMACY 859, 865 (2017).

answer may be that patient support program-related academic publications function as marketing tools directed to healthcare providers. Providers, common consumers of academic medical literature, may learn about the benefits of patient support programs through published studies and subsequently inform patients. This may be a particular draw for companies like AbbVie due to the impending expiration of a key Humira patent and the anticipated entry of several adalimumab biosimilars in 2023.⁸² Similarly, patient support program-focused publications can be understood as a marketing tool to increase sales of MS therapies in response to recent competition in the MS therapeutic space.⁸³

The presence of more than two dozen drug company-sponsored articles in the literature analyzing patient support programs suggests that patient support programs accrue value to drug makers. First, patient support programs may allow drug companies to better compete against specialty pharmacies in the delivery of specialty drug services. Second, patient support programs help patients begin and remain on specialty drugs, which increases a drug maker's profits. Third, and perhaps most importantly, patient support programs give drug makers the key advantage of knowing exactly which patients utilize their therapies—knowledge that companies may effectively convert into profits by the mechanisms later discussed.

The remainder of this Article explores the hidden downsides of patient support program enrollment, which flow from the acquisition, use, and sale of PHI. Part IV examines publicly available patient support program enrollment forms for an illustrative sample of specialty drugs and deconstructs those forms using the provisions of the HIPAA Privacy Rule as a guide. Part V examines the patient support program bargain through an ethical and legal lens, delving into the privacy calculus of information sharing. This Part makes the argument that patient support program-related HIPAA authorizations subject patients to economic duress and coercion. Part VI addresses various ways in which drug makers may use PHI obtained during patient support program enrollment to carry out potentially unlawful activity, and it proposes solutions to better protect PHI, drawing lessons from the patient support program context.

⁸² See Andrew Dunn, *AbbVie Staves Off 6th Humira Biosimilar in US*, BIOPHARMA DIVE (Nov. 7, 2018), <https://www.biopharmadive.com/news/abbvie-staves-off-6th-humira-biosimilar-in-us/541665> [<https://perma.cc/D9Z9-7W43>].

⁸³ See Press Release, Competition in Multiple Sclerosis Market Set to Increase with Launch of New Pipeline Drugs and Entry of New Generics, GlobalData (Dec. 12, 2018), <https://www.globaldata.com/competition-multiple-sclerosis-market-set-increase-launch-new-pipeline-drugs-entry-new-generics> [<https://perma.cc/398D-BJNF>]. Interestingly, MS drug prices have not fallen commensurate with the increased competition. See Kyle Blankenship, *Does Competition Equal Lower Prices? MS Drugs Defied Cost Logic as Challengers Swarmed In*, FIERCE PHARMA (Aug. 29, 2019, 5:56 PM), <https://www.fiercepharma.com/pharma/doescompetition-equal-lower-prices-ms-drugs-defied-cost-logic-as-challengers-swarmed> [<https://perma.cc/8QNY-LPNT>].

IV. A DISSECTION OF PATIENT SUPPORT PROGRAM ENROLLMENT FORMS AND THEIR LEGAL UNDERPINNINGS

In order to enroll in a patient support program, patients must complete enrollment forms that can be faxed, emailed, or electronically submitted to drug companies. These forms consist of three sections: (1) patient information, including protected health information⁸⁴ such as name, address, date of birth, social security number, prescription information, and insurance information; (2) prescriber information, including a signed prescriber attestation that the pharmaceutical therapy in question is medically necessary for the patient requesting enrollment; and (3) a patient authorization for release of health information, requiring the patient's signature and date.

Attention here will be focused on parsing the third element of the enrollment form: the patient authorization for release of PHI, which arises from the constraints of the HIPAA Privacy Rule.⁸⁵ The Privacy Rule, which implemented the privacy requirements of HIPAA, established, “for the first time, a floor of national protections for the privacy of [consumers'] most sensitive information — health information,” providing protections against misuse of PHI and creating “significant new rights to enable [consumers] to understand and control how their health information is used and disclosed.”⁸⁶ The Privacy Rule permits covered entities to make certain uses and disclosures of PHI without specific authorization, such as disclosures to the individual whose health information is at issue, as well as routine uses and disclosures for “treatment, payment, or health care operations.”⁸⁷ Under this rule, PHI used or disclosed is limited to “the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.”⁸⁸

⁸⁴ Protected health information (PHI) is “individually identifiable health information . . . that is (i) [t]ransmitted by electronic media; (ii) [m]aintained in electronic media; or [iii] [t]ransmitted or maintained in any other form or medium.” 45 C.F.R. § 160.103. Individually identifiable information such as name, address, and date of birth, when paired with health information about a past, current, or future physical or mental health condition, information about health care provision including prescribed medication, or payment information for the provision of health care, constitutes PHI for purposes of HIPAA. See U.S. DEP'T OF HEALTH & HUM. SERVS., GUIDANCE REGARDING METHODS FOR DE-IDENTIFICATION OF PROTECTED HEALTH INFORMATION IN ACCORDANCE WITH THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) PRIVACY RULE, 4–5 (Nov. 26, 2012), https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveridentities/De-identification/hhs_deid_guidance.pdf [<https://perma.cc/99X4-JDHC>].

⁸⁵ 45 C.F.R. pts. 160, 164.

⁸⁶ Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182, 53,182 (Aug. 14, 2002) (codified at 45 C.F.R. pts. 160, 164).

⁸⁷ 45 C.F.R. § 164.502(a)(1) (2013). No authorization is needed for covered entities to disclose PHI in several other circumstances, including when the disclosure is used for public health purposes or as part of a limited data set used for research, public health, or health care operations. See 45 C.F.R. § 164.514(e) (2013); see also U.S. DEP'T OF HEALTH & HUM. SERVS., EXAMINING OVERSIGHT OF THE PRIVACY & SECURITY OF HEALTH DATA COLLECTED BY ENTITIES NOT REGULATED BY HIPAA 15, https://www.healthit.gov/sites/default/files/non-covered_entities_report_june_17_2016.pdf [hereinafter EXAMINING OVERSIGHT, ENTITIES NOT REGULATED BY HIPAA] [<https://perma.cc/75XY-L6B4>].

⁸⁸ 45 C.F.R. § 164.502(b) (2013).

For uses and disclosures of PHI not otherwise allowed by the Privacy Rule, an authorization is required.⁸⁹ According to the U.S. Department of Health and Human Services (“HHS”), “[a]n authorization is a detailed document that gives covered entities permission to use protected health information for specified purposes, which are generally other than treatment, payment, or health care operations, or to disclose protected health information to a third party specified by the individual.”⁹⁰

A valid authorization must contain six “core elements” delineated in the Privacy Rule⁹¹: (1) a description of the PHI to be used or disclosed, identified in “a specific and meaningful fashion”;⁹² (2) the parties authorized to disclose PHI;⁹³ (3) the person or class of persons to whom the requested use or disclosure may be made (i.e., recipients of the PHI);⁹⁴ (4) the purpose or purposes of the requested use or disclosure;⁹⁵ (5) an expiration date or event after which the authorization is no longer valid;⁹⁶ and (6) the signature of the individual and date.⁹⁷ Beyond the core elements, regulation requires that the authorization be written in “plain language,”⁹⁸ and that the individual signing the authorization be entitled to a copy of the signed document.⁹⁹ Finally, the authorization must contain statements (“required statements”¹⁰⁰) placing the signing individual on notice of several associated rights and processes: (1) of his or her right to revoke the authorization,¹⁰¹ including any exceptions, and the process by which to revoke;¹⁰² (2) either that the “covered entity may not condition treatment, payment, enrollment, or eligibility for benefits on whether the individual signs the authorization,”¹⁰³ or, if the entity is able to condition its services on the signing of the authorization,¹⁰⁴ the “consequences to

⁸⁹ *Id.* § 164.502(a)(1)(iv), 164.508.

⁹⁰ *What Is the Difference Between “Consent” and “Authorization” Under the HIPAA Privacy Rule?*, U.S. DEP’T OF HEALTH & HUM. SERVS. (July 26, 2013), <https://www.hhs.gov/hipaa/for-professionals/faq/264/what-is-the-difference-between-consent-and-authorization/index.html> [<https://perma.cc/A8Q8-88XX>].

⁹¹ 45 C.F.R. § 164.508(c)(1).

⁹² *Id.* § 164.508(c)(1)(i).

⁹³ *Id.* § 164.508(c)(1)(ii).

⁹⁴ *Id.* § 164.508(c)(1)(iii).

⁹⁵ *Id.* § 164.508(c)(1)(iv).

⁹⁶ *Id.* § 164.508(c)(1)(v).

⁹⁷ *Id.* § 164.508(c)(1)(vi).

⁹⁸ *Id.* § 164.508(c)(3).

⁹⁹ *Id.* § 164.508(c)(4).

¹⁰⁰ *Id.* § 164.508(c)(2).

¹⁰¹ *Id.* § 164.508(c)(2)(i); 164.508(b)(5).

¹⁰² *Id.* § 164.508(c)(2)(i)(A).

¹⁰³ *Id.* § 164.508(c)(2)(ii)(A).

¹⁰⁴ Patient support programs can lawfully condition patient support services on the provision of an authorization because HIPAA’s prohibition on doing so (Prohibition on Conditioning of Authorizations, 45 C.F.R. § 164.508(b)(4) (2013)) does not apply to them, in view of the fact that they are *not* covered entities. For related discussion regarding drug makers’ status as noncovered entities, *see infra* pp. 24–25, 30–31, and 58–60.

the individual of a refusal to sign”;¹⁰⁵ and (3) the potential for PHI disclosed via the signed authorization to be redisclosed without further protections under HIPAA’s Privacy Rule.¹⁰⁶

Tables 1 through 4 of Appendix II provide a breakdown of the components of an illustrative sample of seventeen patient support program enrollment forms associated with various pharmaceutical drugs or drug makers.¹⁰⁷ The purpose of this undertaking is to examine the content of patient support program enrollment forms, with an emphasis on the content of the authorizations required by HIPAA; to assess differences among the language and provisions of the HIPAA authorizations; and to critically evaluate gaps and inadequacies in the authorizations.¹⁰⁸

The enrollment forms examined here were procured from drug company websites and were located using Internet searches of publicly available information. The associated drugs represent an illustrative sample of seventeen drugs identified from the more than 500 specialty drugs on the CVS Specialty Pharmacy Drug List.¹⁰⁹ For every drug, the name of the patient support program and pharmaceutical sponsor were noted. Each enrollment form was assessed for the presence of patient information such as name, date of birth, address, and social security number; prescriber information and prescriber signature as part of an authorization of medical necessity; and whether a prospective enrollee was given the option to enroll in financial and nonfinancial services separately, which I refer to as bifurcated enrollment. Next, each HIPAA authorization was examined for the presence of the six “core elements” described in the previous paragraph, as well as the required statements (placing patients on notice of their right to revoke; of the ability or inability to condition treatment, payment, or eligibility for benefits on signing, and consequences of a refusal to sign; and of the potential for redisclosure). A number of other required statements were noted, including a statement regarding

¹⁰⁵ *Id.* § 164.508(c)(2)(ii)(B).

¹⁰⁶ *Id.* § 164.508(c)(2)(iii).

¹⁰⁷ *See infra* Appendix II. Some patient support programs are drug-specific; others are drug maker-specific, such as Genentech’s Access Solutions and Amgen Assist 360. The programs whose enrollment forms have been examined are not uniformly labeled as patient support programs; some are considered part of drug “access” programs but often contain within them references to associated “patient support programs” or “support services.” Nonetheless, the programs can be classified as patient support programs, as defined in this Article.

¹⁰⁸ The methodology for this section was modeled on a study by Peter Breese, Cornelis Rietmeijer, and William Burman of the content of HIPAA authorizations for clinical research. *See* Peter Breese et al., *Content Among Locally Approved HIPAA Authorization Forms for Research*, 2 J. EMPIRICAL RSCH. ON HUM. RSCH. ETHICS 43, 43–44 (2007).

¹⁰⁹ *CVS Specialty Pharmacy Distribution Drug List*, CVS SPECIALTY (July 2021), <https://www.cvsspecialty.com/education-center/downloads/SpecialtyDrugs.pdf> [<https://perma.cc/3FZT-XGPC>]. As the largest specialty pharmacy, CVS Specialty Pharmacy was chosen as the source for a specialty pharmacy drug list, on the assumption that its list is likely to be the most comprehensive. Due to practical constraints, the patient support program enrollment form for every specialty drug on the CVS Specialty Pharmacy Distribution Drug List was not located; rather, an illustrative sample of drugs was chosen, for which patient support program enrollment forms were then identified.

remuneration in exchange for PHI,¹¹⁰ specification of uses and disclosures made prior to revoking the authorization, and specification that an individual is entitled to a copy of the signed authorization.

Similar to HIPAA authorizations examined in the context of clinical research,¹¹¹ the technical requirements of HIPAA in patient support program enrollment forms were largely met. All authorizations contained the six core elements required by HIPAA. Sixteen of the seventeen (94%) authorizations specified whether the pharmaceutical company would provide remuneration in exchange for the sale of PHI, or for PHI disclosed or used for marketing.¹¹² Of those sixteen forms that made note of remuneration, eleven of the sixteen (69%) specified remuneration to pharmacies or specialty pharmacies.¹¹³ The greatest area of divergence in the HIPAA authorizations was the duration that the authorization was in effect, ranging from two years to ten years, or until a patient canceled or revoked the authorization.¹¹⁴ Similar to the findings of HIPAA authorizations studied in the clinical research context,¹¹⁵ the authorizations had a notable absence of information about whether PHI would be destroyed after an authorization's expiration—although one authorization, that of Genentech's Access Solutions, specified that California residents could request deletion of PHI.¹¹⁶

¹¹⁰ This is required under 45 C.F.R. § 164.508(a)(4)(ii) (2013) (“Such authorization [for the sale of PHI] must state that the disclosure will result in remuneration to the covered entity.”) and 45 C.F.R. § 164.508(a)(3)(ii) (2013) (“If the marketing involves financial remuneration . . . to the covered entity from a third party, the authorization must state that such remuneration is involved.”). In this context, the remuneration takes place from the drug company and affiliates, acting as third parties, to the covered entity that releases PHI on the patient support program enrollee, such as a specialty pharmacy.

¹¹¹ See Breese et al., *supra* note 108.

¹¹² See Appendix II(3).

¹¹³ See *id.*

¹¹⁴ See Appendix II(2). According to the Privacy Rule, patients have the right to revoke a HIPAA authorization at any time. See *Can an Individual Revoke His or Her Authorization?*, U.S. DEP'T OF HEALTH & HUM. SERVS., <https://www.hhs.gov/hipaa/for-professionals/faq/474/can-an-individual-revoke-his-or-her-authorization/index.html> [<https://perma.cc/CAT9-VUBU>]. The revocation does not take effect “until a covered entity which had previously been authorized to make the disclosure receives it.” *Id.* In this respect, most patient support program enrollment forms are inaccurate when they imply that revocation is immediate upon the support program's receipt of written notice of revocation from an enrollee. Enrollment forms should be redrafted to indicate that revocation is not effective until the covered entities that had been authorized to make the disclosure(s) receive the notice of revocation, presumably by way of the drug manufacturer after receiving a patient's written request for revocation.

¹¹⁵ See Breese et al., *supra* note 108, at 44 (finding that only 5% of authorizations (5 of 111 forms examined) had comments regarding when PHI would be destroyed).

¹¹⁶ See Appendix II(4); see also *Patient Consent Form*, GENENTECH ACCESS SOLS., https://www.genentech-access.com/content/dam/gene/accesssolutions/pdfs/patient-consent-form/Genentech-Access-Solutions-Patient-Consent_Form.pdf [<https://perma.cc/PEM9-6RRY>]. Presumably, this provision represents an attempt to comply with the California Consumer Privacy Act of 2018 (“CCPA”), which grants to consumers a “right to request that a business delete any personal information about the consumer which the business has collected from the consumer” and imposes on businesses an obligation to disclose consumers' right to request deletion. CAL. CIV. CODE § 1798.105 (West 2020).

Using these findings as a launching point, the remainder of this Article examines ethical and legal issues associated with the sharing of PHI from covered entities to drug makers during patient support program enrollment, including a discussion of what HIPAA does and does not prohibit, the nature of the bargain between drug makers and patient-enrollees, and how PHI collected via the authorizations just dissected could be put to unlawful uses. The objective of the Parts that follow is to shed light on unforeseen consequences to patients and providers that may result from PHI disclosed pursuant to a valid and lawful HIPAA authorization. The Article ends with proposed revisions to the HIPAA Privacy Rule to modernize and strengthen HIPAA's privacy protections vis-à-vis PHI transferred from covered entities to noncovered entities such as drug makers.

V. PATIENT SUPPORT PROGRAM HIPAA AUTHORIZATIONS: ETHICAL AND LEGAL CONCERNS

The HIPAA Privacy Rule only applies to “covered entities,” which include health care providers, health plans, and healthcare clearinghouses, and the business associates that perform functions on their behalf.¹¹⁷ By specifying conditions under which covered entities may use or disclose PHI, HIPAA provides a legal scaffolding to regulate permissible and impermissible disclosures of identifiable patient health data. Disclosure is defined as “the release, transfer, provision of access to, or divulging in any manner of information outside the entity holding the information.”¹¹⁸ Under HIPAA's Privacy Rule, “[a] covered entity may not use or disclose protected health information, except either: (1) as the Privacy Rule permits or requires; or (2) as the individual who is the subject of the information (or the individual's personal representative) authorizes in writing.”¹¹⁹ It is the second exception that is relevant here.

Importantly, drug manufacturers are neither covered entities nor business associates of covered entities subject to HIPAA's mandates. HIPAA authorizations are a necessary means by which patients authorize release of their PHI from HIPAA-covered entities, such as health care providers and insurers, to drug makers;¹²⁰ the authorization allows HIPAA-covered entities to disclose the signatory's PHI to the designated recipient of the PHI listed in the authorization. In this respect, PHI transfers to drug makers differ from, for instance, autonomously

¹¹⁷ For a definition of covered entity, see 45 C.F.R. § 160.103; *To Whom Does the Privacy Rule Apply and Whom Will It Affect?*, U.S. DEP'T OF HEALTH & HUM. SERVS. NAT'L INST. OF HEALTH, https://privacyruleandresearch.nih.gov/pr_06.asp#:~:text=Covered%20entities%20are%20defined%20in,which%20HHS%20has%20adopted%20standards [<https://perma.cc/8K7W-UEKV>]; and U.S. DEP'T OF HEALTH & HUM. SERVS., OCR PRIVACY BRIEF: SUMMARY OF THE HIPAA PRIVACY RULE 1, 2–3 (2003), <https://www.hhs.gov/sites/default/files/privacysummary.pdf?language=es> [hereinafter OCR PRIVACY BRIEF] [<https://perma.cc/M4RP-WPUM>]. Pharmacies are covered entities under HIPAA. See JOHN J. TRINCKES, JR., *THE DEFINITIVE GUIDE TO COMPLYING WITH THE HIPAA/HITECH PRIVACY AND SECURITY RULES 8–9* (2013).

¹¹⁸ 45 C.F.R. § 160.103 (2013).

¹¹⁹ See OCR PRIVACY BRIEF, *supra* note 117, at 4 (emphasis added).

¹²⁰ Cf. Stacy-Ann Elvy, *Commodifying Consumer Data in the Era of the Internet of Things*, 59 B.C. L. REV. 423, 498 n.384 (2018).

generated biometric health data that patients may voluntarily provide to an app developer. Biometric data, although health-related and patient-identifying, has no initial locus in a covered entity, thereby *originating and remaining* outside of the purview of HIPAA. By contrast, PHI obtained through patient support program enrollment originates from HIPAA-covered entities and is subsequently disclosed to, and collected by, a noncovered entity—the drug manufacturer. The implications of this important distinction are discussed in section VI.C.

The execution of certain patient support program services, such as reimbursement support, may require disclosure of PHI to drug makers (or at the very least, prescription verification).¹²¹ But disclosure of PHI is of questionable necessity for patient-facing behavioral services, such as disease education, nursing support, or injection training. Nevertheless, drug makers almost uniformly condition participation in patient support programs on the provision of HIPAA authorizations, and only some drug makers permit patients to opt into financial and nonfinancial services separately.¹²² The result, this Article argues, is a relationship of unequal bargaining power between drug makers and prospective patient support program enrollees that raises a host of ethical concerns.

First, conditional access to patient support program services casts a shadow on the voluntariness of the consent and its validity under the law. In ethics, voluntariness is a foundational concept that has, at its core, the distinction between freedom and compulsion.¹²³ Financial need can increase vulnerability to coercion, duress, and undue influence.¹²⁴ However, high prices of specialty drugs subject even financially well-off individuals to pressure. Specialty drug copays, which can amount to hundreds or even thousands of dollars per month, deprive chronically ill patients of autonomy and position them to be exploited by drug makers. As discussed in Part II, specialty drugs primarily treat rare or other serious chronic conditions that often have few treatment alternatives. The lack of alternatives for most specialty drugs distinguishes them from the majority of small-molecule drugs with generic substitutes. The interplay of high specialty drug prices, a dearth of alternative therapies, patients' poor health, and the risk of deterioration of a serious chronic condition—or even a hastened death in the absence of treatment—raise the

¹²¹ Manufacturers might argue that patient support programs are necessary from a legal and administrative feasibility standpoint, because in their absence, manufacturers could not verify that a patient was actually receiving a drug based on a legitimate prescription from a licensed provider. Without verification, manufacturers might argue, they run the risk of liability under the Anti-Kickback Statute (42 U.S.C. § 1320a-7b (2018)) or the False Claims Act (31 U.S.C. § 3729 et seq. (2009)) if they were to provide copay support or reimbursement support for drugs that were not legitimately prescribed. Of note, the knowledge requirement under the FCA can be met with actual knowledge, deliberate ignorance of the truth or falsity of the information, or reckless disregard of truth or falsity. 31 U.S.C. § 3729(b)(1) (2009). One of the latter two forms of knowledge might be met if a drug maker provided copay support without verifying prescription information.

¹²² See *infra* Appendix II(1). Only five of the seventeen (29%) enrollment forms allowed patients to choose among various support services and opt into financial and nonfinancial services separately.

¹²³ See John Hyman, *Voluntariness and Choice*, 63 PHIL. Q. 683, 685–86 (2013).

¹²⁴ See Paul S. Applebaum et al., *Voluntariness of Consent to Research: A Conceptual Model*, 39 HASTINGS CTR. REP. 30, 30 (2009).

concern that the provision of HIPAA authorizations to access patient support program services is not truly voluntary.

Another core ethical concern pertains to whether patient support program enrollment fulfills the notice and consent requirements of HIPAA. The ensuing discussion will explore the following questions: Are patients aware of HIPAA authorizations in patient support program enrollment forms? To what extent is their assent to the bargain contained in the HIPAA authorization actually informed? If patients remain unaware of downstream uses and disclosures of their PHI, the stipulation of which HIPAA does not require, does that negate their status as informed parties to the bargain? Is it unethical to deny prospective patient support program enrollees the ability to opt out of data sharing during enrollment, especially given the high price of specialty drugs that has engendered patients' dependence on financial assistance? Does the lack of an opt-out mechanism for data sharing in effect make the release of PHI a quid pro quo, or "price of entry,"¹²⁵ to access support services? And if so, is it problematic—legally, ethically, and morally—that patients are asked to "pay" for drug access with PHI?

Patients encounter HIPAA authorizations during routine interactions with HIPAA-covered entities in the healthcare delivery system, such as during doctor's visits. It is unclear, however, whether patients are cognizant of HIPAA authorizations in patient support program enrollment forms, and to the author's knowledge, that issue has not been investigated. A distinct but related question is *how* patients gain knowledge of the existence of patient support programs in the first place. Drug company websites are the primary source of information regarding drug-specific patient support programs, but at least one drug manufacturer (Celgene) has explicitly denied engaging in direct-to-consumer patient support program advertising.¹²⁶ Healthcare providers may play a role in encouraging patients to enroll in patient support programs, and here, published literature in academic journals on the benefits of patient support programs could be a source of information for providers. Direct-to-physician advertising of drugs may include information about patient support program services, such as drug copay programs, free drug programs, and patient assistance programs, and providers may, in turn, pass this information along to patients. After becoming informed of the existence of patient support programs, patients are unlikely to have discussions with their providers about the benefits and risks of enrollment due to the lack of attention paid to potential risks up to this point.

The extent to which a HIPAA authorization itself achieves informed consent remains an open question. Most examinations of HIPAA authorizations in the

¹²⁵ Cf. Lawrence O. Gostin & Sam F. Halabi, *Health Data and Privacy in the Digital Era*, 320 JAMA 233, 233 (2018) (utilizing the term "price of entry" to describe term-of-service data sharing on the Web).

¹²⁶ See Chris L. Pashos, Lael S. Cragin & Zeba M. Khan, *Effect of a Patient Support Program on Access to Oral Therapy for Hematologic Malignancies*, 69 AM. J. HEALTH-SYSTEM PHARMACY 510, 511 (2012).

academic literature have been in the context of human subjects research.¹²⁷ Whereas clinical research fulfills a public health purpose and data collection in this context is arguably fundamental to the very conduct of research, the public health goals served by patient support programs are less compelling. Nonetheless, studies of HIPAA authorizations in human subjects research can lend valuable guidance to analogous inquiries in the patient support program context.

Studies have cast doubt on patients' ability to fully understand the terms contained in HIPAA authorizations. Complex language in HIPAA authorizations has led to concerns that patients may fail to appreciate fundamental aspects of the research process and their rights within it. Despite HIPAA's "plain language" requirement, prospective research subjects may overlook essential study features—such as the right to withdraw consent and the risks of participation—amidst a deluge of dense legal language.¹²⁸ Prospective patient support program enrollees may likewise feel confused and overwhelmed by lengthy, HIPAA-compliant patient support program enrollment forms, which vary from two to seven pages in length among those sampled here. Or they may simply choose not to read the authorization at all, instead acquiescing to what they perceive to be "boilerplate" HIPAA. Conscious and unconscious cognitive biases—such as the tendency to simplify decisions to a few factors, rely on impartial information, underestimate potential harm from decisions voluntarily undertaken, and overlook remote risks¹²⁹—may all lead patients to sign HIPAA authorizations within patient support program enrollment forms with little contemplation of what they are signing or what risks they may assume.

Scholars and researchers alike have bemoaned a deterrent effect of HIPAA on the conduct of beneficial research¹³⁰ and on participation rates in clinical

¹²⁷ See, e.g., Breese et al., *supra* note 108; see also Timothy J. Beebe et al., *The HIPAA Authorization Form and Effects on Survey Response Rates, Nonresponse Bias, and Data Quality: A Randomized Community Study*, 45 MED. CARE 959 (2007); David Shalowitz & David Wendler, *Informed Consent for Research and Authorization Under the Health Insurance Portability and Accountability Act Privacy Rule: An Integrated Approach*, 144 ANNALS INTERNAL MED. 685 (2006); Kelsey Williams & Paul Colomb, *Important Considerations for the Institutional Review Board When Granting Health Insurance Portability and Accountability Act Authorization Waivers*, 20 OCHSNER J. 95 (2020).

¹²⁸ See Shalowitz & Wendler, *supra* note 127, at 685; David Armstrong et al., *Potential Impact of the HIPAA Privacy Rule on Data Collection in a Registry of Patients with Acute Coronary Syndrome*, 165 ARCHIVES INTERNAL MED. 1125, 1128 (2005) (commenting that "the [HIPAA consent] form itself and the accompanying letter are lengthy and confusing," and that "[t]he size of these documents may have created an exaggerated sense of how involved the process truly was"). For studies assessing the readability of HIPAA authorizations, see Nina Collins et al., *A Cross-Section of Readability of Health Information Portability and Accountability Act Authorizations Required with Health Care Research*, 35 J. ALLIED HEALTH 223 (2006) and Peter Breese et al., Letter to the Editor, *The Health Insurance Portability and Accountability Act and the Informed Consent Process*, 141 ANNALS INTERNAL MED. 897 (2004).

¹²⁹ See Robert A. Hillman & Jeffrey J. Rachlinski, *Standard-Form Contracting in the Electronic Age*, 77 N.Y.U. L. REV. 429, 450–54 (2002).

¹³⁰ Jacquelyn K. O'Herrin et al., *Health Insurance Portability Accountability Act (HIPAA) Regulations: Effect on Medical Record Research*, 239 ANNALS SURGERY 772, 773 (2004) ("Although these HIPAA guidelines were not created to address research per se, the guidelines apply

research,¹³¹ suggesting that at least some individuals take note of the authorizations. Some have argued that HIPAA-mandated terms, such as the potential for redisclosure of PHI and its subsequent lack of protection, may needlessly heighten privacy concerns among prospective study participants, especially in view of the fact that other frameworks provide safeguards for patient privacy in the research setting.¹³²

To the author's knowledge, no studies have yet been undertaken to examine the effect of HIPAA authorizations on patient support program enrollment. The recency of patient support programs makes it likely that most programs post-dated the implementation of the HIPAA Privacy Rule, making pre- and post-HIPAA comparisons infeasible. Because only a signed enrollment form separates prospective enrollees from thousands of dollars of financial assistance and drug access, it stands to reason that patients in need of high-priced specialty drugs may ultimately disregard the terms or presume that the benefits they will derive from sharing PHI outweigh the risks.

A. *The Privacy Calculus of Information Sharing*

When deciding whether to share health information, individuals must weigh the risks of sharing against the benefits. Disclosure is expected to occur when the "overall benefits of disclosure are at least balanced by, if not greater than, the

to records and data sets that contain PHI used in clinical research. . . . With substantial penalties possible for noncompliance, it is not surprising that the guidelines are interpreted conservatively to protect the institution. It is less clear whether these regulations and policies serve the best interests of patients when the analysis of clinical databases and medical records might lead to new insights into prevention or treatment of disease, but are discouraged or abandoned because of regulatory obstacles.").

¹³¹ See Rachel Nosowsky & Thomas J. Giordano, *The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule: Implications for Clinical Research*, 57 ANN. REV. MED. 575, 580–82 (2006); Beebe et al., *supra* note 127, at 963–64; Michael S. Wolf & Charles L. Bennett, *Local Perspective of the Impact of the HIPAA Privacy Rule on Research*, 106 CANCER 474, 477 (2006) (finding a statistically significant reduction in the weekly "accrual" of patients to a randomized clinical trial after HIPAA took effect); Anne L. Dunlop et al., *The Impact of HIPAA Authorization on Willingness to Participate in Clinical Research*, 17 ANNALS EPIDEMIOLOGY 899, 904–05 (2007) (finding, among a sample of 384 African American patients, that "a statistically significant smaller proportion of those in the HIPAA vs. control group indicated willingness to enroll in the clinical research study (27% vs. 39%), with a crude odds ratio = 0.58 (95% confidence interval: 0.38–0.89)," *id.* at 904, and "those in the HIPAA group were significantly more likely to report concerns related to mistrust or fear of research," *id.* at 904–05); David Armstrong et al., *Potential Impact of the HIPAA Privacy Rule on Data Collection in a Registry of Patients with Acute Coronary Syndrome*, 165 ARCHIVES INTERNAL MED. 1125, 1127–28 (2005) (comparing pre- to post-HIPAA conditions and finding a statistically significant reduction in the percentage of patients willing to provide consent to a questionnaire after HIPAA was implemented).

¹³² See Nosowsky & Giordano, *supra* note 131, at 580 (suggesting that HIPAA-mandated language indicating a lack of federal protection for redisclosed PHI "implies a much greater risk to participant privacy than actually exists" in view of the fact that there are other protections afforded to patient data in the research setting, including those promulgated by the Common Rule and institutional requirements).

assessed risk of disclosure.”¹³³ In the setting of Internet and retail transactions, this decision-making process has been conceptualized and modeled as a “privacy calculus” in which “institutional norms of appropriate behavior, anticipated benefits, and unpredictable consequences” function as “predictor[s] of when and whether individuals . . . disclose personal information.”¹³⁴ This section analyzes the decision-making process to enroll in a patient support program using a privacy calculus framework. It posits that patients cannot make informed decisions about whether the benefits of sharing PHI outweigh the risks because current HIPAA regulations do not require specification of downstream uses of patients’ PHI.

The more one stands to benefit from a disclosure, the greater the risks one may tolerate in exchange for those benefits. But, in the context of patient support programs, patients may misperceive and underestimate the risks of disclosure because those risks are not readily apparent and secondary uses are not specified. A key question in the patient support program context is whether patients would agree to disclose their PHI to drug manufacturers *ex ante*, were the terms of the bargain—including future risks—made explicit. To date, no studies have been undertaken to assess patients’ perception of risk associated with patient support program information sharing, but studies in other contexts suggest that many individuals are troubled by privacy risks.¹³⁵

An underestimation of privacy risks associated with health information sharing is a common theme in the privacy literature,¹³⁶ as are trust¹³⁷ and procedural fairness¹³⁸ as remedies for ameliorating data privacy concerns. Privacy can be defined as “the ability of the individual to control the terms under which personal information is acquired and used.”¹³⁹ Professors Mary Culnan and Pamela Armstrong summarize researchers’ findings regarding personal information sharing and privacy concerns:

¹³³ Tamara Dinev & Paul Hart, *An Extended Privacy Calculus Model for E-Commerce Transactions*, 17 INFO. SYS. RSCH. 61, 62 (2006); *see also* Mary J. Culnan & Pamela K. Armstrong, *Information Privacy Concerns, Procedural Fairness, and Impersonal Trust: An Empirical Investigation*, 10 ORG. SCI. 104, 106 (1999).

¹³⁴ Dinev & Hart, *supra* note 133, at 62.

¹³⁵ *See, e.g.*, Richard S. Murphy, *Property Rights in Personal Information: An Economic Defense of Privacy*, 84 GEO. L.J. 2381, 2404–05, 2404 n.115 (1996). In a 1994 survey conducted by Equifax, 84% of respondents reported being “concerned” about threats to their privacy, and 51% reported being “very concerned.” *See id.* at 2405. More recent studies endorse consumers’ continuing concerns about privacy. *See* Brooke Auxier et al., *How Americans Think About Privacy and the Vulnerability of Their Personal Data*, PEW RSCH. CTR. (Nov. 15, 2019), <https://www.pewresearch.org/internet/2019/11/15/how-americans-think-about-privacy-and-the-vulnerability-of-their-personal-data/> [<https://perma.cc/J3A6-G88R>]; *Public Opinion on Privacy*, ELEC. PRIV. INFO. CTR., <https://epic.org/privacy/survey/> [<https://perma.cc/4723-3JFB>].

¹³⁶ *See, e.g.*, Gostin & Halabi, *supra* note 125, at 233.

¹³⁷ *See, e.g.*, Tasha Glenn & Scott Monteith, *Privacy in the Digital World: Medical and Health Data Outside of HIPAA Protections*, 16 CURRENT PSYCHIATRY REP. 1, 6–7 (2014); Culnan & Armstrong, *supra* note 133, at 106.

¹³⁸ Culnan & Armstrong, *supra* note 133, at 106.

¹³⁹ *Id.* at 105 (citing ALAN F. WESTIN, *PRIVACY AND FREEDOM* (1967)).

[I]ndividuals are less likely to perceive information collection procedures as privacy-invasive when (a) information is collected in the context of an existing relationship, (b) they perceive that they have the ability to control future use of the information, (c) the information collected or used is relevant to the transaction, and (d) they believe the information will be used to draw reliable and valid inferences about them.¹⁴⁰

The second factor Culnan and Armstrong identify—individual perception regarding the ability to control future uses of shared information—is perhaps the most compelling element missing from the patient support program bargain. Yet patients may not identify the deficit in their ability to control future uses due to incomplete disclosure regarding secondary uses. HIPAA’s deficiencies, namely the lack of a requirement for specification of downstream uses and the ability of recipients of PHI to redisclose those data, fail to provide patients with adequate notice of and control over how their information may be used. Although drug companies ostensibly comply with HIPAA’s requirements in composing authorizations, where HIPAA’s requirements fall short, drug companies have no incentive or obligation to fill the gap. Drug companies are noncovered entities that are not subject to the Privacy Rule. As a result, the extent to which they are constrained by the terms of the HIPAA authorization itself remains unclear. Even if constrained, the redisclosure provision effectively permits the unfettered redisclosure of the PHI they collect.

Professor Nicolas Terry draws a distinction between the narrower HIPAA-regulated zone,¹⁴¹ which covered entities and their business associates occupy, and the much larger HIPAA-free zone, noting that many stakeholders in health care increasingly handle and exchange health data free from HIPAA’s constraints.¹⁴² Drug makers that obtain PHI from covered entities via HIPAA authorizations can be conceptualized as straddling the HIPAA-free and HIPAA-regulated zones, making it difficult to parse exactly which legal protections continue to adhere to acquired PHI. The obscurity draws attention to the need for regulatory clarification.¹⁴³ For the sake of argument, let us assume that there are some usages of PHI obtained through patient support programs that society might find desirable, such as usages solely for purposes of administering patient support program services (though this usage, in and of itself, should be questioned and contested). Even so, limiting usage of PHI strictly to the purposes for which it was shared and prohibiting other nondisclosed uses provides a fair starting point to address the risks attendant to PHI acquisition in the patient support program context. Section VI.C

¹⁴⁰ *Id.* at 106.

¹⁴¹ Nicolas P. Terry, *Protecting Patient Privacy in the Age of Big Data*, 81 UMKC L. Rev. 385, 387 (2012).

¹⁴² *Id.*

¹⁴³ HHS recognizes that a lack of clarity regarding “where HIPAA oversight begins and ends” is an ongoing problem that “may impede innovation that could improve health or otherwise benefit individuals or the nation.” EXAMINING OVERSIGHT, ENTITIES NOT REGULATED BY HIPAA, *supra* note 87, at 5.

proposes relevant reforms to HIPAA in this vein, in addition to proposing an expansion of HIPAA's mandates to noncovered entities that receive PHI from disclosing covered entities.

Concerns regarding disclosure of PHI during patient support program enrollment share some similarity to the privacy concerns surrounding digitized "big data" that have proliferated in recent years.¹⁴⁴ Big data in health care holds vast, unrealized promise for research, clinical care, public health, and population-level health management.¹⁴⁵ Consequently, data brokers are sometimes presumed to have good intentions for use of aggregated, anonymized data sets to further those ends. That, of course, does not eliminate the possibility that deidentified data within big datasets might be reidentified,¹⁴⁶ or that the data could be subject to abuse, tainted by bias,¹⁴⁷ or used for purposes individuals and society would condemn,¹⁴⁸ which may entail unauthorized sharing. To be sure, the risks of big data in health care remain real and loom large. Yet the risks from disclosure of PHI during patient support program enrollment differ in several important respects.

First, patient support program enrollment poses a more direct threat to individual privacy than does health-related big data. The most direct and apparent

¹⁴⁴ See, e.g., W. Nicholson Price II & I. Glenn Cohen, *Privacy in the Age of Medical Big Data*, 25 NATURE MED. 37, 38–39 (2019); Nicole Martinez-Martin, *Big Data, Corporate Surveillance and Public Health*, 20 AM. J. BIOETHICS 79, 79–80 (2020); Jennifer Salerno et al., *Ethics, Big Data and Computing in Epidemiology and Public Health*, 27 ANNALS EPIDEMIOLOGY 297, 298 (2017). For a "taxonomy" of big data in the realm of public health, see Stephen J. Mooney & Vikas Pejaver, *Big Data in Public Health: Taxonomy, Machine Learning, and Privacy*, 39 ANN. REV. PUB. HEALTH 95, 96–97 (2018).

¹⁴⁵ See, e.g., Hagop Kantarjian & Peter Paul Yu, *Artificial Intelligence, Big Data, and Cancer*, 1 JAMA ONCOLOGY 573, 574 (2015) (predicting that "[i]n years to come, large databases using artificial intelligence will complement each other and may be incorporated into large cancer open networks that inform, educate, and help cancer treatment and research"); Eric J. Topol, *High-Performance Medicine: The Convergence of Human and Artificial Intelligence*, 25 NATURE MED. 44, 44 (2019) (contending that "[a]lmost every type of clinician, ranging from specialty doctor to paramedic, will be using AI technology, and in particular deep learning, in the future"); Xinzhi Zhang et al., *Big Data Science: Opportunities and Challenges to Address Minority Health and Health Disparities in the 21st Century*, 27 ETHNICITY & DISEASE 95, 96–99 (2017); Roland Gamache et al., *Public & Population Health Informatics: The Bridging of Big Data to Benefit Communities*, 27 Y.B. MED. INFORMATICS 199, 203 (2018).

¹⁴⁶ See Liangyuan Na et al., *Feasibility of Reidentifying Individuals in Large National Physical Activity Data Sets from Which Protected Health Information Has Been Removed with Use of Machine Learning*, 1 JAMA NETWORK OPEN 1, 2 (2018).

¹⁴⁷ See, e.g., Ravi B. Parikh et al., *Addressing Bias in Artificial Intelligence in Health Care*, 322 JAMA 2377, 2378 (2016) ("Because of its reliance on historical data, which are based on biased data generation or clinical practices, AI can create or perpetuate biases that may worsen patient outcomes.").

¹⁴⁸ See, e.g., Press Release, Fed. Trade Comm'n, *FTC Imposes \$5 Billion Penalty and Sweeping New Privacy Restrictions on Facebook* (July 24, 2019), <https://www.ftc.gov/news-events/press-releases/2019/07/ftc-imposes-5-billion-penalty-sweeping-new-privacy-restrictions> [<https://perma.cc/8ZE2-A43S>] (announcing a \$5 billion penalty imposed on Facebook after government investigations revealed that the company "undermine[d] users' privacy preferences" by "shar[ing] users' personal information with third-party apps that were downloaded by the user's Facebook 'friends'").

harms resulting from disclosure via patient support programs flow from individual, non-anonymized uses of data for targeted marketing and fraudulent schemes that can be linked to particular patients taking particular pharmaceutical drugs. Drug makers act on behalf of individual, named patients when providing copay support, negotiating prior authorizations, and communicating with insurers and providers. Just as the PHI collected during patient support program enrollment serves specific patients, so too can it subject those patients, as well as their providers and insurers, to a risk of harm. The most potent dangers of big data, on the other hand, involve *reidentified* data used for similar purposes: targeted marketing and consumer fraud schemes aimed at discrete individuals.¹⁴⁹ In the latter case, harm would presumably occur only after data have been aggregated, anonymized, and later reidentified to reestablish associations to unique individuals.

On this point, however, another nuance is worth noting. It is unclear whether drug companies, in addition to executing patient support program services for named patients, also deidentify patient support program-related PHI, aggregate it, and sell it to third parties. The HIPAA authorizations for Mallinckrodt's Acthar gel patient support program and Takeda's *EntyvioConnect* suggest that deidentification and later uses or sales of deidentified data may be occurring.¹⁵⁰ Once data are deidentified, the HIPAA Privacy Rule imposes no restrictions on their use or disclosure,¹⁵¹ nor does the Privacy Rule subject noncovered entities to standards for deidentification.¹⁵² Links to online privacy policies are insufficient to put patients on notice of this important additional outflow of their data. Patients with serious chronic illnesses could suffer various forms of discrimination and emotional injury if, for example, deidentified patient support program enrollment data sold to third parties were later reidentified and revealed their illnesses.

Patient support programs may pose a higher risk of privacy-related harm than public health uses of big data for another important reason: the questionable

¹⁴⁹ See, e.g., Kathryn C. Montgomery et al., *Children's Privacy in the Big Data Era: Research Opportunities*, 140 PEDIATRICS S117, S118 (2017) (noting that e-commerce "relies on continuous data collection and monitoring of online patterns to target individual users").

¹⁵⁰ See Appendix II(4); see also *Acthar Referral Form*, ACTHAR GEL (REPOSITORY CORTICOTROPIN INJECTION), https://www.actharhcp.com/tatic/pdf/US-2100637_Acthar%20IS%20Combo%20Referral%20Form-Digital.pdf [<https://perma.cc/4YGH-8HD9>]; *EntyvioConnect Enrollment Form*, ENTYVIO (VEDOLIZUMAB), <https://www.entyviohcp.com/Content/pdf/EntyvioConnect-Enrollment-Form.pdf> [<https://perma.cc/A9XF-XJLG>]. The *EntyvioConnect* enrollment form, for example, has within its HIPAA authorization the following language: "I understand that employees of the Companies only use my Protected Health Information for the purposes described herein, to administer the EntyvioConnect Patient Support Program or as otherwise required or allowed under the law, *unless information that specifically identifies me is removed.*" *EntyvioConnect Enrollment Form*, *supra* (emphasis added). By implication, this suggests that removal of identifying information (that is, deidentification) renders the health data subject to uses not specified in the authorization.

¹⁵¹ See OCR PRIVACY BRIEF, *supra* note 117, at 4.

¹⁵² EXAMINING OVERSIGHT, ENTITIES NOT REGULATED BY HIPAA, *supra* note 87, at 15 (noting that "there is currently little understanding of how [noncovered entities'] sharing of so-called de-identified or anonymous information impacts individuals' privacy, and whether the data a [noncovered entity] anonymizes may be less de-identified than would be the case under HIPAA").

trustworthiness of pharmaceutical companies as data custodians. Pharmaceutical manufacturers, as profit-driven entities, often prioritize industry profits over patient well-being and population health goals.¹⁵³ List prices for drugs in the hundreds of thousands of dollars for a course of therapy demonstrate, at the least, disregard for the affordability of drugs that companies produce and market. Patterns of strategic and arguably anticompetitive activity by large, multinational pharmaceutical companies to extend periods of government granted monopoly power¹⁵⁴ should elevate our level of skepticism toward drug makers as fair, impartial, and trusted data brokers for patient-level PHI, especially PHI specific to those who consume their drugs—the lifeblood of their profits. At the very least, drug manufacturers that become custodians of patient-level PHI should be required to mitigate conflicts of interest in a rigorous and fully transparent manner.

Traditionally, special protection accorded to health data helps ensure a continuing relationship of trust between patients and providers.¹⁵⁵ Patient support programs illuminate another reason for conferring special protection on health data: to ensure trust between patients and the corporate entities that manufacture and sell medically necessary and often lifesaving pharmaceutical therapies. Drug makers' ostensible charity toward patient foundations and their willingness to offer drugs with little to no out-of-pocket cost can be considered a self-aggrandizing strategy from which drug makers ultimately get more than they give. Patient support program-derived financial support can be considered the very tip of the iceberg of high drug prices: rather than lower prices to make them truly affordable, drug companies reduce, often temporarily, patients' share of the cost. In effect, temporary cost-sharing reductions achieved through patient support programs are a clever sleight of hand because they increase drug sales without lowering prices, thus ensuring inflated levels of reimbursement continue to flow to the manufacturer.

¹⁵³ See Marcia Angell, *Excess in the Pharmaceutical Industry*, 171 CANADIAN MED. ASS'N J. 1451, 1451 (2004) (“The excesses of the pharmaceutical industry are perhaps the clearest example of the folly of allowing health care expenditures and policies to be driven by largely unregulated market forces and the profit-making imperatives of investor-owned businesses.” *Id.* at 1453.); Tara Bannow, *Pharma Profits Highest in Healthcare*, MODERN HEALTHCARE (Aug. 1, 2019, 6:21 PM), <https://www.modernhealthcare.com/finance/pharma-profits-highest-healthcare> [<https://perma.cc/6A47-S5GW>]; Beth Snyder Bulik, *Does Pharma Value Profits Over Patients? More than 9 of 10 Americans Think So, Poll Says*, FIERCEPHARMA (Jan. 19, 2017, 7:30 PM), <https://www.fiercepharma.com/marketing/pharma-value-profits-over-patients-say-more-than-1-10-americans-new-harris-poll> [<https://perma.cc/B9BY-AP3B>] (summarizing results from a Harris Poll finding that fewer than 10% of Americans “believe that pharma and biotech companies put patients before profits”).

¹⁵⁴ See generally Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499 (2016) (describing “three generations of games pharmaceutical companies play to keep generics off the market and maintain monopoly pricing,” *id.* at 499); see also CONG. RSCH. SRV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING 15–31 (2020) (describing controversial patenting practices such as evergreening, product hopping, and pay-for-delay settlements that some argue “‘game[] the patent system’ to maximize profits and forestall competition,” *id.* at 1).

¹⁵⁵ See Bonnie Kaplan, *How Should Health Data Be Used? Privacy, Secondary Use, and Big Data Sales*, 25 CAMBRIDGE Q. HEALTHCARE ETHICS 312, 315 (2016).

Research organizations and companies analyzing health-related big data promise useful tools and services,¹⁵⁶ data infrastructure to lower healthcare costs and improve clinical outcomes,¹⁵⁷ and data-generated insights that will purportedly transform medicine.¹⁵⁸ Such uses of big data offer great benefits that may justify health data sharing. In contrast to research or data analytics companies, drug makers appear poorly suited to function as innovative, service-oriented data custodians of large quantities of PHI. The risk of targeted marketing in particular should make us question whether *any* patient-level PHI should be entrusted to drug makers. The potential for manipulative marketing—a glaring red-flag in the privacy calculus—should not be understated. Section VI.B details several recent instances of manipulative marketing by large pharmaceutical companies.

B. Do HIPAA Authorizations Subject Patients to Economic Duress?

If the HIPAA authorization is conceptualized as part of a larger bargain between drug makers and patient-enrollees for drug access, an argument can be made that the circumstances of the bargain subject patients to economic duress. First, though, I will address why we should avail ourselves of contract law rather than simply conduct a moral analysis, which I turn to in the next section.

Increasingly, data privacy implicates contract law; consumers are asked to agree to privacy policies and terms of service as part of clickwrap agreements when using apps or Internet websites, for example.¹⁵⁹ They often share private information after “agreeing” to obscure terms in boilerplate contracts¹⁶⁰ devised by landlords,

¹⁵⁶ See, e.g., Josh Mandel, *Cloud Providers Unite on Frictionless Health Data Exchange*, MICROSOFT AZURE (July 30, 2019), <https://azure.microsoft.com/en-us/blog/cloud-providers-unite-on-frictionless-health-data-exchange/> [<https://perma.cc/32B9-AEWX>].

¹⁵⁷ See David W. Bates et al., *Big Data in Health Care: Using Analytics to Identify and Manage High-Risk and High-Cost Patients*, 33 HEALTH AFFS. 1123, 1124–27 (2014).

¹⁵⁸ See, e.g., Maurie Markman, *How Can We Encourage Cancer Patients To Share Their Health Data?*, STAT (Aug. 9, 2016), <https://www.statnews.com/2016/08/09/cancer-research-patient-data/> [<https://perma.cc/GR6D-JBBS>].

¹⁵⁹ See Juliet M. Moringiello & William L. Reynolds, *From Lord Coke to Internet Privacy: The Past, Present, and Future of the Law of Electronic Contracting*, 72 MD. L. REV. 452, 479–80 (2013); see also Hillman & Rachlinski, *supra* note 129, at 454–60 (noting that “[b]usinesses . . . use their knowledge and experience in both environments to exploit consumers, knowing that consumers reliably, predictably, and completely fail to read the terms employed in standard-form contracts,” *id.* at 432–33, and noting later that “businesses have incentives . . . to impose hidden risks on consumers where possible,” *id.* at 440); Adam Gatt, *Electronic Commerce — Click-Wrap Agreements: The Enforceability of Click-Wrap Agreements*, 18 COMPUT. L. & SEC. REP. 404, 405–07 (2002). For a discussion of privacy in the context of electronic agreements, see Moringiello & Reynolds, *supra*, at 456 & n.24, 477–80. The authors argue that “[c]onsumer protection may be more important in electronic contracting . . . because electronic communications make it easier for consumers . . . to give up sensitive personal information without realizing it.” *Id.* at 478–80.

¹⁶⁰ For a comprehensive discussion of the subject of boilerplate contracts, see MARGARET JANE RADIN, *BOILERPLATE: THE FINE PRINT, VANISHING RIGHTS, AND THE RULE OF LAW* (2012). Radin makes a very important point regarding why people often do not read the terms of boilerplate contracts: “We don’t believe that we will ever need to exercise our background legal rights. We don’t expect misfortune to befall us. As psychological research has shown, we are not able to make

insurance companies, student lenders, employers, and a variety of other parties. An examination of data privacy is incomplete without consideration of the contracts that underlie data exchanges. Patient support program-related HIPAA authorizations are, in essence, contracts between a patient and a drug manufacturer that authorize covered entities to disclose patient-enrollees' PHI to the drug manufacturer's support program and affiliated parties.

For the sake of argument, I postulate that patient support program enrollees, as a class, could choose to pursue a class action against a drug manufacturer for fraudulent and deceptive activity in connection with patient support programs. HIPAA itself does not support a private right of action for violations of its provisions,¹⁶¹ and as discussed in the previous sections, it is not clear that drug manufacturers engage in any obvious HIPAA violations in the course of conducting patient support programs. Nonetheless, consumers who are deceived by false or misleading statements of the purposes of requested uses and disclosures of PHI in a HIPAA authorization and suffer injury as a result may have a right of action under state privacy laws and state or federal consumer protection laws.¹⁶² Deceptive communications with patients regarding uses and disclosures of personally identifying information may violate section 5(a) of the Federal Trade Commission Act,¹⁶³ for which there is no private right of action but for which the Federal Trade Commission ("FTC") itself can bring an investigation and enforcement action.

accurate assessments of risks." *Id.* at 12. These points are particularly apropos in the patient support program context.

¹⁶¹ *See, e.g.,* *Acara v. Banks*, 470 F.3d 569, 571 (5th Cir. 2006) ("HIPAA provides both civil and criminal penalties for improper disclosures of medical information. However, HIPAA limits enforcement of the statute to the Secretary of Health and Human Services. Because HIPAA specifically delegates enforcement, there is a strong indication that Congress intended to preclude private enforcement. . . . Every district court that has considered this issue is in agreement that the statute does not support a private right of action." (citations omitted)); *Dinerstein v. Google, LLC*, 484 F. Supp. 3d 561, 582 (N.D. Ill. 2020) (noting, however, that "the fact that there is no right of action under a federal statute does not preempt or otherwise bar a viable state law claim").

¹⁶² For example, the New Jersey Consumer Fraud Act. N.J. STAT. ANN. § 56:8–2 (West 1976) (making unlawful the "unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression, or omission, in connection with the sale or advertisement of any merchandise or real estate"). Often, but not always, state consumer fraud statutes will require that plaintiffs suffer a loss. In New Jersey, in order to have a private cause of action, a consumer must demonstrate an "ascertainable loss of money[] or property, real or personal" due to a practice in violation of the Consumer Fraud Act. *Id.* § 56:8–19.

¹⁶³ 15 U.S.C. § 45(a)(1) (2012) ("Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful."). Unfair or deceptive practices could include "failing to comply with an entity's own privacy policy, deceptively failing to disclose material information about the use of personally identifiable information, or failing to reasonably secure this information." EXAMINING OVERSIGHT, ENTITIES NOT REGULATED BY HIPAA, *supra* note 87, at 3. In a recent settlement with Flo Health, Inc., FTC alleged violations of section 5(c) of the Federal Trade Commission Act after the company deliberately violated its own privacy policy against sharing intimate patient health information in its AI-based period and ovulation tracker. *See* Complaint at 3, *In the Matter of Flo Health, Inc.* (No. 1923133) (stating that the company "promised [in its privacy policies] that third parties could not use Flo App users' personal information 'for any other purpose except to provide services in

In the context of such a lawsuit, patient support program enrollees could plead, *inter alia*, duress in the signing of patient support program enrollment forms.¹⁶⁴ Duress is a legal doctrine that can be invoked to challenge the enforceability of a contract when a party is wrongfully coerced either to enter into a contract in the first instance or to later modify it.¹⁶⁵ (In section VI.A.ii, I will also discuss how it is that patient support program enrollees could demonstrate a legally cognizable injury sufficient to confer standing and to establish damages on a classwide basis.) I also address at the end of this section why courts should consider patient support program contracts voidable rather than grant enrollees what may appear to some as enrollees' "desired" alternative: allow the exchange of PHI for drug access, regardless of the circumstances of the bargain or the downstream consequences.

Duress can take one of two forms. In the first, one party uses physical compulsion, such as force, to extract a manifestation of assent that would otherwise not be given.¹⁶⁶ Assent under such circumstances does not establish a contract.¹⁶⁷ In the second, an improper threat by one party induces a manifestation of assent by the other.¹⁶⁸ The second form of duress is relevant here. To assess duress in this case, we must first ask whether the threat imposed by the drug manufacturer is improper. Here, the threat is the exclusion of a patient from support services, including financial assistance essential to drug access, unless the patient assents to a HIPAA authorization.

When evaluating whether a threat is improper, "[i]t is enough if the threat actually induces assent . . . on the part of one who has no reasonable alternative."¹⁶⁹ Patients who have been prescribed specialty drugs that remain under patent protection often have no therapeutic alternatives. The financial devastation that would result from being forced to pay the full out-of-pocket cost of a therapy effectively leaves patients with no reasonable alternative but to assent to the manufacturer's terms and conditions for drug access.¹⁷⁰

A threat is improper, first, "if the resulting exchange is not on fair terms," and second, if "what is threatened is otherwise a use of power for illegitimate ends."¹⁷¹

connection with the App," *id.* at 3, but later "conveyed the health information of millions of users to . . . third parties for years," *id.* at 4).

¹⁶⁴ While I do not intend to exhaust the claims or legal theories that may form part of a hypothetical class action complaint in this context, the duress argument presented here is meant to provide one possible framework by which patient support program enrollees could seek relief under the law. For a short history of the doctrine of duress and its expansion during the twentieth century to include economic threats, see Daniel P. O'Gorman, "*Sign or Die!*": *The Threat of Imminent Physical Harm and the Doctrine of Duress in Contract Law*, 85 TENN. L. REV. 423, 424–29 (2018).

¹⁶⁵ See Alan Schwartz & Robert E. Scott, *Contract Theory and the Limits of Contract Law*, 113 YALE L.J. 541, 566 (2003); Oren Bar-Gill & Omri Ben-Shahar, *The Law of Duress and the Economics of Credible Threats*, 33 J. LEGAL STUDIES 391, 392 (2004).

¹⁶⁶ RESTATEMENT (SECOND) OF CONTRACTS § 174 (AM. L. INST. 1981).

¹⁶⁷ *Id.* § 174 cmt. a.

¹⁶⁸ *Id.* § 175.

¹⁶⁹ *Id.* § 175 cmt. b.

¹⁷⁰ And patients currently lack a civil remedy for exploitatively high drug prices.

¹⁷¹ RESTATEMENT (SECOND) OF CONTRACTS § 176(2).

If there is a connection between PHI acquisition via HIPAA authorizations and subsequent unlawful FCA and AKS violations by pharmaceutical companies, as section VI.A.i postulates, then the second condition—a use of power for illegitimate ends—is met. But even placing the putative connection between HIPAA authorizations and unlawful kickbacks aside, a variety of grounds exist to reach an affirmative answer as to whether the threat is improper. First, as a result of the deficiencies of HIPAA, patients lack information regarding downstream uses of their PHI. Thus, they are unable to object to downstream uses, and they are unable to control uses and disclosures of PHI after assenting to the authorization. Second, PHI can be used to augment profits of pharmaceutical companies while harming patients financially by, for example, targeting marketing toward specific patients and prescribers to induce patients to remain on more expensive specialty drugs for longer periods of time than necessary.¹⁷² The threat of exclusion from patient support program services is thus improper because the exchange that enrollment demands is not on fair terms.

A threat is also improper if “the effectiveness of the threat in inducing the manifestation of assent is significantly increased by prior unfair dealing by the party making the threat.”¹⁷³ Importantly, the financial component of patient support program services, arguably the primary draw to patient support program participation, is derivative of drug manufacturer-imposed prices.¹⁷⁴ Drug manufacturers set the very prices that obstruct patients’ access to critical drugs,

¹⁷² For a fuller articulation of the process by which PHI may be used to induce a lengthier period of specialty drug use, see section VI.A.ii, pp. 46–51.

¹⁷³ RESTATEMENT (SECOND) OF CONTRACTS § 176(2)(b).

¹⁷⁴ “[A]n analysis of economic duress involves three factors: (1) whether one side accepted the terms of another involuntarily, (2) whether the circumstance permitted no alternative but to accept the terms offered, and (3) whether the acceptance of the terms resulted from the coercive acts of the opposite party.” *Centric Corp. v. Morrison-Knudsen Co.*, 731 P.2d 411, 416–17 (Okla. 1986). Case law supports a claim of economic duress when it can be proven to be “the result of the defendant’s conduct and not . . . the plaintiff’s necessities,” whereas “the mere stress of business conditions will not constitute duress where the defendant was not responsible for those circumstances.” *Fruhauf Sw. Garment Co. v. United States*, 126 Ct. Cl. 51, 62 (Ct. Cl. 1953); *see also Dunes Hosp., LLC v. Country Kitchen Int’l, Inc.*, 623 N.W.2d 484, 490 (S.D. 2001) (“There must be a demonstration of acts on the part of the defendant which produced economic duress. It ‘must be proven by evidence that the duress resulted from the defendant’s wrongful and oppressive conduct and not by the plaintiff’s necessities.’” (emphasis added) (citation omitted)); *Rumsfeld v. Freedom N.Y., Inc.*, 329 F.3d 1320, 1330 (Fed. Cir. 2003) (elaborating on the requirement of coercion in the third prong of economic duress by noting that “an act can be coercive without being illegal. . . . [C]oercion may be supported by a finding that the [opposite party] . . . violat[ed] the covenant of good faith and fair dealing implicit in every contract.”). Based on these articulations of the elements of economic duress, an argument can be made that drug manufacturers “manufacture” (in addition to their drugs) the circumstances that drive patients to consent to patient support programs and related programs by setting unreasonably high prices. The act of setting prices unreasonable to the ordinary person for medically necessary, lifesaving drugs is “wrongful and oppressive conduct” and a “violation of the covenant of good faith and fair dealing.” It is the modern equivalent of “holding a gun to the head” of a person with a serious illness, with an antidote in the other hand, and demanding that the sick individual consent to the terms one presents. A willingness of drug makers to provide financial assistance for pharmaceutical drugs, effectively lowering the cost patients face, belies the absence of a “need” for a price as high as manufacturers have set.

impose unjustified price increases that often outpace inflation,¹⁷⁵ and then establish avenues of access, which many fittingly dub “access programs.” Whether exorbitant prices and unjustified price increases during a period of government-granted monopoly power constitute “unfair dealing” is not a novel question, but one of particular importance in this context.

A patient who declines to participate in a patient support program may well lack alternative means of financing out-of-pocket costs and may be unable to navigate the complexities of insurance reimbursement independently. The threat here is thus a threat of economic harm to patients if they forgo drug manufacturer-derived financial assistance for a drug they require, and a deterioration of health—indirect physical harm—if they forgo drug access entirely. Drug makers can place the force of law behind the improper threat because their bargain appears compliant with the HIPAA Privacy Rule, a regulation whose original purpose never contemplated the uses to which it is currently being put.¹⁷⁶

If the threat is improper, as I have argued, then the resulting contract is voidable at the election of the threatened party.¹⁷⁷ However, this remedy fails insofar as it would prevent patients from reaping the benefits of drug access. Yet, if courts decline to recognize the contract as voidable, they affirm a non-optimal, social welfare-reducing bargain,¹⁷⁸ effectively becoming complicit in drug makers’

¹⁷⁵ See Juliette Cubanski & Tricia Neuman, *Price Increases Continue to Outpace Inflation for Many Medicare Part D Drugs*, KAISER FAM. FOUND. (Feb. 04, 2021), <https://www.kff.org/medicare/issue-brief/price-increases-continue-to-outpace-inflation-for-many-medicare-part-d-drugs> [<https://perma.cc/E5YD-4RLN>] (reporting that 50% of Part D drugs had list price increases from July 2018 to July 2019 that surpassed the inflation rate and also making note of President Biden’s campaign proposals to restrict drug price increases to the inflation rate).

¹⁷⁶ See, e.g., Nicolas P. Terry, *Regulatory Disruption and Arbitrage in Health-Care Data Protection*, 17 YALE J. HEALTH POL’Y L. & ETHICS 143, 199–205 (2017). Terry argues that “HIPAA was a reasonable approach to health-care data protection in the last decade of the twentieth century. At the time, both ‘privacy’ and security threats primarily arose from inside the health-care system,” but “[f]ast-forward to 2009, and policymakers seemed unable to look to the future. The HITECH Act was designed to improve the HIPAA system just enough to absorb the unprecedented growth of EHRs, which the same legislation was about to subsidize.” *Id.* at 200. Terry ends with an exhortation that “legislation providing for data minimization and context-based limitations is urgently required” in light of “serious[] threat[s]” from the “disruption and arbitrage displayed in big data and mobile spaces.” *Id.* Although some of Terry’s specific policy proposals are targeted toward HIPAA’s security protections rather than its privacy protections, Terry does argue in favor of a “custodian-agnostic” definition of data protected by HIPAA and recommends, among other things, that “[a]ny ‘data concerning health’ collected by non-HIPAA covered entities must only be used for the limited purpose for which it was collected.” *Id.* at 205.

¹⁷⁷ See RESTATEMENT (SECOND) OF CONTRACTS § 175(1) cmt. d. It is worth noting that economic duress, when invoked as a defense, has been granted infrequently. See *Dunes Hosp.*, 623 N.W.2d at 492 (noting that “many states have adopted the modern doctrine of ‘business compulsion’ or what is sometimes referred to as ‘economic duress,’” but later acknowledging that “the defense of economic duress will not generally be available absent special, unusual or extraordinary circumstances”). The stubbornly persistent problem of exorbitant drug prices, however, demands creative solutions, and economic duress may offer one such solution.

¹⁷⁸ Does the patient support program bargain increase or decrease the net social product? This Article does not undertake an economic analysis, but if one accepts the argument that the patient support program bargain is undergirded by improper threats, then one could argue that the patient

continuing schemes to maintain high prices, of which patient support programs are a part. It may actually be a better decision, as a matter of public policy, for courts to recognize as voidable patient support program-related HIPAA authorizations on a large scale.¹⁷⁹ Voiding patient support program contracts would eliminate the financial subsidies that drug makers currently provide to patients through patient support programs and temporarily deprive patients of drug access, unless they secure financial support from other sources to purchase drugs. This legal strategy would be expected to precipitate a significant reduction in demand for drug companies' unreasonably priced drugs.¹⁸⁰ In so doing, it may cause drug makers to choose to apply patient support program-related "subsidies" directly to drug prices in order to maintain preexisting levels of utilization, thereby inducing a voluntary lowering of drug prices.¹⁸¹

In sum, a court remedy granting patients the power to void HIPAA authorizations in patient support program enrollment forms on the basis of duress is one potential avenue to address coercive patient support program bargaining and perhaps even induce lower drug prices. A more durable solution, however, may entail a rewriting and modernization of HIPAA to recalibrate the terms of the coercive bargaining it has helped to spawn.

C. Is the Patient Support Program Bargain a Threat or Merely an Offer?

In response to the argument that patient support programs subject patients to economic duress, an objection might be raised that drug companies, which are under no obligation to provide patient support program services, merely make *offers* to patients, similar to the way in which an employer makes an offer of employment, however undesirable the nature of the work, to the willing employee. The employer's offer, however, does not constitute a threat, and a financially needy person's acceptance of that offer does not represent an acceptance under duress because it results from the offeree's necessities rather than the offeror's conduct.¹⁸² The patient support program scenario, however, is distinct. Correctly classifying the patient support program bargain as a threat, not an offer, is critical to the analysis, not only because a threat is a precondition to economic duress, but also because threats normally carry a negative valence and are morally problematic,

support program contracts are welfare-reducing, not welfare-enhancing. *Cf.* O'Gorman, *supra* note 164, at 429 (citing RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 115 (6th ed. 2003)).

¹⁷⁹ It may also be possible to void the patient support program enrollment contract on the basis of other grounds for procedural unconscionability, if courts were to find that drug companies misrepresented their intended purposes for uses and disclosures of PHI, for example. *Cf.* Hillman & Rachlinski, *supra* note 129, at 456–57.

¹⁸⁰ For a discussion of the effects of a proposal to prohibit drug makers from providing any financial assistance for drugs, which may be the de facto consequence of making voidable patient support program enrollment forms, *see infra* pp. 62–63.

¹⁸¹ Of course, drug makers may not voluntarily lower prices and could instead accept significant reductions in demand for their drugs. Maintaining prices at their current level, however, is unlikely to remain a viable option for drug companies in the absence of company-derived forms of financial assistance.

¹⁸² *See* sources cited *supra* note 174.

whereas offers are generally viewed positively and function in a manner that is option enhancing.¹⁸³ This section argues that the patient support program bargain is properly conceptualized as a threat, not an offer. In the case of very high-priced therapies, patients lack the freedom to choose whether to accept the bargain manufacturers have proposed for drug access. Rather than expand options available to patients, the patient support program bargain removes important options. In this manner, drug companies have become the proverbial “highway robber” who confronts his targets with a charge that essentially equates to “your money, or your life.”¹⁸⁴

As an initial matter, drug companies make a threat that is a predicate to their threat of exclusion from patient support program services: the threat to withhold a medically necessary drug if a patient, or a patient’s insurer, does not pay the price the drug company has set. Increasingly, drug companies set prices that any reasonable person would find excessive—such as Spinraza’s (nusinersen) \$750,000 figure for the first year of treatment¹⁸⁵ or the \$2.1 million price tag for the gene therapy Zolgensma (onasemnogene abeparvovec-xioi).¹⁸⁶

Some accounts of coercive threats, such as that of legal philosopher and bioethicist Alan Wertheimer, require a rights violation as a prerequisite to a finding of coercion.¹⁸⁷ In the United States, there is no right to health care generally or to pharmaceutical drugs specifically at the federal level, perhaps other than the right to screening and stabilization during a medical emergency pursuant to the Emergency Medical Treatment and Labor Act.¹⁸⁸ However, both state and federal laws may create legal rights and entitlements to medical therapies. For example, provisions of the ACA entitle holders of private insurance to evidence-based preventive medications and services with no cost sharing,¹⁸⁹ and individuals with

¹⁸³ See Andrew Hetherington, *The Real Distinction Between Threats and Offers*, 25 SOC. THEORY & PRAC. 211, 211–212 (2009).

¹⁸⁴ *Id.* at 211.

¹⁸⁵ See Julie Appleby, *Drug Puts a \$750,000 “Price Tag on Life,”* KAISER HEALTH NEWS (Aug. 2, 2017), <https://khn.org/news/drug-puts-a-750000-price-tag-on-life/> [<https://perma.cc/3KBC-FQSP>].

¹⁸⁶ See Rob Stein, *At \$2.1 Million, New Gene Therapy Is the Most Expensive Drug Ever*, NPR (May 24, 2019, 3:52 PM), <https://www.npr.org/sections/health-shots/2019/05/24/725404168/at-2-125-million-new-gene-therapy-is-the-most-expensive-drug-ever> [<https://perma.cc/M2P8-KJ7D>].

¹⁸⁷ For a concise yet thorough exegesis of Wertheimer’s account of coercion, see I. Glenn Cohen, *Regulating the Organ Market: Normative Foundations for Market Regulation*, 77 LAW & CONTEMP. PROBS. 71, 75–79 (2014).

¹⁸⁸ See *Emergency Medical Treatment & Labor Act (EMTALA)*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA> [<https://perma.cc/SD8U-YTAG>].

¹⁸⁹ See *Background: The Affordable Care Act’s New Rules on Preventive Care*, CTRS. FOR MEDICARE & MEDICAID SERVS. (July 14, 2010), <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/preventive-care-background> [<https://perma.cc/B7SY-QCCV>]. Patients may be entitled to the HIV pre-exposure prophylactic drug Descovy (emtricitabine/tenofovir), for example, which has an average retail price of more than \$2,000 for a thirty-day supply, with zero cost sharing. See *Affordable Care Act Preventive Items and Services*, EXPRESS SCRIPTS,

HIV-AIDS, for example, have sued to exert this right after being charged high levels of cost-sharing for critical HIV-AIDS medications.¹⁹⁰ Furthermore, many state laws and state constitutions provide protections with respect to health that could potentially undergird a rights claim.¹⁹¹ Thus, it is possible that a patient could claim a rights violation when a drug company sets a price for a rare or chronic disease therapy that runs afoul of certain legal entitlements.

Most accounts of coercion in moral philosophy begin with the coercer's communication of a conditional proposal, typically involving a threat. By analogy here, the patient support program proposal can be expressed as a biconditional in the following pattern: "If you do A, I will do B, but if you do not do A, then I will not do B."¹⁹² In the patient support program context, the proposal amounts to: "if you sign the authorization, I will give you access to the drug (by providing financial assistance and reimbursement support), but if you do not sign the authorization, then I will not give you access." Understanding that a signature effectively supplies the drug company with a patient's PHI, the statement would amount to the following: "If you provide your PHI, I will give you access to the drug, but if you do not provide your PHI, then I will not give you access." Next, understanding that drug access can mean life or death (or severely impaired quality of life) for certain patients, the statement becomes: "your PHI or your life" for some, and "your PHI or your health" for others.

This bargain can only be properly understood as a threat in the context of the prices that drug companies have set, and with an awareness of the importance of the drugs in question to the survival or quality of life of the patients who consume them. A few examples here can be instructive. The average annual cost of an orphan drug in 2017 was \$123,543;¹⁹³ by one estimation, the annual cost per patient of Humira in 2017 was \$69,295,¹⁹⁴ and the annual cost of Remicade (infliximab), another TNF inhibitor, was \$31,531.¹⁹⁵ In 2019, the highest priced orphan therapies, such as Actimmune (interferon gamma-1b), a drug used to treat a rare immunologic condition called chronic granulomatous disease, and Ravicti (glycerol phenylbutyrate), which treats a rare metabolic disorder of the urea cycle,

scripts.com/art/open_enrollment/ACA-Drug-List.pdf [https://perma.cc/R26S-FEQW]; *Descovy*, GOODRX, <https://www.goodrx.com/descovy> [https://perma.cc/64L8-WAHQ].

¹⁹⁰ See Ryan Lee, *HIV/AIDS Group: Insurance Companies Discriminating Against Georgians Living with HIV*, GA. VOICE (Nov. 28, 2017), <https://thegavoice.com/news/atlanta/hivaids-group-insurance-companies-discriminating-georgians-living-hiv/> [https://perma.cc/DN36-UFSY] ("In 2016, [the AIDS Research Consortium of Atlanta] and the Harvard [C]enter [for Health Law and Policy Innovation] filed a complaint [against Humana and Cigna] regarding HIV medication being restricted to the highest tiers . . .").

¹⁹¹ See Elizabeth Weeks Leonard, *State Constitutionalism and the Right to Health Care*, 12 J. CONST. L. 1325, 1347–66 (2010).

¹⁹² Scott Altman, *Divorcing Threats and Offers*, 15 LAW & PHIL. 209, 209 (1996).

¹⁹³ *How Big Pharma Makes Big Profits on Orphan Drugs*, AHIP, <https://orphanrug.ahip.org/> [https://perma.cc/Y8UF-BTFN].

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

had list prices that exceeded \$500,000 for a year of therapy.¹⁹⁶ In 2021, Actimmune and Ravicti, both made by Horizon Therapeutics, were among the top five most expensive drugs in the United States by one ranking¹⁹⁷ and had list prices for a 30-day course that exceeded \$55,000.¹⁹⁸

According to Professor Scott Altman’s analytical framework for coercion, to determine whether a “proposal commits the prima facie wrong of coercion,” the answer must be “yes” to the counterfactual question: “[i]f this proposer could not impose the condition, would the proposer have given the benefit or withheld the harm anyway?”¹⁹⁹ Here, if a drug company could not impose the patient support program conditional proposal of PHI for drug access, would it have provided drug access anyway? The answer is very likely *yes*. Drug companies provide patient support program services, both financial and nonfinancial, not out of beneficence or charity, and not out of a need for PHI, but for a self-serving reason: patient support program participation increases drug utilization and, in turn, a company’s receipt of reimbursement for a drug. If drug companies could achieve the same level of utilization of pharmaceutical drugs absent patient support program services, they would have no incentive to provide those services in the first place. This logic can be taken one step further: if the law effectively voided the patient support program bargain, drug companies would nonetheless provide partial financial assistance for drug access, in the form of a lowering of drug prices, because it ultimately benefits the companies.²⁰⁰ This logic also leads to the following conclusion: if all drug company-provided financial assistance for pharmaceutical drugs were prohibited by law, drug companies would lower the price of their drugs, a matter I will return to in section VI.C.

¹⁹⁶ See John Carroll, *The New Top 10 Most Expensive Drugs on the Planet*, ENDPOINTS (Apr. 28, 2017, 7:38 AM), <https://endpts.com/the-new-top-10-most-expensive-drugs-on-the-planet> [<https://perma.cc/B9ZB-CZ6D>]. List price, or wholesale acquisition cost, has been compared to a “sticker price.” It does not account for rebates and discounts that a drug manufacturer may choose to provide.

¹⁹⁷ See Lauren Chase, *The 20 Most Expensive Prescription Drugs in the U.S.A.*, GOODRX (Feb. 8, 2021, 8:00 AM), <https://www.goodrx.com/blog/20-most-expensive-drugs-in-the-usa/> [<https://perma.cc/9W34-YYZR>] (listing the twenty most expensive self-administered drugs in the United States in 2021).

¹⁹⁸ See *id.*

¹⁹⁹ Altman, *supra* note 192, at 211.

²⁰⁰ This line of reasoning would also lead to the conclusion that the threat imposed by drug companies is not a credible threat. *Cf.* Oren Bar-Gill & Omri Ben-Shahar, *Credible Coercion*, 83 TEX. L. REV. 717 (2005). Professors Oren Bar-Gill and Omri Ben-Shahar provide an analytic framework to assess whether a threat is credible:

If that situation arrives — if the threatening party can no longer coerce the other party to surrender to his will — what would the threatening party prefer to do? If at that moment the threatening party perceives his payoff from carrying out the threatened outcome to exceed his payoff from not doing so, his threat is credible. If it is in the interest of the threatening party not to carry out the threatened outcome, his threat is not credible.

Id. at 722.

VI. REFORMING HIPAA IN THE 21ST CENTURY

A. *Patient Support Programs Illuminate the Shortfalls of HIPAA*

The modern process of drug distribution and delivery imposes a natural separation between drug manufacturers and patients; drug companies typically cede control over their drugs to distributors,²⁰¹ which distribute drugs to their penultimate destinations such as hospitals, doctors' offices, retail pharmacies, and specialty pharmacies. These entities in turn dispense drugs to patients, the final consumers. Patient support programs erase the separation between drug manufacturers and patients, affording drug manufacturers an unprecedented degree of proximity to patient end-users. Patient support program enrollment makes certain data points immediately available to the drug manufacturer, but the manufacturer also gains the ongoing ability to access PHI regarding prescription fills for each enrolled patient—data derived from specialty pharmacies.

The data-sharing scheme, as it exists, is lawful because no U.S. data privacy law prohibits drug manufacturers from gathering PHI from covered entities (with authorization), nor does current law place sufficient restrictions on its use. The HIPAA Privacy Rule does require a statement of the purpose or purposes of the requested use or disclosure, but often purposes are conveyed in broad, vague terms. Catch-all phrases such as “conducting data analytics, market research, and other internal business activities” and carrying out “general business and administrative purposes” leave opaque exactly what a drug manufacturer will do with the data it collects. The omission of a requirement in the Privacy Rule to identify all secondary uses of PHI, the failure to protect PHI from redisclosure, and the explicit allowance of sales of PHI after provision of an authorization all afford patients grossly inadequate data protection. Thus, it is not a lack of compliance with HIPAA, but rather HIPAA's shortfalls that currently permit drug manufacturers to collect and later reuse (and potentially misuse) PHI on each patient support program participant.

The next sections describe two controversial drug company tactics and elucidate, for each, a nexus to PHI collection, potentially mediated by patient support programs. The first section references recent Justice Department settlements with drug makers over kickback schemes that involved data exchanges between drug manufacturers and specialty pharmacies. It postulates that patient support program-related HIPAA authorizations could have provided an ostensibly legal basis for such exchanges. The second section postulates a role for patient support program-mediated reimbursement coordination in a tactic referred to as a “soft switch,” the conversion of a drug's customer base (i.e., the patient population

²⁰¹ See Terry Hisey et al, *The Role of Distributors in the U.S. Health Care Industry*, HEALTHCARE DISTRIB. ALL. (IN COLLABORATION WITH DELOITTE) (2019), <https://www.hda.org/~media/pdfs/publications/hda-role-of-distributors-in-the-us-health-care-industry.ashx> [<https://perma.cc/U6FN-S6LR>] (noting that 92% of pharmaceutical sales involve a drug distributor, *id.* at 3).

on a particular therapy) from one brand-name formulation to another without removal of the original brand-name drug from the market.

1. The Role of PHI in Foundation-Related Kickback Schemes

Recent federal investigations have exposed drug company kickbacks to quasi-independent patient foundations that cover Medicare beneficiaries' copays. Kickbacks were timed to coincide with the enrollment of particular patients in federal healthcare programs and coverage of their copay obligations.²⁰² As was mentioned earlier in this Article, patients covered in federal healthcare programs are ineligible to receive drug company-sponsored forms of financial assistance because such financial assistance would constitute improper inducement for goods and services ultimately charged to federal healthcare programs in violation of the Anti-Kickback Statute.²⁰³ AKS effectively "prohibits third parties, such as co-pay foundations, from conspiring with pharmaceutical companies" to induce the purchase of pharmaceutical drugs covered by federal health care programs.²⁰⁴

In recent years, DOJ settled with ten pharmaceutical companies over allegedly unlawful activity in association with foundations that cover patient copays.²⁰⁵ The schemes DOJ identified implicate data exchanges that patient support program enrollment may have helped mediate. For example, in 2018, DOJ settled with Pfizer over FCA violations in connection with three Pfizer drugs: Sutent (sunitinib malate), Inlyta (axitinib), and Tikosyn (dofetilide).²⁰⁶ The press release describing the settlement detailed Pfizer's alleged practices: "Pfizer worked with a third-party specialty pharmacy to transition some portion of . . . patients to the [Patient Access Network F]oundation, which covered the patients' Medicare copays and caused Medicare claims to result from the filling of the patients' Sutent and Inlyta prescriptions."²⁰⁷ The government alleged that Pfizer later "made donations to the foundation and *thereafter received data from the foundation, via the specialty pharmacy*, confirming that the foundation funded the Medicare copays of Sutent and Inlyta patients."²⁰⁸

HIPAA authorizations signed by patient support program enrollees seeking access to Sutent and Inlyta, two chemotherapeutic agents, could have provided the legal basis for the data transfers that allegedly occurred between specialty

²⁰² See *supra* TAN 58–60.

²⁰³ See *supra* TAN 51.

²⁰⁴ Press Release, Dep't of Just. U.S. Att'ys Off., Dist. of Mass., Foundations Resolve Allegations of Enabling Pharmaceutical Companies to Pay Kickbacks to Medicare Patients (Oct. 25, 2019), <https://www.justice.gov/usao-ma/pr/foundations-resolve-allegations-enabling-pharmaceutical-companies-pay-kickbacks-medicare> [<https://perma.cc/FBD3-7WM9>]; see also 42 U.S.C. § 1320(b).

²⁰⁵ See Press Release, Novartis, *supra* note 59.

²⁰⁶ See Press Release, Pfizer, *supra* note 59.

²⁰⁷ *Id.*; see also Sydney Lupkin, Pfizer Settles Kickback Case Related to Copay Assistance for \$24M, KAISER HEALTH NEWS (May 24, 2018), <https://khn.org/news/pfizer-settles-kickback-case-related-to-copay-assistance-for-24m> [<https://perma.cc/X9DX-X4EF>].

²⁰⁸ See Press Release, Pfizer, *supra* note 59 (emphasis added).

pharmacies and Pfizer. Not coincidentally, both of these drugs have an associated patient support program: “Pfizer Oncology Together.”²⁰⁹ Prospective consumers of Sutent and Inlyta presumably sought financial assistance from Pfizer Oncology Together. Pfizer then likely directed those patients to the foundations—a service that, according to the Pfizer Oncology Together enrollment form, enrollees authorize the drug company to carry out on their behalf.²¹⁰ With knowledge of enrollees’ financial status and authorization to acquire their PHI, Pfizer not only knew of their Medicare eligibility but could also engage in data exchanges regarding them, both with the foundation and with specialty pharmacies. Although DOJ’s enforcement action brought the alleged kickback schemes to public attention, the data exchanges that made the scheme possible seem to have been overlooked.

To provide another example, United Therapeutics agreed to pay a \$210 million monetary penalty to settle allegations of illegal kickbacks paid to a purportedly independent foundation, which covered patient copays for several United Therapeutics’ drugs, including the drug Adcirca (tadalafil).²¹¹ According to the DOJ press release for that settlement:

[f]rom February 2010 through January 2014, . . . [United Therapeutics] routinely obtained data from the foundation detailing how many patients on each [United Therapeutics pulmonary arterial hypertension] drug the foundation had assisted and how much the foundation had spent on those patients. . . . [T]he government alleged that [United Therapeutics] used this data to decide the amount to donate to the foundation.²¹²

In essence, the company allegedly referred Medicare patients who were prescribed its drugs to the foundation for copay assistance and subsequently provided funding to the foundation, “not [as] charity for [pulmonary arterial hypertension] patients generally, but rather . . . [as] a way to funnel money to patients taking [United Therapeutics] drugs.”²¹³ Here, again, patient support program-mediated authorizations may have provided United Therapeutics with the semblance of a lawful contract authorizing United Therapeutics to guide patients to the foundation it had funded, and subsequently, to gather the data necessary to track

²⁰⁹ See Row 9, Appendix II.

²¹⁰ See *Patient Support Program & Patient Assistance Enrollment Form*, PFIZER ONCOLOGY TOGETHER, https://www.pfizeroncologytogether.com/sites/default/files/Pfizer_Oncology_Together_Enrollment_Form.pdf [<https://perma.cc/MF7A-5Q9V>].

²¹¹ See Press Release, Dep’t of Just. U.S. Att’y’s Off., Dist. of Mass., United Therapeutics Agrees to Pay \$210 Million to Resolve Allegations that It Paid Kickbacks Through a Co-Pay Assistance Foundation, (Dec. 20, 2017), <https://www.justice.gov/usao-ma/pr/united-therapeutics-agrees-pay-210-million-resolve-allegations-it-paid-kickbacks-through> [<https://perma.cc/5DZ9-FVGW>].

²¹² *Id.*

²¹³ *Id.*

their copay coverage.²¹⁴ Each of the kickback schemes DOJ prosecuted may have similar links to patient support programs.²¹⁵

The mechanisms postulated here, which link patient-specific data exchanges to unlawful activity, illuminate the deficiencies of HIPAA and the urgency of reform. Although patient support program-mediated data collection and data exchanges do not appear to violate the terms of HIPAA itself, these exchanges should be unlawful; usurpations of personally identifiable health data for illegal kickback schemes should qualify as privacy violations for which companies face liability.²¹⁶ Even so, a privacy default rule that prevents companies from conducting PHI transfers with third parties may actually deter kickback schemes more effectively than ex post monetary penalties and corporate integrity agreements imposed to address fraud that has already been committed.

2. Patient Support Program Data Collection as a Means to Targeted Marketing and Product Hopping

Some might argue that the risk of harm to patients from patient support programs is too speculative or too remote to establish Article III standing or to demonstrate a loss required to bring an action under state consumer protection laws. This is not, in fact, the case. This section demonstrates how patient support program data can be used to accomplish a strategy called “product hopping.” If a group of patient support program enrollees could demonstrate that they were the subjects of product hopping and were essentially switched to a new, higher-priced formulation of a brand drug in connection with their participation in a patient support program, a concrete and particularized injury, redressable by the courts, could be established.²¹⁷ The harm to patients ultimately takes the form of pecuniary

²¹⁴ The patient support program for United Therapeutics, which is called “ASSIST: Access Solutions and Support Team,”²¹⁴ is described in Row 16 of Appendix II.

²¹⁵ As a brief additional example, in 2020, Sanofi settled with DOJ over allegations of fraud for payments to charitable patient foundations in relation to the drug Lemtrada, the patient support program of which—*MS One to One*—was described earlier in this paper. See *supra* TAN 73–76. According to DOJ, “[t]o effectuate its scheme, Sanofi worked with its third-party reimbursement hub to identify Medicare patients for whom physicians had prescribed Lemtrada, but who had not yet received infusions of the drug because they lacked sufficient funds to afford the co-pays for Lemtrada.” See Press Release, Sanofi, *supra* note 59. Sanofi’s third-party reimbursement hub likely “identif[i]ed Medicare patients . . . [who] lacked sufficient funds to afford . . . Lemtrada” among the enrollees to the Lemtrada patient support program, *MS One to One*. *Id.*

²¹⁶ A regulation in this regard could be modeled on the predecessor to the European Union’s General Data Protection Regulation (GDPR), the European Data Protection Directive (DPD), which “create[d] liability for companies that misuse or unlawfully process personal data.” See Michael L. Rustad & Thomas H. Koenig, *Towards a Global Data Privacy Standard*, 71 FLA. L. REV. 365, 374 (2019).

²¹⁷ The injury to patients from product hopping is concrete (that is, real and not abstract) and particularized (personal and individual to the plaintiff), and is therefore legally cognizable. Cf. *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339–42 (2016) (making clear that a particularized injury is one that “must affect the plaintiff in a personal and individual way,” *id.* at 339 (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992))), as distinct from the independent injury-in-fact

injury due to a lengthier period of time during which subjects of product hopping receive a more expensive brand drug.

It is possible for drug makers to use data from patient support program enrollment to induce patients to remain on more expensive brand drugs long after generics, biosimilars, or other less expensive alternative drugs enter the market. This can occur in one of two ways. First, drug makers can use consent obtained during patient support program enrollment to market new formulations of brand drugs directly to enrollees.²¹⁸ HIPAA authorizations often include among the “purposes of the use or disclosure” marketing to patients by mail, phone, text, or email. Second, drug makers can conduct pharmaceutical detailing to promote new formulations of branded pharmaceutical drugs.²¹⁹ Traditionally, drug companies direct detailing to high-volume prescribers using prescriber-identifying information, which drug makers buy in the aggregate from companies like IQVIA (formerly named Quintiles IMS), and its predecessor IMS Health²²⁰ but which lacks patient-identifying information due to HIPAA.²²¹ Detailing could be accomplished

requirement for concreteness, which means that the injury “must actually exist” and must be “real, and not abstract,” *id.* at 340 (internal quotation omitted)).

²¹⁸ Consent for marketing is sometimes folded into the HIPAA authorization, where marketing is listed among purposes of the requested use or disclosure. *See, e.g., Actimmune (Interferon Gamma-1B) Patient Enrollment Form*, HORIZON PATIENT SERVS., <https://www.lzndocs.com/ACTIMMUNE-Patient-Enrollment-Form.pdf> [<https://perma.cc/GMQ6-C4JC>]. In other cases, there is an optional marketing “opt in” within the enrollment form, separate and apart from the HIPAA authorization. *See, e.g., MySource: Afstyla Antihemophilic Factor (Recombinant), Single Chain, Enrollment Form*, CSL BEHRING (on file with author).

²¹⁹ Detailing refers to the marketing practice in which pharmaceutical drugs are promoted to healthcare providers via one-on-one interactions between providers and pharmaceutical company representatives. Detailing often takes place in doctors’ offices. For recent literature describing pharmaceutical detailing and its potential to influence prescribers, see B. Joseph Guglielmo, *The Cost of Pharmaceutical Company Detailing Visits and Medication Samples*, 180 JAMA 595 (2020); Ashleigh C. King et al., Letter, *A National Survey of the Frequency of Drug Company Detailing Visits and Free Sample Closets in Practices Delivering Primary Care*, 180 JAMA 592 (2020); Ian Larkin et al., *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33 HEALTH AFFS. (MILLWOOD) 1014 (2014); and Ian Larkin et al., *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 JAMA 1785 (2017).

²²⁰ *See* Adam Tanner, *This Little-Known Firm Is Getting Rich off Your Medical Data*, FORTUNE (Feb. 9, 2016), <https://fortune.com/2016/02/09/ims-health-privacy-medical-data/> [<https://perma.cc/4JSF-ULM7>] (“IMS buys bulk data from pharmacy chains such as CVS . . . , doctor’s electronic record systems such as Allscripts, claims from insurers such as Blue Cross Blue Shield and from others who handle your health information. The data is anonymized—stripped from the identifiers that identify individuals. In turn, IMS sells insights from its more than half a billion patient dossiers mainly to drug companies.”); *see also* Press Release, IQVIA, QuintilesIMS Is Now IQVIA (Nov. 6, 2017), <https://www.iqvia.com/newsroom/2017/11/quintilesims-is-now-iqvia> [<https://perma.cc/UDG2-EAL4>]; Press Release, IQVIA, IMS Health and Quintiles to Merge (May 3, 2016), <http://iqvia2017ir.q4web.com/investors/press-releases/press-release-details/2016/IMS-Health-and-Quintiles-to-Merge/default.aspx> [<https://perma.cc/HQ76-C5XP>].

²²¹ *See* Robert Steinbrook, *For Sale: Physicians’ Prescribing Data*, 354 NEW ENG. J. MED. 2745, 2746 (2006) (“The current controversy is about collecting and selling physicians’ prescribing information, not data that identify patients, whose confidentiality is protected under the Health Insurance Portability and Accountability Act.”).

with far greater precision, ease, and effectiveness if drug manufacturers knew exactly which providers prescribe particular drugs to particular, named patients—a task that patient support program enrollment makes possible.

The patient-prescriber linkage found in patient support program enrollment data positions drug manufacturers to do more than simply market their products with precision; it positions them to accomplish a tactic termed “product hopping.” Product hopping entails introduction into the market of a reformulated version of a brand-name drug, usually as a key patent for the original formulation approaches expiration, followed by a series of measures to shift the customer base from the old, patent-expiring formulation to the newly patent-protected formulation.²²² The new formulation could involve, for example, a new dosage, a new route of administration, or a combination of two separate drugs in a single treatment.²²³ AstraZeneca, for instance, carried out a product hop from the patent-expiring reflux drug Prilosec (omeprazole) to Nexium (esomeprazole)—an isolated enantiomer of omeprazole—despite no discernible therapeutic benefits of the new product.²²⁴ A product hop to a formulation with marginal benefits over a prior formulation is not uncommon.

Scholars Michael Carrier and Steve Shadowen break down product hopping into two component steps: “(1) reformulating the product in a way that makes a generic version of the original product not substitutable; and (2) encouraging doctors to write prescriptions for the reformulated rather than the original product, i.e., switching the prescription base from the original to the reformulated product.”²²⁵ By cannibalizing sales of the original brand drug, the reformulated drug prevents generics to the original formulation from gaining market share. A brand drug company thereby maintains its monopoly for a particular therapy.

Product hops have been further categorized in the literature into “hard” and “soft” switches, a hard switch being an instance in which the brand drug company withdraws the original formulation from the market such that it can no longer be prescribed,²²⁶ and a soft switch being an instance in which the original formulation is kept on the market while the brand company aggressively markets the new formulation to steal market share from generic entrants.²²⁷ The New York State

²²² See Nicholas S. Downing et al., *Avoidance of Generic Competition by Abbott Laboratories’ Fenofibrate Franchise*, 172 ARCH. INTERNAL MED. 724, 725–28 (2012); Vincent C. Capati & Aaron S. Kesselheim, *Drug Product Life-Cycle Management as Anticompetitive Behavior: The Case of Memantine*, 22 J. MANAGED CARE & SPECIALTY PHARMACY 339, 339–41 (2016).

²²³ See Vrushab Gowda et al., *Identifying Potential Prescription Drug Product Hopping*, 39 NATURE BIOTECH. 414, 414 (2021).

²²⁴ See *id.*

²²⁵ Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 171 (2016).

²²⁶ The withdrawal of the original product entails more than simply terminating sales; drug companies have gone so far as to buy back supplies of the original product from pharmacies and change NDC codes for the original product to “obsolete” such that the original drug could no longer be subject to automatic substitution with a generic. See *id.* at 192.

²²⁷ See *id.*; see also Gowda et al., *supra* note 223.

Attorney General's Office summarized common drug company tactics to accomplish product switches in a complaint alleging Sherman Act violations by Forest Laboratories in connection with a hard switch from Namenda (memantine) immediate release to Namenda extended release:

There are various tactics that a branded manufacturer may use to try to encourage physicians and patients to switch to its new follow-on drug prior to generic entry. Commonly, the company will aggressively promote the follow-on drug and stop marketing the original drug. The company will typically advocate to physicians that the new product is superior and should be prescribed instead of the original. At the extreme end of the spectrum, a pharmaceutical company may seek to *force* physicians and patients to make the switch to the new drug. This might be accomplished by restricting the distribution and availability of the original drug, or completely removing the original product from the market[,] . . . leaving patients with no option but to switch.²²⁸

Much attention has been paid to the timing of introduction of a new formulation relative to market entry of a generic equivalent to the original drug.²²⁹ Attention has also been paid to the potential for consumer welfare-reducing, anticompetitive effects from product hopping,²³⁰ especially when the original formulation is withdrawn from the market during a hard switch. Less attention has been paid, however, to *how* drug companies accomplish step two of Carrier and Shadowen's framework—switching of the prescription base to the reformulated product—during a soft switch when the original product is kept on the market. It is the second step in Carrier and Shadowen's framework that may implicate patient support programs and the consent to interface with an enrollee's provider and insurance plan that patient support program authorizations grant. Conduct of drug companies, however, may exceed mere encouragement of prescriptions for the new formulation, as Carrier and Shadowen suggest, and may instead approach a form of targeted inducement, using patient-level data obtained through patient support program enrollment.

Patient-level data linking patients to particular prescribers, when taken with the relatively small size of the patient populations that consume specialty drugs, make a translation of the customer base from one formulation to another all the more easily accomplished. Important to this discussion is the fact that drug companies are permitted, because of the consent obtained during patient support program

²²⁸ Complaint at 14, *New York ex rel. Schneiderman v. Actavis, PLC*, 787 F.3d 638 (2d Cir. 2015) (No. 14-cv-7473).

²²⁹ See Carrier & Shadowen, *supra* note 225, at 176–78.

²³⁰ For a sampling, though by no means exhaustive list, of the law review articles on product hopping, see Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, 2007 MICH. ST. L. REV. 631; Mark S. Levy, *Big Pharma Monopoly: Why Consumers Keep Landing on "Park Place" and How the Game Is Rigged*, 66 AM. U. L. REV. 247 (2016); and Michael A. Carrier, *Provigil: A Case Study of Anticompetitive Behavior*, 3 HASTINGS SCI. & TECH. L.J. 441 (2011).

enrollment, to broker many payment-related services,²³¹ including the prior authorization process. Prior authorization assistance is a fundamental element of the financial assistance portion of a patient support program.²³² With authorization to broker payment-related services in hand, a drug maker can send physicians prior authorization forms for each patient support program enrollee taking a particular drug, replacing the prior authorization for the *old formulation* with a prior authorization for the *newly reformulated drug*.²³³ By taking control of the prior authorization process and interfacing with both physicians and insurers, a drug manufacturer positions itself to unduly influence physician prescribing. Prior authorizations are a particularly critical gateway to accessing expensive specialty drugs, and the brokering of prior authorizations allows drug makers to influence prescribing and reimbursement in the same stroke.

Interestingly, the language of coercion surfaces in the antitrust suits involving allegations of product hopping. Courts have found consumer coercion in hard switches as opposed to soft switches, reflecting the consumer welfare-reducing effects of hard switches on consumer choice.²³⁴ Though coercion as used in the antitrust context does not match precisely with the schema for coercion in moral philosophy, the intuition is very similar: Hard switches diminish, or remove entirely, a patient's free choice of products in the marketplace because the original brand drug, which may be the only therapeutic option before generics enter the

²³¹ Patient support programs determine a patient's eligibility for drug coverage under a health plan, mediate the prior authorization process, and may conduct claims adjudication, all of which can be characterized as payment-related activities under HIPAA. See 45 C.F.R. § 164.501 (2013) (defining activities that qualify as "payment" under HIPAA, which include "determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims," "billing, claims management, collection activities, . . . and related health care data processing," "review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges," and "utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services"). In effect, then, patient support programs authorize drug makers to assume responsibility for many payment-related functions normally conducted by health insurers.

²³² Take, for example, Acthar gel. Per the website for the Acthar gel patient support program, "[i]f you have insurance, Acthar Patient Support works with your insurance company. . . . *Acthar Patient Support will collect the required paperwork from your doctor and submit the information to your insurance company — you don't have to manage the process.* Your Case Manager will provide you with updates on the status of your approval process so you know what's going on every step of the way." *Acthar Gel Patient Support*, *supra* note 69 (emphasis added).

²³³ This anecdote is based on actual occurrences communicated to the author of this Article during a telephone interview with employees of a generic pharmaceutical company. The employees recounted the practices of a maker of brand-name medications.

²³⁴ See, e.g., *Abbott Labs. v. Teva Pharms., Inc.*, 432 F. Supp. 2d 408, 421 (D. Del. 2006) ("The court in *Berkey Photo* noted that consumers in that case were 'not compelled' to purchase the new film, in part because 'Kodak did not remove any other films from the market when it introduced the new one.' Indeed, 'the situation [in that case] might be completely different if, upon introduction of the new system, Kodak had ceased producing film in the [old] size, thereby compelling camera purchasers to buy [the new] camera. In the absence of free consumer choice, the basis for judicial deference is removed.'" (citations omitted) (citing and distinguishing *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 & n.39 (2d Cir. 1979))).

market, is no longer available. When drug makers carry out a soft switch using prior authorizations sent to the prescriber of each patient support program enrollee, it may similarly diminish the extent to which free choice exists on the part of enrollees and their prescribers to *choose* the new formulation. This is especially true if busy prescribers unthinkingly fall prey to the tactic. At the very least, prescribers should be made aware that they could be subjected to this practice.

In order to avoid patient support program-derived data and consent from being co-opted for anticompetitive purposes like product hopping, regulation should prohibit patient-level PHI from being used to target patients and their prescribers. In this respect, privacy law reforms are in alignment with, and can advance the goals of, antitrust law. Several states have made attempts to block the use of prescriber-identifying data for drug company marketing, but these attempts have been stymied in the courts. The next section draws lessons from three pertinent cases—*IMS Health Inc. v. Mills*,²³⁵ *IMS Health Inc. v. Ayotte*,²³⁶ and *Sorrell v. IMS Health Inc.*²³⁷—to argue that a renewed attempt to restrict patient- and prescriber-identifying data sales may withstand legal challenges.

*B. Limits on the Disclosure, Use, and Sale of PHI:
Lessons from Sorrell and Related Cases*

Attempts by several states to prohibit the disclosure, use, and sale of prescriber-identifying data for pharmaceutical marketing purposes faced constitutional challenges after data miners and drug companies alleged violations of their First Amendment right to free speech in the marketing context. In the 2011 decision *Sorrell v. IMS Health Inc.*, the Supreme Court found unconstitutional on First Amendment grounds a Vermont law requiring prescriber consent before prescriber-identifying records could be used in the marketing of prescription drugs.²³⁸ Based on the majority's analysis in *Sorrell* and in light of the findings in this Article, the following prohibition might pass constitutional muster: *the sale or exchange for value of patient- and prescriber-identifying data by any entity, save for limited exceptions, is prohibited, unless both patient and provider opt out of the privacy protections under this statute.* Key to a proper analysis of whether such a statute could survive First Amendment scrutiny is identification of the government's asserted interests, which were arguably misidentified in *Sorrell* and related cases.

At issue in *Sorrell* was a 2007 Vermont law that required prescriber consent for the sale, licensing, or use of prescriber-identifying records for marketing and promotion of prescription drugs.²³⁹ Other non-promotional uses of prescriber-identifying prescription records—such as research, law enforcement, and formulary

²³⁵ 616 F.3d 7 (1st Cir. 2010).

²³⁶ 550 F.3d 42 (1st Cir. 2008).

²³⁷ 564 U.S. 552 (2011).

²³⁸ *Id.* at 577–79.

²³⁹ *Id.* at 558–59. The law both prohibited pharmacies and related entities from *allowing* information to be used for marketing without consent, and specifically prohibited pharmaceutical manufacturers and marketers from *using* the information for marketing without consent. *Id.*

compliance—were exempted from the act’s requirements.²⁴⁰ The act also allocated funds expressly designed for counter-detailing, a practice that informs providers of cost-effective alternatives to brand-name therapies in order to correct for a “one-sided” marketplace of ideas dominated by drug manufacturer promotion.²⁴¹ The Court of Appeals for the Second Circuit reversed the district court’s finding of constitutionality of the Vermont law, concluding that the law violated the First Amendment rights of pharmaceutical manufacturers and data miners because it did “not directly advance the substantial state interests asserted by Vermont” and was “not narrowly tailored to serve those interests.”²⁴² Similar statutes in New Hampshire²⁴³ and Maine,²⁴⁴ however, had been upheld against constitutional challenges. Faced with a circuit split, the Supreme Court in *Sorrell* upheld the Second Circuit ruling of unconstitutionality, finding that the Vermont law “enact[ed] content- and speaker-based restrictions on the sale, disclosure, and use of prescriber-identifying information”²⁴⁵ by disfavoring a particular type of speech (marketing) by a particular class of speakers, namely drug manufacturers.²⁴⁶

Several lessons from *Sorrell* can be applied to the patient support program context. First, the majority’s line of reasoning in *Sorrell* suggests that a broader ban on utilization of identifying information would have been more likely to pass muster constitutionally than a ban directed exclusively at drug makers. A blanket prohibition on use of patient- and prescriber- identifying information by *all entities*, save for very limited exceptions such as law enforcement, would escape the charge that the regulation enables information use only “by those speakers whose message the State supports.”²⁴⁷ And, if a statute analogous to that of Vermont contained only the first of its three prohibitions—the prohibition on *sale or exchange for value* of prescriber-identifying information—and expanded that prohibition to apply to any third party (not just to drug manufacturers for marketing and promotion), it

²⁴⁰ *Id.* at 559–60.

²⁴¹ *Id.* at 561 (citing 2007 Vt. Acts No. 80, § 1(3)–(4)).

²⁴² *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 267 (2d Cir. 2010).

²⁴³ *See IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008). The New Hampshire statute prohibited sale, licensure, transfer, or use of patient-identifiable and prescriber-identifiable prescription records “for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient’s insurance provider or the agent of either; health care research; or as otherwise provided by law.” *Id.* at 47 (citing N.H. REV. STAT. ANN. § 318:47-f (2006)). Notably, the prohibition did not apply to “collection, use, transfer, or sale of patient and prescriber de-identified data by zip code, geographic region, or medical specialty for commercial purposes.” N.H. REV. STAT. ANN. § 318:47-f (2006).

²⁴⁴ *See IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010). The Maine statute allowed providers to opt into confidentiality protection, and so effectively permitted them to decline to share their data for use in detailing. *Id.* at 17. Pharmacies were prohibited from “selling, transferring, or licensing opted-in Maine prescribers’ identifying data for a marketing purpose.” *Id.* at 18.

²⁴⁵ *Sorrell*, 564 U.S. at 563–64.

²⁴⁶ *Id.* at 564.

²⁴⁷ *Id.* at 574.

would seem to eliminate the content- and speaker-based restrictions the majority found violative of the First Amendment.²⁴⁸

Second, a key distinction exists between the statutory language suggested above and that at issue in *Sorrell*: the Vermont law aimed to regulate prescriber-identifying information only,²⁴⁹ whereas a more effective statute would apply to both patient- and prescriber-identifying information. Data miners, like the erstwhile IMS Health, which initiated the trio of related suits discussed here, “aggregate . . . [pharmacy] data to reveal individual physician prescribing patterns.”²⁵⁰ Patient-identifying data are absent from such aggregations, and, in fact, the data are purposely “stripped of patient information, to protect patient privacy”²⁵¹ pursuant to HIPAA. However, patient support programs provide drug companies with the benefit of linked patient- and prescriber-identifying information, which can be used for targeted marketing and other ends of questionable legitimacy. As I have argued, patient- and prescriber-identifying information poses a greater danger to patients than data that are merely prescriber-identifying. Therefore, the state has a more substantial interest in regulating the former than it does the latter.

Third, the government has a substantial interest in protecting the health of patients from deceptive, misleading, and otherwise unsavory marketing practices, the dangers of which become clear upon review of drug makers’ marketing practices. In the *Sorrell* line of cases, the state wrongly emphasized prescribers’ rights to avoid unwanted communications rather than focusing on the rights of patients. Health care cost containment and prescriber confidentiality were primary among the interests that the Supreme Court and circuit courts weighed against the burdens on speech.²⁵² In *Mills*, the First Circuit’s rejection of a First Amendment

²⁴⁸ Prohibiting *disclosure, use, or sale* of patient- and prescriber-identifying information by any entity for any purpose, not simply marketing, is another potential way to eliminate content- and speaker-based restrictions, but it is far broader in its reach. I have proposed limiting the prohibition to *sale or exchange for value* of patient- and prescriber-identifying information because this prohibition may ultimately preempt many of the most concerning uses of patient- and prescriber-identifying information without the charge that the government interest could have been served as well by a more limited restriction.

²⁴⁹ Regulated data included prescribers’ names and addresses, “the name, dosage, and quantity of the drug, the date and place the prescription is filled, and the patient’s age and gender.” *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 267 (2d Cir. 2010). Patient information was thus not identifying.

²⁵⁰ *Id.*

²⁵¹ *Id.*; see also *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 45 (1st Cir. 2008) (“To protect patient privacy, prescribers’ names are encrypted, effectively eliminating the ability to match particular prescriptions with particular patients.”).

²⁵² See *Sorrell*, 564 U.S. at 572 (“The State’s asserted justifications for § 4631(d) come under two general headings. First, the State contends that its law is necessary to protect medical privacy, including physician confidentiality, avoidance of harassment, and the integrity of the doctor-patient relationship. Second, the State argues that § 4631(d) is integral to the achievement of policy objectives—namely, improved public health and reduced healthcare costs.”). The First Circuit in *Ayotte* noted that the New Hampshire legislature was motivated to protect the “integrity of physician decisionmaking” and address the “inflationary impact [of detailing] on drug prices.” *Ayotte*, 550 F.3d at 54.

challenge to a Maine statute resembling Vermont's was predicated in part on the fact that the statute "directly serve[d] Maine's substantial interest in vindicating Maine prescribers' rights to avoid unwanted targeting by detailers . . . on the basis of their individual prescribing histories."²⁵³ Similarly, in *Sorrell*, the government asserted an interest in prescriber confidentiality, but the Court argued that the Vermont statute's prohibitions were "not drawn to serve that interest" because entities other than pharmaceutical manufacturers and marketers could purchase and use prescriber-identifying information.²⁵⁴ Patients' privacy interests did not play a prominent role in the government's arguments or the Court's analysis; instead, the prescriber's privacy interests were central.

Justice Kennedy, writing for the Court in *Sorrell*, rejected "coerc[ion] and harass[ment]" by "'a few' physicians" as insufficiently weighty interests to "sustain a broad content-based rule," noting that doctors are free to refuse detailing visits.²⁵⁵ But the pervasiveness of detailing makes his reference to "'a few' physicians" appear off the mark. Moreover, the analysis makes no mention of the harm that patients have suffered from aggressive off-label promotion of pharmaceutical drugs in certain less studied populations, including children and the elderly.²⁵⁶ The "persuasive" drug company marketing, as Justice Kennedy described it,²⁵⁷ could be more accurately characterized as manipulative, unbalanced, and, in some cases, intentionally deceptive and misleading,²⁵⁸ types of marketing which the state has a substantial interest in avoiding.

²⁵³ *IMS Health Inc. v. Mills*, 616 F.3d 7, 20 (1st Cir. 2010).

²⁵⁴ *Sorrell*, 564 U.S. at 572.

²⁵⁵ *Id.* at 575.

²⁵⁶ For example, in 2012, GlaxoSmithKline (GSK) pleaded guilty to misbranding the antidepressant Paxil (paroxetine), as well as other GSK drugs, and agreed to a \$3 billion settlement with DOJ, which made history as the single largest dollar settlement for health care fraud in the United States to that date. Press Release, Dep't of Just., Off. of Pub. Affs., GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), <https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report> [<https://perma.cc/23D4-F2AK>] [hereinafter Press Release, GlaxoSmithKline]. GSK promoted off-label use of Paxil in patients under the age of 18 for at least five years (1998 to 2003) following the completion of a GSK clinical trial finding insufficient evidence of efficacy and serious psychiatric adverse events in young people. *Id.*; United States' Complaint at 3, 8, 10, *United States ex rel. Thorpe v. GlaxoSmithKline*, No. 11-10398-RWZ (D. Mass. Oct. 26, 2011) [<https://perma.cc/R8X3-XM5H>]. Using a company-funded medical journal article published in the *Journal of the American Academy of Child and Adolescent Psychiatry*, GSK made inaccurate claims to providers about the drug's efficacy in treating depression in young people and minimized its risks. *Id.* at 6–9, 15. It was not until 2006 that GSK modified its label according to an FDA request to include a black-box warning regarding the elevated risk of suicidality in children and adolescents on selective serotonin reuptake inhibitors such as Paxil. *Id.* at 12.

²⁵⁷ *Sorrell*, 564 U.S. at 576 ("If pharmaceutical marketing affects treatment decisions, it does so because doctors find it persuasive.").

²⁵⁸ For a discussion of the social psychology of marketing and its influence on physicians, see Sunita Sah & Adriane Fugh-Berman, *Physicians Under the Influence: Social Psychology and Industry Marketing Strategies*, 41 J. L. MED. & ETHICS 665 (2013). A study of whistleblower-initiated complaints against drug companies for fraudulent off-label promotion found that, in 76%

Ultimately, *Sorrell* minimizes the importance of the state's interest in limiting false, deceptive, and manipulative pharmaceutical detailing while presenting an overly sanguine view of detailing. The Vermont law may have withstood constitutional scrutiny if it could have been shown that silencing unwanted or disfavored speech, which was the majority's characterization of the practical effect of the Vermont law, in reality amounted to limiting false or misleading speech that could harm patients and threaten the public welfare. That is precisely what the state, if it were to defend the hypothetical statutory language proposed here, should emphasize. "Fear that people would make bad decisions if given truthful information" may not justify a content-based burden on speech,²⁵⁹ as Justice Kennedy wrote, but fear that people will make bad decisions if given *bad* information may justify such a burden.²⁶⁰ The majority in *Sorrell* too readily rested its decision on a presumption of truthful and non-misleading pharmaceutical promotion.

Translating the lessons of *Sorrell* to patient support programs, the government's substantial interest in protecting patients from false, misleading, and deceptive marketing may have the greatest force in a First Amendment analysis, whereas a provider's right to avoid unwanted communications should recede as an extant but less substantial interest. The prescriber, as the learned intermediary, is a mere conduit to a prescription for a medically necessary therapy, and one for which the prescriber does not typically bear any financial burden. The prescriber's interest in avoiding marketing manipulation extends only so far as the health of patients is concerned. Here, too, the individual interest in being free from deceptive marketing that could influence the consumption of costly and potentially harmful pharmaceutical drugs should supersede a larger societal interest in reducing overall healthcare costs. Patients' interests should tip the scales against any commercial speech interest that data miners or drug companies attempt to assert.

of complaints, plaintiffs alleged that drug companies had provided physicians with "self-serving presentations of the scientific literature" that conveyed "false or unbalanced study data [in order] to support[] the unapproved use." See Aaron S. Kesselheim et al., *Strategies and Practices in Off-Label Marketing of Pharmaceuticals: A Retrospective Analysis of Whistleblower Complaints*, 8 PLOS MED. 1, 5 (2011).

²⁵⁹ *Sorrell*, 564 U.S. at 577.

²⁶⁰ Cf. *Friedman v. Rogers*, 440 U.S. 1 (1979) (upholding a Texas statute designed to "protect the public from the deceptive and misleading use of optometrical trade names," *id.* at 15, against a constitutional challenge, and noting that "the First Amendment, as we construe it today, does not prohibit the State from insuring that the stream of commercial information flow cleanly as well as freely," *id.* at 10 (citation omitted)). In *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447 (1978), the Court noted that "[in-person solicitation of business] may actually dissuade the individual and societal interest in facilitating informed and reliable decisionmaking" because "[u]nlike a public advertisement, which simply provides information and leaves the recipient free to act upon it or not, in-person solicitation may exert pressure and often demands an immediate response." *Id.* at 457. Likewise, a similar conclusion might be reached that in-person detailing "dissuade[s] the individual and societal interest in facilitating informed and reliable decisionmaking" about the prescribing of pharmaceutical drugs.

A prohibition on the sale or exchange for value of patient- and prescriber-identifying information may survive constitutional scrutiny²⁶¹ for another noteworthy reason: the First Amendment only protects commercial speech when it is “neither misleading nor related to unlawful activity.”²⁶² “[T]here can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity,”²⁶³ the Court wrote, noting further that “[t]he government may ban forms of communication more likely to deceive the public than to inform it, or commercial speech related to illegal activity.”²⁶⁴ Even assuming drug manufacturers did not engage in misleading marketing, connections between patient support program data and arguably anticompetitive product hopping or fraudulent foundation-related kickbacks could constitute “relati[on] to illegal activity” sufficient to justify denying First Amendment protection to the data *qua* speech²⁶⁵ obtained as a result of patient support program enrollment.

Perhaps the *Sorrell* Court’s stance on the relative value of pharmaceutical detailing should not be faulted; much of the literature on product hopping emerged after *Sorrell* was decided, and foundation-related kickbacks, too, are a recent occurrence. The critical connections made in this Article between the collection of patient- and prescriber-identifying information and injurious (and potentially unlawful) drug maker activities underscore the non-innocuous nature of pharmaceutical marketing. Moreover, they make evident that the larger effects of targeted detailing—more expansively defined as the use of patient- and prescriber-identifying information for a company’s economic ends—extend beyond a tailored sales pitch during an unwelcome visit to a prescriber’s office. Drug company tactics to maximize pharmaceutical drug sales at the expense of patients and competitors are pervasive and well documented. Taking the realities of drug company marketing tactics in totality, a challenge to the constitutionality of a statute akin to that at issue in *Sorrell*—but modified to prohibit the sale or exchange for value of patient- and prescriber-identifying information by any entity, outside of a limited number of circumscribed exceptions—might be decided differently on

²⁶¹ *Central Hudson Gas and Electric Corporation v. Public Service Commission*, 447 U.S. 557 (1980), is widely credited with setting out a form of intermediate scrutiny that courts apply when assessing the constitutionality of prohibitions on commercial speech. To withstand intermediate scrutiny, a regulation must directly advance a substantial government interest and be narrowly tailored to achieve that interest. *Id.* at 564–65.

²⁶² *Id.* at 564.

²⁶³ *Id.* at 563.

²⁶⁴ *Id.* at 563–64.

²⁶⁵ Both *Ayotte* and *Mills* treated the transfer of prescriber-identifying data from data miners to detailers as conduct, not speech, but the opinions argued that even if the data were viewed as commercial speech, the state regulation burdening that speech could survive intermediate scrutiny under *Central Hudson*. See *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 52–53 (1st Cir. 2008); *IMS Health Inc. v. Mills*, 616 F.3d 7, 19–20 (1st Cir. 2010). In contrast, the Supreme Court in *Sorrell* held that disclosure and sale of prescriber-identifying information constituted speech for purposes of the First Amendment analysis. See *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 570 (2011). For sake of argument here, the Article presumes patient- and prescriber-identifying data are tantamount to speech.

the merits. Indeed, Justice Kennedy’s fleeting reference at the end of the *Sorrell* opinion to permissible content-based restrictions on speech when there is a legitimate government interest in “protecting consumers from ‘commercial harms’”²⁶⁶ seems well suited to the patient support program context.

Finally, courts have treated opt-in mechanisms for prescriber privacy protection as less restrictive and less likely to invoke “concerns about state paternalism”²⁶⁷ than uniform prohibitions on use of prescriber-identifying information. Applied to patient support program enrollment, however, a privacy opt-in mechanism to trigger confidentiality of patient- and provider-identifying information may not be enough. For the reasons discussed earlier, patients may fail to appreciate the dangers of information sharing in the patient support program context, and so may opt into confidentiality protections at a lower rate than might be expected in the presence of more complete information. For this reason, a default prohibition on the sale of patient- and prescriber-identifying information, with the option to permit sale of one’s information,²⁶⁸ may be a superior mechanism to optimize patient and prescriber confidentiality.

C. Reforming HIPAA: The Path Forward

A recent Notice of Proposed Rulemaking set out several proposed changes to the HIPAA Privacy Rule to strengthen individuals’ right of access to their own PHI²⁶⁹ and to enable information sharing in certain contexts.²⁷⁰ Although these changes aim largely to facilitate sharing of health information, additional modifications to the Privacy Rule to strengthen patients’ right to control uses and disclosures are in order. This section synthesizes lessons from the preceding discussion of patient support programs to make several specific recommendations for modifications to HIPAA to better protect patients’ control of their PHI.

Useful to this discussion are some key principles of the European Union’s General Data Protection Regulation (“GDPR”), which went into effect in May 2018. GDPR governs the processing of personally identifiable information (“PII”)

²⁶⁶ *Sorrell*, 564 U.S. at 579 (citing *Cincinnati v. Discovery Network*, 507 U.S. 410, 426 (1993)).

²⁶⁷ *Mills*, 616 F.3d at 22 (“[Opt-in mechanisms] regulate speech . . . only when private individuals choose not to be subject to certain kinds of communications, not simply because the state has identified particular communications as harmful.”).

²⁶⁸ The privacy default suggested here—conferring an ability to opt out of privacy protections—is equivalent to an opt-in regime for information sharing.

²⁶⁹ For example, a proposed modification would require covered entities to provide copies of PHI within 15 days. Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 Fed. Reg. 6,446, 6,460 (proposed Jan. 21, 2021) (to be codified at 45 C.F.R. pt. 160, 164). Another proposed modification would “expressly prohibit a covered entity from imposing unreasonable identity verification measures on an individual (or his or her personal representative) exercising a right under the Privacy Rule.” *Id.* at 6,470.

²⁷⁰ For example, a proposed modification would expressly grant permission for PHI to be disclosed without need for an authorization from covered entities to social service agencies and community based organizations that provide case management and “individual-level care coordination.” *Id.* at 6,476.

of EU residents by governmental and nongovernmental entities within and outside of the EU.²⁷¹ Among the data processing principles that GDPR embodies are purpose limitation; data retention; and data integrity and confidentiality.²⁷² First, purpose limitation requires that data be “collected and used only for specified, explicit, and legitimate purposes.”²⁷³ Second, personal data should be retained only as long as needed. Third, it should be processed with integrity and in a manner that maintains confidentiality.²⁷⁴ These principles translate readily to PHI data governance. Based on these principles and the vulnerabilities to which PHI is subject, several practical modifications to the HIPAA Privacy Rule are proposed below.

1. Impose a heightened standard for specifying purposes of the uses and disclosures of PHI in a HIPAA authorization: require that all uses and disclosures be explicit and stated with particularity.

In the spirit of the GDPR principles of purpose limitation, integrity, and confidentiality, entities seeking access to PHI through a HIPAA authorization should be required to specify purposes of each requested use or disclosure *with particularity*. A heightened standard for specification of purposes of requested uses and disclosures will place patients on notice and help maintain integrity and confidentiality of PHI, even when it is transferred to noncovered entities. Such a requirement will enhance individual agency over how PHI is used and disclosed; those who object to clearly articulated purposes or secondary uses can decline to provide consent. Notice of all intended uses of PHI, and a prohibition on purposes not expressly specified within an authorization, can also deter data brokers from unlawful or socially undesirable downstream activity.

2. Create a carve-in to include noncovered entities that receive PHI from covered entities explicitly within HIPAA’s mandates.

It is worth emphasizing again that drug manufacturers are not covered entities under HIPAA. HIPAA’s restricted reach currently leaves out many commercial entities that attain, buy, sell, and share health data. As legal scholars Lawrence Gostin and Sam Halabi have argued, “[t]he law should do more to affect companies that now collect and transfer personal data as readily as HIPAA-covered entities,”²⁷⁵ drug makers included. Noncovered entities that obtain PHI from covered entities should be brought within HIPAA’s mandates, and there is a strong argument to be made that PHI disclosed from a covered entity to a noncovered

²⁷¹ *Perspectives on the General Data Protection Regulation of the European Union: Hearing on Privacy Rights and Data Collection in a Digital Economy Before the S. Comm. on Banking, Hous., & Urb. Affs.*, 116th Cong. 4–5 (2019) (statement of Peter H. Chase, Senior Fellow, German Marshall Fund).

²⁷² *Id.* at 5.

²⁷³ *Id.*

²⁷⁴ *Id.*

²⁷⁵ Gostin & Halabi, *supra* note 125, at 234.

entity should be entitled to the same protections that covered entities must bestow upon the data.

Arguably, personally identifying health data should be subject to privacy protections whether or not the health data originated in a covered entity. Of course, this would entail a sweeping expansion of HIPAA. A more incremental change, and one tailored to the patient support program context, would include subsuming within HIPAA's purview noncovered entities that receive PHI from disclosing covered entities. It stands to reason that PHI originating in a covered entity should be owed a higher degree of protection, and one commensurate with the level of protection a covered entity must apply in the handling of those very data.

This underscores another important point: HIPAA's framework for PHI protection makes a distinction between covered entities and business associates of covered entities, on the one hand, and noncovered entities on the other. This distinction, however, is not the distinction best suited to regulate the modern-day trade in PHI; of course, that is because the HIPAA Privacy Rule was not designed with those ends in mind. A framework in which privacy protections attach to PHI, no matter the party to which it is transferred, would provide more comprehensive protection. Such a change would help meet patients' reasonable expectations regarding the degree of confidentiality and protection the law affords their PHI, and it would avoid a scenario of dramatic divergences in degrees of protection depending on the entity to which PHI is transferred.

3. Once brought within the bounds of HIPAA, all noncovered entities that receive PHI should be excepted from the redisclosure provision contained in the HIPAA Privacy Rule. Redisclosure by covered entities should be prohibited unless stated with particularity among uses and disclosures, including the parties to whom redisclosure will occur and the purposes of the redisclosure.

HIPAA authorizations must contain a statement, which the patient support program enrollment forms sampled here universally provide, that PHI once disclosed may be redisclosed with impunity and without limitation.²⁷⁶ This escape-valve provision effectively erases the protections of the rest of the Privacy Rule, rendering PHI protection a mere illusion. Although the redisclosure provision makes little sense from a patient privacy standpoint, there is another wrinkle in the Privacy Rule with respect to redisclosure: as the HIPAA Privacy Rule is currently written and interpreted, HHS cannot force noncovered entities that receive PHI from covered entities to specify in an authorization whether they intend to make future redisclosures of that PHI for remuneration. HHS summarizes:

Where the recipient of protected health information pursuant to an authorization is a third party that is not a covered entity or business associate, we do not have authority to require that entity to disclose to the disclosing covered entity or business associate whether it plans to further exchange the protected health information for

²⁷⁶ HIPAA authorizations must warn of "[t]he potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer . . . protected by this subpart." 45 C.F.R. § 164.508(c)(2)(iii) (2013).

remuneration for purposes of including such information on the authorization form. . . . In any event, the Privacy Rule retains the requirement that an authorization inform the individual of the potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and to no longer be subject to the Privacy Rule.²⁷⁷

In effect, noncovered entities have no legal obligations under the Privacy Rule to reveal either to the disclosing entity or to patients their plans or intentions to redisclose PHI obtained through an authorization. The redisclosure provision thereby effectively creates a disclosure rule: a default rule that permits future PHI sharing without authorization.

An issue basic to disclosure rules is whether subsequent sharing should be a default: “[W]hen personal information is obtained in a voluntary transaction, and sometimes when it is obtained without consent, the fundamental question is whether a rule permitting subsequent disclosure is superior, *as a default rule*, to a rule requiring privacy.”²⁷⁸ Why should a default rule permitting information sharing be superior to a privacy default in this context? Arguably, a privacy default better adheres to the fundamental principles for health data protection. It is important to recall that, for the reasons discussed earlier, patients do not properly value their PHI at the time of entering into the patient support program contract, with a tendency to underestimate the value of PHI to drug manufacturers and third parties. A privacy default, therefore, may produce a more just and efficient outcome by correcting for patients’ undervaluation of PHI at the time of contracting.

The HIPAA Privacy Rule would benefit from a default rule in which redisclosure by noncovered entities is not permitted. Covered entities—arguably more reliable data custodians—should be permitted to redisclose only when patients are notified *and* provide consent to the purposes and recipient of the redisclosure. The foregoing modifications would markedly enhance PHI protection.

Redisclosure often takes place through resale. Scholar Bonnie Kaplan aptly summarizes the unbounded risks associated with redisclosure of PHI through resale: “Data that can be sold, can be sold and replicated anywhere and, once sold, may be used for good or ill. Tracing the chain of data sales and use is difficult, making transparency and consent nearly impossible the further data are transferred from the original source.”²⁷⁹ Recommendations (2) and (3) above, in combination, will help limit the transferability of PHI beyond the entity to whom disclosure is authorized in the case of noncovered entities—in other words, the buck stops with

²⁷⁷ Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act, 78 Fed. Reg. 5,566, 5,608 (Jan. 25, 2013) (to be codified at 45 C.F.R. pts. 160, 164).

²⁷⁸ Murphy, *supra* note 135, at 2383.

²⁷⁹ Kaplan, *supra* note 155, at 319.

the noncovered entity and further redisclosure is not permitted—and it will increase transparency of redisclosures in the case of covered entities.²⁸⁰

4. Sale or exchange for value of PHI should be prohibited, or at a minimum, a framework for mandatory reporting and tracking of PHI sales by a federal government agency should be instituted.

Remuneration in exchange for PHI lacks a compelling justification; these exchanges form part of an obscure, highly profitable, data-driven industry that operates covertly—removed from the public eye and largely free from regulatory scrutiny. The lack of robust individual property rights in PHI in the United States facilitates these sales and helps explain both *why* they occur with such frequency and why patients are unaware of them. Not only should sales of PHI be tracked and reported to government agencies that monitor competition and consumer protection-related matters, such as the FTC or DOJ, but PHI sales should also be subject to mandatory reporting to the Office of the National Coordinator for Health Information Technology (“ONC”).²⁸¹

5. A more comprehensive framework is needed to govern PHI that becomes integrated with other types of health and non-health data.

When data outside of HIPAA protection, such as user-generated app data, credit card data, or banking data, are combined with PHI obtained via HIPAA authorizations, patients become even more vulnerable to manipulation, as the orbit of a person’s private, personally identifiable information shrinks. Recently, tech companies have begun to merge disparate data sources, including patient data from private healthcare systems, to develop health histories as part of consumer profiles.²⁸² Some drug manufacturers admit within their online privacy policies to

²⁸⁰ For more general arguments in favor of “use-transferability restrictions” for personal data and “opt-in defaults,” see Paul M. Schwartz, *Property, Privacy and Personal Data*, 117 HARV. L. REV. 2056, 2095–2106 (2004). Schwartz’s opt-in default is in line with the argument proposed here for redisclosure by covered entities: “[I]t would permit the transfer for an initial category of use of personal data, but only if the customer is granted an opportunity to block further transfer or use by unaffiliated entities. Any further use or transfer would require the customer to opt in—that is, it would be prohibited unless the customer affirmatively agrees to it.” *Id.* at 2098. Schwartz later acknowledges, however, that “many data-processing institutions are likely to be good at obtaining consent on their terms regardless of whether the default requires consumers to authorize or preclude information-sharing. . . . These entities provide services that most people greatly desire.” *Id.* at 2103. “For this reason,” Schwartz continues, “sophisticated consumer protection regimes do not rely exclusively on information-forcing defaults.” *Id.* at 2104.

²⁸¹ The ONC was established with the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009. See *About ONC*, HEALTHIT.GOV (Feb. 14, 2019), <https://www.healthit.gov/topic/about-onc> [<https://perma.cc/SM62-SDUS>].

²⁸² See, e.g., Rob Copeland, *Google’s “Project Nightingale” Gathers Personal Health Data on Millions of Americans*, WALL ST. J. (Nov. 11, 2019), <https://www.wsj.com/articles/google-s-secret-project-nightingale-gathers-personal-health-data-on-millions-of-americans-11573496790> [<https://perma.cc/49AS-DUAG>]; see also Sidney Fussell, *Google’s Totally Creepy, Totally Legal Health-Data Harvesting*, ATLANTIC (Nov. 14, 2019), <https://www.theatlantic.com/technology/archive/2019/11/google-project-nightingale-all-your-health-data/601999/> [<https://perma.cc/Z9W8-XJTG>] (noting that Google is “amassing a trove of

creating consumer profiles of their own,²⁸³ which are put to undisclosed uses. Professors I. Glenn Cohen and Michelle Mello have argued for a new regulatory regime for health-related data not currently within the reach of HIPAA,²⁸⁴ one that will “hold data users accountable for departures from authorized uses of data.”²⁸⁵ Such a regime is urgently needed, and this Article only begins to scratch the surface of what such a regime might include.

* * * *

A final matter regarding patient support programs warrants attention—namely, whether drug makers should administer patient support programs in the first instance. There is reason to doubt whether a principled basis exists for drug makers’ maintenance of patient support programs as they fit into the larger pharmaceutical drug distribution and delivery ecosystem. High manufacturer-imposed prices for specialty drugs are the impetus behind patient support programs; drug companies have assumed an intermediary role to ensure drug coverage and reimbursement, a gap that drug makers arguably should not fill. And the apparently gratuitous patient support program services raise drug prices in more ways than one: first, because drug makers may pass costs of patient support program services on to consumers in the form of higher drug prices; second, because drug makers may use valuable patient support program-derived data to target marketing, thwart competition, and maintain high prices; and third, because patient support program-derived financial assistance helps maintain inflated reimbursement flowing to drug manufacturers from public and private payers. With respect to the third point, society incurs a cost when patients consume specialty drugs that would otherwise be unattainable due to price because, even if patients see little in the way of cost-sharing, public and private payers bear the brunt of unreasonable prices.

A policy prohibiting all drug maker-derived financial assistance for pharmaceutical drugs could have the salutary effect of inducing an eventual lowering of drug prices; after all, without patient support programs, manufacturers could not achieve reasonable levels of utilization. (A concern, of course, with this proposal is that patient access will suffer until a reduction in price occurs.) Specialty pharmacies, hospitals, and clinics, which are closer to the point of drug dispensation, may be better suited to provide the behavioral components of patient

data about our shopping habits, the prescriptions we use, and where we live, and few regulations are governing how it uses these data”).

²⁸³ In Pfizer’s online privacy policy, for example, it admits to collecting data in order to draw “inferences . . . from any of the information identified above to create a profile about a resident reflecting the resident’s preferences, characteristics, psychological trends, predispositions, behavior, attitudes, intelligence, abilities, and aptitudes.” See *Pfizer Privacy Policy U.S.*, PFIZER, <https://www.pfizer.com/Privacy> [<https://perma.cc/X23T-62TA>] (quotation available in part (K) of the table labeled “Categories of Personal Data that We Collect and Disclose”). This disclosure was made pursuant to the CCPA of 2018, which provided Californians with additional rights to know how businesses use the data they collect (§ 1798.110), to opt out of the sale of personal information (§ 1798.120), and to request deletion of personal information (§ 1798.105).

²⁸⁴ See I. Glenn Cohen & Michelle M. Mello, *HIPAA and Protecting Health Information in the 21st Century*, 320 *JAMA* 231, 232 (2018).

²⁸⁵ *Id.*

support program services that aim to educate patients and improve drug adherence. And even if drug makers might logically shoulder the burden of patient support program financial and nonfinancial support, patient privacy would be better served if patient support programs were managed by independent third parties with strict firewalls blocking transfer of PHI back to drug makers. As patient support programs currently operate, nothing prevents a drug maker from acquiring patient-specific data on every ostensibly consenting enrollee, and nothing stops a drug maker from putting those data to uses that ultimately harm patients and society.

VII. CONCLUSION

Acquisition of PHI on every patient support program enrollee represents hidden value that accrues to drug companies when they offer otherwise-gratuitous patient support program services. Reining in undesirable uses of patient- and prescriber-level data obtained through patient support programs requires modernization of the HIPAA Privacy Rule—a task that is long overdue. A clearly defined set of privacy protections for PHI transferred from covered entities to non-covered entities and a rewriting of HIPAA’s redisclosure provision are sorely needed. Only with proper protection of PHI can patients, providers, and policymakers find comfort knowing that adequate safeguards exist to prevent manipulation of pharmaceutical prescribing, utilization, and reimbursement.

APPENDIX I. PSPs IN THE PUBLISHED LITERATURE

Authors; Year of Publication; Country	Drug; Target Disease or Population	Patient Support Program (PSP); PSP services	PSP Sponsor	Study Funding Source/Pharma-related Disclosures
Bourdin et al.;^{i,ii} 2019 and 2020; Switzerland	Fingolimod; relapsing-remitting MS (RRMS)	Fingolimod-Patient Support Program (F-PSP); medication adherence support and pharmacovigilance (tracking adverse reactions, medical test reminders, symptom monitoring, patient education)	Pharmacy-based; Unrestricted grant from Novartis Pharma Schweiz AG	One or more authors is a consultant to a pharmaceutical company
Lenz & Harms;ⁱⁱⁱ 2020; Germany	Various disease-modifying therapies (DMTs) for RRMS	Varied; Betaplus, MS Gateway (Bayer); MS Life (Biogen); Adveva (Merck Serono); Mein MS Service (Mylan); MSUNDICH, Extracare (Novartis); MS Begleiter (Sanofi-Genzyme); Aktiv mit MS (Teva)	Various pharmaceutical companies (see column 3)	Study was funded by a grant from Teva One or more authors received support from a pharmaceutical company
Roche, McCarry & Mellors;^{iv} 2014; Republic of Ireland	Subcutaneous interferon beta-1a; MS	MySupport program; telephone and text messaging; website access; face-to-face support from a MySupport nurse; in-person injection training	Merck Serono	One or more of the authors is employed at a pharmaceutical company (Merck Serono); the study was supported by Merck
Wharton et al.;^v 2020; Canada	Liraglutide; those with BMI greater than or equal to 30 or greater than or equal to 27 with at least one weight-related comorbidity and previous failed weight management efforts	SaxendaCare; weekly emails; one-on-one personalized meetings with a nurse or dietician; website materials; curriculum for weight management; injectable pen training; reminders for dosing/refills	Novo Nordisk	One or more of the authors is employed at a pharmaceutical company (Novo Nordisk); the study was sponsored by Novo Nordisk A/S
Rubin et al.;^{vi} 2017; United States	Humira (adalimumab); patients with Crohn's, UC, rheumatoid arthritis, psoriasis, psoriatic arthritis, or ankylosing spondylitis	AbbVie sponsored-PSP for all adalimumab-approved indications; Nurse Ambassador; financial assistance (HUMIRA protection plan); injection training, pen disposal, and medication reminders	AbbVie	Study design, conduct, and financial support were provide by AbbVie; one or more authors received financial support from AbbVie
Sato et al.;^{vii} 2018; Japan	Teriparatide; patients with osteoporosis	Eli Lilly-sponsored PSP; call center support; monthly calendar with daily injection checklist; certificates of recognition at periodic time intervals for those who maintained treatment	Eli Lilly Japan	Study was sponsored, designed, and funded by Eli Lilly Japan
Katsarava et al.;^{viii} 2015; Germany	IFN beta-1a (Avonex); RRMS	MS-CARE (patient management program or PMP); injection training; nursing support, motivation, advice; quarterly visits; disease education	Biogen GmbH	One or more authors was employed by a pharmaceutical company (Biogen GmbH)
Srulovici et al.;^{ix} 2018; Israel	Humira (adalimumab)	AbbVie-sponsored PSP; injection training; welcome kit; bag; sharps bin; call center access; informational magazines; nurse support	AbbVie	Study was funded by Biogen Study design, conduct, and financial support were provided by AbbVie

Authors; Year of Publication; Country	Drug; Target Disease or Population	Patient Support Program (PSP); PSP services	PSP Sponsor	Study Funding Source/Pharma-related Disclosures
Marshall et al.; ^{xxi} 2018; Canada	Humira (adalimumab); patients with immune-related inflammatory diseases	AbbVie Care PSP; care-coach calls (CCCs); patient education; injection training; delivery and disposal of supplies; financial assistance; patient reminders; directed contact with registered nurses; “comprehensive reimbursement assistance”	AbbVie	Study design, conduct, and financial support were provided by AbbVie
Landtblom et al.; ^{xii} 2019; Sweden	Rebif; RRMS	MySupport Plus, a PSP provided by an independent vendor, Health Solutions; phone calls, text messages, and emails from an MS nurse regarding device management, treatment effects, exercise and physical activity, treatment adherence, and motivation	Merck	One or more authors was employed by a pharmaceutical company (Merck) The study was funded by Merck
Samawi et al.; ^{xiii} 2019; Canada	Trifluridine/tipiracil; metastatic colorectal cancer	Taiho Pharma Canada’s Patient Support Program	Taiho Pharma Canada	One or more authors was employed by a pharmaceutical company (Taiho Pharma Canada)
Zhou et al.; ^{xiv} 2018; USA	Insulin glargine; type 2 diabetics	COACH PSP; tailored disease education, product support, encouragement of lifestyle changes; online tools; educational emails; text messages; phone calls	Sanofi	Study was supported by Sanofi
Moss et al.; ^{xv} 2010; United States	Asacol (mesalamine), product of Proctor & Gamble); ulcerative colitis patients	Nurse-delivered PSP; disease-specific information; phone calls from a nurse to assess risk for noncompliance and intervene with psychological techniques to improve adherence	Script Assist (CenCorp Health Solutions)	The study was funded by an investigator-initiated grant from Proctor & Gamble, which had no role in the study design, study conduct, or manuscript preparation
Drulovic et al.; ^{xvi} 2017; Serbia	Interferon beta-1b; multiple sclerosis	Betaplus program; specialist nurse support; handling and administration training; personalized reminder service	Bayer	One or more authors received funding from pharmaceutical companies
Pozzilli et al.; ^{xvii} 2011; Europe, Middle East, Asia	Betaferon (Interferon-beta-1b); multiple sclerosis	Betaplus program; specialist nurse, personalized text messaging with refill reminders and infection reminders; web resources	Bayer	The study was funded by Bayer Schering Pharma AG. One or more authors received funding from pharmaceutical companies
Brixner et al.; ^{xviii} 2019; United States	Humira (adalimumab); patients with all ADA-approved indications	HUMIRA Complete PSP; medication counseling; training; virtual reminders; Nurse Ambassador program	AbbVie	One or more authors was employed by a pharmaceutical company (Bayer Schering) One or more authors was employed by a pharmaceutical company (AbbVie) Study design, conduct, and financial support were provided by AbbVie
Brixner et al.; ^{xix} 2019; United States	Humira (adalimumab); patients with all ADA-approved indications	HUMIRA Complete PSP; medication counseling; training; virtual reminders; Nurse Ambassador program	AbbVie	One or more authors was employed by a pharmaceutical company (AbbVie)

Authors; Year of Publication; Country	Drug; Target Disease or Population	Patient Support Program (PSP); PSP services	PSP Sponsor	Study Funding Source/Pharma-related Disclosures
Besette et al.; ^{xx} 2018; Canada	Humira (adalimumab); patients with ankylosing spondylitis	AbbVie Care PSP (AC-PSP); Care Coach calls (CCCs); patient education; injection training; delivery and disposal of supplies; financial assistance; patient reminders; direct contact with trained registered nurses	AbbVie	Financial support for the study was provided by AbbVie One or more authors was employed by a pharmaceutical company (AbbVie) The study was funded by AbbVie
Van den Bosch et al.; ^{xxi} 2017; Europe, Israel, Mexico, Puerto Rico, and Australia	Humira (adalimumab); patients with rheumatoid arthritis	AbbVie Care PSP (AC-PSP); Care Coach calls (CCCs); patient education; injection training; delivery and disposal of supplies; financial assistance; patient reminders; direct contact with trained registered nurses	AbbVie	The study was funded by AbbVie. AbbVie contributed to study design, data collection, and analysis One or more authors was employed by a pharmaceutical company (AbbVie)
Narula et al.; ^{xxii} 2018; Canada	Humira (adalimumab); patients with Crohn's disease	AbbVie Care PSP (AC-PSP); Care Coach calls (CCCs) by Wellness Care Managers to provide training, education, and customized coaching; self-injection training; comprehensive reimbursement assistance; delivery and disposal of supplies	AbbVie	The study was funded by AbbVie. AbbVie contributed to study design, interpretation of data, and review and approval of the publication One or more authors was employed by a pharmaceutical company (AbbVie)
Jones et al.; ^{xxiii} 2017; Canada	Infliximab; patients with various autoimmune inflammatory disorders (Crohn's disease, ulcerative colitis, psoriasis, rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis)	BioAdvance PSP; one-on-one support from a BioAdvance coordinator who assists with patient education and coordinating infusions; assistance with drug shipment and follow-up; reimbursement and financial assistance	Janssen	The study was funded by Janssen. One or more authors received fees from Janssen One or more authors was employed by a pharmaceutical company (Janssen)
Freidel et al.; ^{xxiv} 2015; Germany	Extavia (Interferon beta-1b); RRMS	Extracare; MS nurses provide telephone counseling, training on injection techniques, and assistance with management of side effects; starter bag for carrying the medication; written guide; DVD on how to perform the injections	Novartis	One or more authors was employed by a pharmaceutical company (Novartis) Financial support for the study was provided by Novartis Pharma GmbH
Pashos, Kragin & Khan; ^{xxv} 2012; United States	Revlimid (lenalidomide); Thalomid (thalidomide); Multiple myeloma and myelodysplastic syndrome	Celgene Patient Support (CPS) Program; CPS specialist investigates health insurance benefits; facilitates prior authorizations; assists with appeal support after insurance denials, navigates Medicare and other coverages; assesses copay options; monitors the status of pending prescriptions; administers the process of applying for free medication; guides patients	Celgene	One or more authors was employed by a pharmaceutical company (United BioSource and Celgene) Celgene funded the study

Authors; Year of Publication; Country	Drug; Target Disease or Population	Patient Support Program (PSP); PSP services	PSP Sponsor	Study Funding Source/Pharma-related Disclosures
Jones et al.;^{xxvi} 2013; United States	Copaxone (glatiramer acetate); RRMS	through restricted-distribution programs (RDPs) Shared Solutions support program; customized, continuous, holistic nursing support	Teva	One or more authors was employed by a pharmaceutical company (Teva) Study funding was provided by Teva
Kohlmann et al.;^{xxvii} 2013; Germany	Betaferon (interferon beta-1b); MS	German BETAPLUS PSP; nurse telephone calls; nurse home visits; patient hotline; mail education materials, online offerings, such as chat rooms for peer-to-peer interactions and online patient education materials	Bayer	One or more authors was employed by a pharmaceutical company (Bayer and United BioSource Corporation) One or more author(s) is a consultant to a pharmaceutical company

APPENDIX II (1): ENROLLMENT FORM – BASIC FEATURES

Drug: Brand (generic)	PSP name	Pharmaceutical Sponsor	Patient information (Name, DOB, address, phone, SSN)	Prescriber information (contact information, NPI) or prescriber signature (authorization of medical necessity)	Bifurcated enrollment: Option to enroll in disease support or financial programs separately
Adepas (riociguat)	myAIM	Bayer	Y (no SSN)	Y (both)	Y
				Also diagnosis and prescription information	
Afstyla (recombinant Factor VIII for hemophilia)	My Source	CSL Behring	Y	Y (both)	N
Betaseron (interferon beta-1b)	BETAPLUS	Bayer	Y	Y (both)	N
*Not drug specific	Access Solutions	Genentech	Y (no SSN)	N	Y ("Patient consent to enroll in optional disease-specific education, support programs, market research and communication that may be considered marketing. I understand my PII may be needed for me to participate in these programs.")
Actimmune	Horizon Patient Services	Horizon	Y (no SSN)	Y (both)	N
Copaxone	Shared Solutions	Teva	Y (no SSN)	Y (both)	N
Various Amgen products: Aranesp (darbepoetin alfa); Imylgic (talimogene laherparepvec); Kyprolis (carfilzomib); Neulasta (pegfilgrastim); Neulasta Onpro kit; Nplate (romiplostim); Riabni (rituximab-arrx); Vectibix (panitumumab); Blincyto (blinatumomab); Kanjinti (trastuzumab-anns); Mvasi (bevacizumab-awwb); Neupogen (filgrastim); Prolia (denosumab); Xgeva (denosumab)	Amgen Assist 360: Amgen Nurse Navigator Program	Amgen	Y (no SSN)	N	N
Wakix (pitolisant)	None	Harmony Biosciences	Y (last four of SSN)Also: diagnosis and prescription	Y (both)	N

Drug: Brand (generic)	PSP name	Pharmaceutical Sponsor	Patient information (Name, DOB, address, phone, SSN)	Prescriber information (contact information, NPI) or prescriber signature (authorization of medical necessity)	Bifurcated enrollment: Option to enroll in disease support or financial programs separately
AROMASIN® (exemestane);BOSULIF® (bosutinib);BRAFTOVI® (encorafenib);DAURISMO™ (glasdegib sodium);EMCYT® (estramustine phosphate sodium);IBRANCE® (palbociclib);INLYTA® (axitinib);LORBRENA® (lorlatinib);MEKTOVI® (binimetinib);SUTENT® (sunitinib malate);TALZENNA® (talazoparib);VIZIMPRO® (dacomitinib);XALKORI® (crizotinib);BESPONSA® (inotuzumab ozogamicin);CAMPTOSAR® (irinotecan hydrochloride);ELLENCER® (epirubicin hydrochloride);IDAMYCIN® (idarubicin hydrochloride);MYLOTARG™ (gemtuzumab ozogamicin);TORISEL® (temsirolimus);NIVESTYM® (filgrastim-aafi);NYVEPRIA™ (pegfilgrastim-apgf);RETACRIT® (epoetin alfa-epbx);RUXIENCETM (rituximab-pvvr);TRAZIMERA™ (trastuzumab-qyyp);ZIRABEV™ (bevacizumab-bvzr)	Oncology Together	Pfizer	Y	Y (both) Also diagnosis and prescription information	Y
Xeljanz (tofacitinib)	Xelsource	Pfizer	Y (no SSN)	Y (both)Also diagnosis and prescription information	Y
Xembify (immune globulin subcutaneous human-klhw)	Xembify Connexions	Grifols	Y (no SSN)	Y (prescriber signature and date only)	Y (Optional Xembify Connexions patient education program enrollment)
Entyvio (vedolizumab)	EntyvioConnect	Takeda	Y (no SSN)	Y (both)	N
Acthar Gel (corticotropin injection)	Acthar Patient Support	Mallinckrodt Pharmaceuticals	Y (no SSN)	Y (both) - also documentation of treatment history	N

Drug: Brand (generic)	PSP name	Pharmaceutical Sponsor	Patient information (Name, DOB, address, phone, SSN)	Prescriber information (contact information, NPI) or prescriber signature (authorization of medical necessity)	Bifurcated enrollment: Option to enroll in disease support or financial programs separately
Synribo (omacetaxine mepesuccinate) injection (subcutaneous) Bendeka (bendamustine hydrochloride) injection Granix (tbo-filgrastim) injection Truxima (rituximab-abbs) injection Trisenox (arsenic trioxide) injection Treanda (bendamustine hydrochloride) injection Herzuma (trastuzumab-pkrb) injection Xenazine (tetrabenazine)	CORE (Comprehensive Oncology Reimbursement Expertise) Program	Teva Pharmaceuticals	Y (including SSN)	Y (both)	N
Xenazine (tetrabenazine)	XENAZINE Information Center	Lundbeck	Y (no SSN)	Y (both)	N
*Not drug specific	Assist (Access Solutions and Support Team)	United Therapeutics	Y (including SSN)	Y (both)	N
Ajovy (fremanezumab-vfrm) injection	Shared Solutions	Teva	Y (no SSN)	Y (both)	N

APPENDIX II (2): HIPAA AUTHORIZATION - CORE ELEMENTS

PSP name	Description of the PHI to be used or disclosed	ID of the persons/entities authorized to make the disclosure	ID of the persons/entities authorized to make use of the disclosure (recipients of the PHI)	Description of the purpose(s) of the requested use or disclosure	Expiration date or event	Signature of the individual and date
myAIM	Y; name, address, phone number, prescription, treatment, and insurance information	Y ("my healthcare providers, pharmacies, and health plan insurers")	Y ("Bayer and its agents")	Y (Purpose/uses: (1) to communicate with my healthcare providers, insurers, and myself, (2) to provide educational materials (myAIM) support services, including providing Adempas to me; (3) to allow Bayer to learn how well the Adempas Patient Support Program is working)	Y; ten years after signing	Y
My Source	Y; "appropriate PHI"	Y ("my healthcare providers, including pharmacies and insurance providers")	Y ("CSL Behring, entities in connection with the administration of My Source, and contractors")	Y (Purpose/uses: "(1) to establish my eligibility for benefits; (2) to communicate with my healthcare providers and me about my medical care; (3) to facilitate the provision of products, supplies, or services by a third party (4) to register me in any applicable product registration program required for my treatment.")	Y; two years after signing	Y
BETAPLUS	Y (Name, address, and telephone number; relevant medical records and financial information; eligibility for assistance; treatment and how it is coordinated; medication and when you receive it; participation in the BETAPLUS program)	Y ("your doctors, pharmacies, and health insurance benefit providers")	Y ("Bayer and the companies it works with")	Y (To ensure the accuracy and completeness of this form; To arrange for nursing services and other ongoing support, including education, training, and communication; To help you with reimbursement questions; To see if you qualify for financial or copay assistance; To determine your eligibility for other programs, foundations, or alternate sources of funding to help with the costs of obtaining BETASERON; To communicate with you, your healthcare providers, and your insurers about your treatment with BETASERON; To provide information on coverage and reimbursement to your	Y (at the end of your participation in the Program or 5 years after signing, whichever comes first)	Y

PSP name	Description of the PHI to be used or disclosed	ID of the persons/entities authorized to make the disclosure	ID of the persons/entities authorized to make use of the disclosure (recipients of the PHI)	Description of the purpose(s) of the requested use or disclosure	Expiration date or event	Signature of the individual and date
Access Solutions	Y (Name and birthdate; Address, telephone number and email address; Important financial information, as necessary; Information on your medical condition, as necessary; Information about your health benefits or health insurance coverage)	Y ("my physician, pharmacy and my health plan(s)")	Y ("Genentech and/or Genentech Patient Foundation")	healthcare providers; To make relevant educational materials or product information available to you; To evaluate healthcare provider prescribing patterns and do other sales research; To comply with laws) Y (Purpose: "facilitating my access to Genentech products and providing the services described below, and (ii) further disclose my PII to others who are assisting them in these services, and to my health care provider(s), health care entities, pharmacies, and health plan(s) for purposes of providing these services")	Y (three years from signing or enrollment, whichever comes first)	Y
Horizon Patient Services	Y (individually identifiable health information, including "medical records, insurance coverage information, and my name, address and telephone number")	Y ("my healthcare providers, my health insurance carriers, and my pharmacies")	Y ("Horizon Therapeutics plc and its affiliates and their respective agents and representatives (collectively, "Horizon"), including third parties authorized by Horizon to administer drug support and to dispense drugs (collectively, "Horizon Patient Services")	Y (Purposes: "(1) to establish eligibility for benefits; (2) to communicate with healthcare providers and me about my medical care; (3) to facilitate the provision of products, supplies, or services by a third party including, but not limited to, specialty pharmacies; (4) to register me in any applicable product registration program required for my treatment; (5) to enroll me in eligible patient support programs offered by Horizon Patient Services™ and/or Horizon, including nursing or patient access support services (government-reimbursed programs may not be eligible for all support services offered; please contact Horizon Patient Services for determination); and (6) to send me marketing	Y ("the duration of remaining on this treatment or 10 years from the date of signing, whichever is greater")	Y

PSP name	Description of the PHI to be used or disclosed	ID of the persons/entities authorized to make the disclosure	ID of the persons/entities authorized to make use of the disclosure (recipients of the PHI)	Description of the purpose(s) of the requested use or disclosure	Expiration date or event	Signature of the individual and date
				information related to my treatment or condition (or related products or services in which I might be interested) and to contact me occasionally to obtain my feedback (for market research purposes only) about my treatment, my condition, or my experience with Horizon")		
Shared Solutions	Y ("my personal health information on this form as well as information related to my medical condition, treatment, care management, prescriptions and health insurance")	Y ("my healthcare providers, pharmacies and health plan(s)")	Y ("Teva Pharmaceuticals USA, Inc. and its affiliates, contractors and agents, including its third party patient support program service provider (collectively "Teva")"	Y (Purposes: "provide me with access to services related to my prescribed medication and/or medical condition ("Program"), including (i) enrollment in the Program; (ii) conducting benefits investigation and coordinating my insurance coverage, which may include allowing a Teva field based representative to access my information and engage with my healthcare providers directly, if necessary; (iii) if needed, determining my eligibility for and coordinating financial assistance; (iv) coordinating prescription fulfillment and product replacement; (v) providing nursing support, including product administration training and education; (vi) facilitating quality and adverse event reporting activities; (vii) conducting data analytics, market research and Program related business activities; (viii) contacting me by direct mail or by electronic or telephonic means to the contact information on this form or to any future contact information provided by me or on my behalf in connection with carrying out	Y ("This Authorization will remain in effect until the Program ends.")	Y

PSP name	Description of the PHI to be used or disclosed	ID of the persons/entities authorized to make the disclosure	ID of the persons/entities authorized to make use of the disclosure (recipients of the PHI)	Description of the purpose(s) of the requested use or disclosure	Expiration date or event	Signature of the individual and date
Amgen Assist 360: Amgen Nurse Navigator Program	Y ("personal information, including personal health information")	Y ("derived from a Health Care provider, health care plan, pharmacy, pharmaceutical company, laboratory and/or their contractor ("Health Care Provider")")	Y ("Amgen and its contractors and business partners")	<p>the Program services, including adherence related communications, reminders, and support, for which the third party service provider may receive financial remuneration from the manufacturer of your medication)</p> <p>Y (To operate, administer, enroll me in, and/or continue my participation in Amgen's Amgen Assist 360™ program or any other Amgen-affiliated patient support services and activities related to my condition or treatment (for example, co-pay card programs, reimbursement assistance programs, drug coverage verification, nurse educator services, adherence programs, and disease management support); To contact, with my permission, my doctor and the rest of my Health Care team and share with them my health information that may be useful for my care; To provide me with informational and promotional materials relating to Amgen products and services, and/or my condition or treatment; To improve, develop, and evaluate products, services, materials, and programs related to my condition or treatment)</p>	Y ("earlier of (5) years or until my participation in the program ends through my cancellation, unless a shorter time period is required by state law")	Y
None	Y ("my personal health information, including information related to my medical condition, treatment, care management, health insurance coverage and claims, and any other	Y ("my physicians or other healthcare providers and staff, my health insurance company, and my pharmacy providers")	Y (Harmony Biosciences and its representatives, agents, and contractors)	Y (I authorize Harmony to receive, use, and disclose my protected health information to (i) enroll me in and contact me about Harmony medication support programs; (ii) provide me with educational materials, information, and services; (iii) verify, investigate, assist with,	Y (ten (10) years, or such shorter timeframe required by applicable law, from the day I sign it as indicated by the date next to my	Y

PSP name	Description of the PHI to be used or disclosed	ID of the persons/entities authorized to make the disclosure	ID of the persons/entities authorized to make use of the disclosure (recipients of the PHI)	Description of the purpose(s) of the requested use or disclosure	Expiration date or event	Signature of the individual and date
	information contained on this treatment form")			and coordinate insurance coverage with my insurers; (iv) coordinate prescription fulfillment and refills; (v) assist with analyses related to the quality, efficacy, and safety of my treatment as well as patient access and adherence; (vi) to share and provide access to information generated by WAKIX for You that may be useful for my care; and (vii) to improve, develop, and evaluate WAKIX for You, its offerings, and materials. I authorize Harmony to contact me to provide such services and information by mail, email, fax, telephone call, and text message (including calls and text messages made with an automatic telephone dialing system or a prerecorded voice), as well as other mutually agreed-upon means."	signature unless otherwise canceled earlier)	
Oncology Together	Y ("I understand that my health information includes information relating to my medical condition, treatment, and insurance coverage, as well as identifying information about me (including, for example, my name, address, and date of birth).")	Y ("my physicians, pharmacies, laboratories, and other healthcare providers")	Y (Pfizer Inc., the Pfizer Patient Assistance Foundation, Pfizer affiliates and its vendors)	Y ("My health information will be shared with Pfizer so that Pfizer may provide me with various support and information to help me access a Pfizer medicine, which may include the following, depending on your program (collectively, "Patient Support Activities"): Providing benefits investigations/verification and reimbursement support, including: Assisting with identification of prior authorization requirements and Assisting with identification of requirements of your insurer for appeal of a denied claim; Determining my eligibility for	4 years from date of signature, unless patient withdraws sooner	Y

PSP name	Description of the PHI to be used or disclosed	ID of the persons/entities authorized to make the disclosure	ID of the persons/entities authorized to make use of the disclosure (recipients of the PHI)	Description of the purpose(s) of the requested use or disclosure	Expiration date or event	Signature of the individual and date
Xelsource	Y ("my health information includes information relating to my medical condition, treatment, and insurance coverage, as well as identifying information about me (including, for example, my name, address, and date of birth)")	Y ("my physicians, pharmacies, laboratories, and other healthcare providers, and my health insurers")	Y (Pfizer Inc., the Pfizer Patient Assistance Foundation, Pfizer affiliates and its vendors)	and helping me access co-pay support or free drug programs; Sending me a device and starter kit (where appropriate); Communicating with my Healthcare Providers about a Pfizer medicine and Patient Support Activities; Providing me with financial assistance resources and information if I'm eligible; Providing me with disease management and other educational materials, as well as information about Pfizer's products, services, and programs, and may include sending me surveys about my experience with Pfizer products, services, and programs. Pfizer also may use my health information for quality assurance purposes and to evaluate and improve our operations and services.") Y ("collectively, "Patient Support Activities"): Providing benefits investigations/verification and reimbursement support, including: Assisting with identification of my insurer's prior authorization requirements and assisting with identification of my insurer's requirements for appealing a denied claim; Determining my eligibility for and helping me access co-pay support or free drug programs; Sending the patient a starter kit (where appropriate); Communicating with my Healthcare Providers about a Pfizer medicine and Patient	4 years from date of signature, unless patient withdraws sooner	Y

PSP name	Description of the PHI to be used or disclosed	ID of the persons/entities authorized to make the disclosure	ID of the persons/entities authorized to make use of the disclosure (recipients of the PHI)	Description of the purpose(s) of the requested use or disclosure	Expiration date or event	Signature of the individual and date
Xembify Connexions	Y ("personal and health information")	Y ("my healthcare providers, pharmacies, health plans, or payers ("my healthcare organizations"))	Y (Grifols, its affiliates, agents, and contractors)	Support Activities; Providing me with financial assistance resources and information if I'm eligible; Providing me with disease management and other educational materials, as well as information about Pfizer's products, services, and programs, and may include sending me surveys about my experience with Pfizer products, services, and programs. Pfizer also may use my health information for quality assurance purposes and to evaluate and improve our operations and services.)	5 years from date of signature or shorter, as required by law or state of residence	Y
<i>EntyvioConnect</i>	Y ("my protected health information, including, but not limited to, information relating to my medical condition, treatment, care management, and health insurance, as well as all information provided on this form	Y (" my physician, health insurance, and pharmacy providers (including any specialty pharmacy that receives my prescription) "	Y ("Takeda Pharmaceuticals U.S.A., Inc. and its present or future affiliates, including the affiliates and service providers that work on Takeda's behalf in connection with the EntyvioConnect Patient Support	Y (" for the purpose of facilitating the provision of the EntyvioConnect Patient Support Program products, supplies, or services as selected by me or my physician and may include (but not be limited to) verification of insurance benefits and drug coverage, prior authorization education, financial assistance with	within 5 years from the date it is signed	Y

PSP name	Description of the PHI to be used or disclosed	ID of the persons/entities authorized to make the disclosure	ID of the persons/entities authorized to make use of the disclosure (recipients of the PHI)	Description of the purpose(s) of the requested use or disclosure	Expiration date or event	Signature of the individual and date
	("Protected Health Information")		Program (the "Companies")	co-pays, patient assistance programs, and other related programs. I authorize the Companies to 1) receive, use, and disclose my Protected Health Information in order to enroll me in EntyvioConnect and contact me, and/or the person legally authorized to sign on my behalf, about EntyvioConnect; 2) provide me, and/or the person legally authorized to sign on my behalf, with educational materials, information, and services related to EntyvioConnect; 3) verify, investigate, and provide information about my coverage for Entyvio, including but not limited to communicating with my insurer, specialty pharmacies, and others involved in processing my pharmacy claims to verify my coverage; 4) coordinate prescription fulfillment; and 5) use my information to conduct internal analyses."		
Acthar Patient Support	Y ("health information relating to my medical condition, treatment and insurance coverage (my "Health Information")")	Y ("my physician(s), my health insurance company and my pharmacy providers")	Y ("Mallinckrodt ARD LLC ("Mallinckrodt"), the distributor of Acthar, and its agents, authorized designees and contractors, including Mallinckrodt reimbursement support personnel and United BioSource LLC ("UBC") or any other operator of	Y ("(1) provide certain services to me, including reimbursement and coverage support, patient assistance and access programs, medication shipment tracking, and home injection training, (2) provide me with support services and information associated with my Acthar therapy, (3) serve internal business purposes, such as marketing research, internal financial reporting and	agreement is "in effect for 5 years unless a shorter period is provided for by state law or until the conclusion of any ongoing coverage support, whichever is longer,"	Y

PSP name	Description of the PHI to be used or disclosed	ID of the persons/entities authorized to make the disclosure	ID of the persons/entities authorized to make use of the disclosure (recipients of the PHI)	Description of the purpose(s) of the requested use or disclosure	Expiration date or event	Signature of the individual and date
			Acthar Patient Support on behalf of Mallinckrodt (collectively, 'Manufacturer Parties'')	operational purposes, and (4) carry out the Manufacturer Parties' respective legal responsibilities."		
CORE (Comprehensive Oncology Reimbursement Expertise) Program	Y ("my personal health information on this form as well as information related to my medical condition, treatment, care management, prescriptions, and health insurance")	Y ("my healthcare providers, pharmacies, and health plan(s)")	Y ("Teva Pharmaceuticals USA, Inc. and its affiliates, contractors and agents, including their third party patient support program service provider (collectively "Teva")")	Y ("to provide me with access to services related to my prescribed medication and/or medical condition ("Program"), including (i) enrollment in the Program; (ii) conducting benefits investigation and coordinating my insurance coverage, which may include allowing a Teva field based representative to access my information and engage with my healthcare provider directly, if necessary; (iii) if needed, determining my eligibility for and coordinating financial assistance; (iv) coordinating prescription fulfillment and product replacement; (v) providing nursing support; (vi) facilitating quality and adverse event reporting activities; (vii) conducting data analytics, market research, and Program related business activities; (viii) contacting me by direct mail or by electronic or telephonic means to the contact information on this form or to any future contact information provided by me or on my behalf in connection with carrying out the Program services, including adherence related communications, reminders, and support, for	Y ("This Authorization will remain in effect until the Program ends.")	Y

PSP name	Description of the PHI to be used or disclosed	ID of the persons/entities authorized to make the disclosure	ID of the persons/entities authorized to make use of the disclosure (recipients of the PHI)	Description of the purpose(s) of the requested use or disclosure	Expiration date or event	Signature of the individual and date
XENAZINE Information Center	Y ("my personal health information related to this prescription form or my use or potential use of XENAZINE, including my personal contact information on this form (collectively, my "Information")")	Y ("my healthcare providers (including pharmacy providers) and health plans")	Y ("the patient support program called the XENAZINE Information Center (the "Program")")	<p>which the third party service provider may receive financial remuneration from the manufacturer of your medication")</p> <p>Y ("(1) establish my benefit eligibility; (2) communicate with my healthcare providers and health plans about my benefit and coverage status and my medical care; (3) provide support services, including facilitating the provision of XENAZINE to me, as well as any information or materials related to such services or Lundbeck products, including promotional or educational communications; (4) evaluate the effectiveness of XENAZINE support programs; (5) report safety information, including in communications with the US Food and Drug Administration and other government authorities; (6) contact me regarding this prescription form or my use or potential use of XENAZINE and provide me with related patient support communications, including through messages left for me that disclose that I take or may take XENAZINE; and (7) allow Lundbeck to analyze the usage patterns and the effectiveness of Lundbeck products, services, and programs and help develop new products, services, and programs, and for other Lundbeck general business and administrative purposes.")</p>	Y ("10 years from the date it is signed by me or such timeframe as allowed by law.")	Y

PSP name	Description of the PHI to be used or disclosed	ID of the persons/entities authorized to make the disclosure	ID of the persons/entities authorized to make use of the disclosure (recipients of the PHI)	Description of the purpose(s) of the requested use or disclosure	Expiration date or event	Signature of the individual and date
Assist (Access Solutions and Support Team)	Y ("my personal health information, including information about my insurance, prescriptions, and medical condition ("My Information"))")	Y ("my health care providers, including the pharmacies I use, and my health insurance plan(s)")	Y ("United Therapeutics and its contractors and business partners, including the Access Solutions and Support Team (ASSIST) (collectively "United Therapeutics"))")	Y ("Support services (and related information and materials) related to any of United Therapeutics' products, including but not limited to, online support, financial assistance services, compliance and persistency, and other therapy support services; Conduct data analytics, market research, and other internal business activities; Information about United Therapeutics' products, services and programs, and other topics of interest for marketing, educational, or other purposes")	Y ("This authorization will expire in ten (10) years after the date it is signed unless a shorter period is mandated by state law or if I revoke the authorization earlier")	Y
Shared Solutions	Y ("my personal health information on this form as well as information related to my medical condition, treatment, care management, prescriptions and health insurance")	Y ("my healthcare providers, pharmacies and health plan(s)")	Y ("Teva Pharmaceuticals USA, Inc. and its affiliates, contractors and agents, including their third party patient support program service provider (collectively "Teva"))")	Y ("provide me with access to services related to my prescribed medication and/or medical condition ("Program"), including (i) enrollment in the Program; (ii) conducting benefits investigation and coordinating my insurance coverage, which may include allowing a Teva field based representative to access my information and engage with my healthcare providers directly, if necessary; (iii) if needed, determining my eligibility for and coordinating financial assistance; (iv) coordinating prescription fulfillment and product replacement; (v) providing nursing support, including product administration training and education; (vi) facilitating quality and adverse event reporting activities; (vii) conducting data analytics, market research and Program related business	Y ("This Authorization will remain in effect until the Program ends.")	Y

PSP name	Description of the PHI to be used or disclosed	ID of the persons/entities authorized to make the disclosure	ID of the persons/entities authorized to make use of the disclosure (recipients of the PHI)	Description of the purpose(s) of the requested use or disclosure	Expiration date or event	Signature of the individual and date
				activities; (viii) contacting me by direct mail or by electronic or telephonic means to the contact information on this form or to any future contact information provided by me or on my behalf in connection with carrying out the Program services, including adherence related communications, reminders, and support")		

APPENDIX II (3): HIPAA AUTHORIZATION - REQUIRED NOTICE AND REQUIRED STATEMENTS

PSP name	Right to revoke	Use of data obtained prior to revoking the authorization	Information about the ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the authorization	Consequence of refusal to sign authorization	Potential for re-disclosure	Notice if the provider will receive remuneration for the sale of PHI, or if PHI used or disclosed for marketing will involve financial remuneration	Copy to individual
myAIM	Y	Y ("Cancellation does not apply to information already received.")	Y ("refusal will not affect my treatment, medication coverage, or eligibility for benefits.")	Y ("I will not, however, be able to receive educational materials and coordination support of the Adempas Patient Support Program.")	Y ("Once my information is disclosed to Bayer it will no longer be protected by federal privacy laws or as dictated by applicable state law and may be given out (re-disclosed) by Bayer.")	Y ("Bayer will pay certain providers, such as my pharmacy to receive this information about me)	Y
My Source	Y	N	Y ("my decision on whether to sign this authorization will not affect my ability to receive treatment or insurance benefits outside of My Source")	Y ("I understand that if I do not sign this authorization, I may be ineligible for participation in My Source and for the reimbursement assistance and treatment support it provides.")	Y ("I understand that once my PHI is disclosed under this authorization, it may no longer be protected by federal law and could be disclosed to other parties.")	N	Y
BETAPLUS	Y	Y ("If you revoke this authorization, it will not affect any actions your healthcare providers or your health plan may already have taken")	Y ("Your medical treatment, payments, insurance enrollment, or eligibility for insurance benefits do not depend on your signing this form")	Y ("If you do not sign this form, you will not receive assistance through BETAPLUS")	Y ("Persons or entities that receive your PHI under this authorization may not be required by privacy laws (such as HIPAA) to protect the information and may share it with others without your permission, if permitted by the laws that apply to them")	Y (Certain healthcare providers, such as pharmacies, may receive payment from Bayer in connection with the disclosure of your PHI. They may also receive payment for using and disclosing your PHI to provide you with various communications)	Y
Access Solutions	Y	Y ("this will not apply to PII already used or shared or when it is required by law. If I	Y ("my health care providers and health insurer may not condition either my	Y ("I can choose not to sign this form, but Genentech and	Y ("HIPAA may no longer protect or prohibit the redisclosure of the PII disclosed to	Y ("Some of these disclosures may constitute a sale of PII. If so, I have the right	Y

PSP name	Right to revoke	Use of data obtained prior to revoking the authorization	Information about the ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the authorization	Consequence of refusal to sign authorization	Potential for re-disclosure	Notice if the provider will receive remuneration for the sale of PHI, or if PHI used or disclosed for marketing will involve financial remuneration	Copy to individual
		reside in California, I also have the right to request that Genentech and/or the Genentech Patient Foundation delete my PII, although deletion is not required under certain circumstances.")	treatment or my payment, enrollment or eligibility for benefits on signing this form.")	Genentech Patient Foundation will not be able to assist me without it.")	Genentech and/or Genentech Patient Foundation by my health care provider or others covered by the HIPAA laws.")	to opt out of the sale of my PII if I reside in California.")	
Horizon Patient Services	Y	Y ("this cancellation will not apply to any information used or disclosed by my healthcare providers and/or health insurance carriers based on this Authorization before they are notified that I have cancelled it")	Y ("I understand that Horizon, as well as my healthcare providers, cannot require me, as a condition of having access to medications, prescription drugs, treatment, or other care, to sign this Authorization")	N	Y ("I understand that information disclosed pursuant to this Authorization in some cases may be redisclosed by the recipient and no longer protected by HIPAA or other privacy laws")	Y ("I understand the pharmacies may receive a fee from Horizon in exchange for (1) providing me with certain materials and information described above, and (2) using or disclosing certain health information pursuant to this Authorization.")	Y
Shared Solutions	Y	Y ("any cancellation will not apply to any information already disclosed pursuant to this Authorization")	Y ("I understand that my treatment, payment for treatment, insurance enrollment, or eligibility for insurance benefits will not be directly affected if I do not sign this Authorization.")	Y ("However, if I do not sign this Authorization, I may not be able to receive Program services.")	Y ("I understand that once my information is disclosed, it may be subject to redisclosure by the recipients and no longer protected by federal privacy law.")	Y ("the third party service provider may receive financial remuneration from the manufacturer of your medication")	Y
Amgen Assist 360: Amgen Nurse Navigator Program	Y	Y ("I also understand that if a Health Care Provider is disclosing my personal health information to Amgen on an ongoing basis,	Y ("I understand that Amgen, as well as Health Care Providers, cannot require me, as a condition of	Y ("If I cancel my consent, I will no longer qualify for the services described.")	Y ("I understand that once my personal health information has been disclosed to Amgen, federal privacy laws may	Y ("certain Health Care Providers (such as pharmacies and specialty pharmacies) may receive remuneration from	Y

PSP name	Right to revoke	Use of data obtained prior to revoking the authorization	Information about the ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the authorization	Consequence of refusal to sign authorization	Potential for re-disclosure	Notice if the provider will receive remuneration for the sale of PHI, or if PHI used or disclosed for marketing will involve financial remuneration	Copy to individual
		my cancellation with Amgen will be effective with respect to any such Health Care Providers as soon as they receive notice of my cancellation.")	having access to medications, prescription drugs, treatment, or other care, to sign this Authorization.")	"I understand I cannot participate in the listed services and/or programs without signing this Authorization or an equivalent authorization with my Health Care Providers"	no longer apply and protect it from further disclosure")	Amgen in exchange for disclosing my personal health information and/or for using my information to contact me with communications about Amgen products which have been prescribed to me (for example, medication reminder programs) and other patient support services")	
None	Y	Y ("Canceling this Authorization will end my consent to further disclosure of my health information to Harmony by my Providers after they are notified of my cancellation, but will not affect previous disclosures by them pursuant to this Authorization.")	Y ("I further understand that my treatment, payment for treatment, insurance enrollment, or eligibility for insurance benefits are not conditioned upon my agreement to sign this Authorization.")	Y ("However, if I do not sign the Authorization or later cancel it, I will not be able to receive Harmony's support services.")	Y ("Once my health information has been disclosed to Harmony, I understand that federal privacy laws no longer protect the information.")	Y ("I understand that my pharmacy provider may receive remuneration from Harmony in exchange for the health information and/or for any support services provided to me.")	Y
Oncology Together	Y	Y ("This withdrawal will not affect the use or sharing of my health information that took place before I withdraw my approval.")	Y ("choosing not to sign will not affect my ability to receive treatment from my Healthcare Providers or payment from my health insurer.")	Y ("However, if I do not sign this form, the Pfizer Oncology Together may not be able to provide me with assistance.")	Y ("I understand that once my health information is shared, it may no longer be protected by federal privacy law.")	Y ("Select pharmacies may receive remuneration from Pfizer in exchange for my health information and/or for any Patient Support Activities provided to me.")	Y
Xelsource	Y	Y ("This withdrawal will not affect the use or sharing of my health information that took	Y ("I understand that I do not have to sign this form, and choosing not to sign will not affect my	Y ("However, if I do not sign this form, XELSOURCE may	Y ("I understand that once my health information is shared, it may no longer be	Y ("Select pharmacies may receive remuneration from Pfizer in exchange for my health information	Y

PSP name	Right to revoke	Use of data obtained prior to revoking the authorization	Information about the ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the authorization	Consequence of refusal to sign authorization	Potential for re-disclosure	Notice if the provider will receive remuneration for the sale of PHI, or if PHI used or disclosed for marketing will involve financial remuneration	Copy to individual
		place before I withdraw my approval.")	ability to receive treatment from my Healthcare Providers or payment from my health insurer.")	not be able to provide me with assistance.")	protected by federal privacy law.")	and/or for any Patient Support Activities provided to me.")	
Xembify Connexions	Y	N	N	N	Y ("I understand that once my information is shared with Grifols, my information may not be protected by federal health privacy laws.")	Y ("I understand that my pharmacy may receive compensation in connection with sharing my information with Grifols as allowed under this Authorization.")	N
<i>EntyvioConnect</i>	Y	Y ("I understand that such cancellation will not apply to any information already used or disclosed through this Authorization.")	Y (" I understand that I may refuse to sign this Authorization and that refusing to sign this Authorization will not change the way my physician, health insurance, and pharmacy providers treat me.")	Y ("I also understand that if I do not sign this Authorization, I will not be able to receive EntyvioConnect Patient Support Program products, supplies, or services.")	Y ("I understand that Protected Health Information disclosed under this Authorization may no longer be protected by federal privacy law.")	Y ("Further, I understand that my healthcare provider may receive financial remuneration from Takeda Pharmaceuticals U.S.A. for marketing services")	Y
Acthar Patient Support	Y	Y ("it will not apply to information they have already disclosed to Manufacturer Parties based on this authorization")	Y ("my physician and pharmacy will not condition my treatment on my agreement to sign this authorization form, and my health plan or health insurance company will not condition payment for my treatment, insurance enrollment or eligibility for insurance benefits on	N	Y ("Once my Health Information has been disclosed to Manufacturer Parties, I understand that it may be redisclosed by them and no longer protected by federal and state privacy laws.")	Y ("I understand that my pharmacies and other Designated Parties may receive payment in connection with the disclosure of my Health Information as provided in this authorization.")	Y

PSP name	Right to revoke	Use of data obtained prior to revoking the authorization	Information about the ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the authorization	Consequence of refusal to sign authorization	Potential for re-disclosure	Notice if the provider will receive remuneration for the sale of PHI, or if PHI used or disclosed for marketing will involve financial remuneration	Copy to individual
CORE (Comprehensive Oncology Reimbursement Expertise) Program	Y	Y ("my cancellation will not apply to any information already disclosed pursuant to this Authorization")	my agreement to sign this authorization form") Y ("I understand that my treatment, payment for treatment, insurance enrollment, or eligibility for insurance benefits will not be directly affected if I do not sign this Authorization.")	Y ("if I do not sign this Authorization, I may not be able to receive Program services.")	Y ("I understand that once my information is disclosed, it may be subject to redisclosure by the recipients and no longer protected by federal privacy law.")	Y (contacting me by direct mail or by electronic or telephonic means to the contact information on this form or to any future contact information provided by me or on my behalf in connection with carrying out the Program services, including adherence related communications, reminders, and support, for which the third party service provider may receive financial remuneration from the manufacturer of your medication)	Y
XENAZINE Information Center	Y	Y ("such withdrawal will not affect any uses and disclosures of my Information prior to the Program's receipt of the notice")	Y ("I understand that if I refuse to sign this Authorization, that will not affect my right to treatment or payment of benefits for health care.")	N	Y ("once my Information has been disclosed to the Program, federal privacy law may no longer restrict its use or disclosure and that it may be redisclosed to others")	Y ("I understand that my pharmacy provider(s) may receive remuneration in exchange for the provision of my Information as authorized above")	Y
Assist (Access Solutions and Support Team)	Y	Y ("If I do revoke the authorization, I understand the revocation will apply only to uses and	Y ("I understand that my health care treatment and health insurance eligibility and coverage will	Y ("but that if I do not sign, I may not be eligible to receive education and patient support	Y ("I understand that federal privacy laws may not regulate the use and disclosure of My Information once it is	Y ("I understand that my health care providers (including specialty pharmacies) may receive	Y

PSP name	Right to revoke	Use of data obtained prior to revoking the authorization	Information about the ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the authorization	Consequence of refusal to sign authorization	Potential for re-disclosure	Notice if the provider will receive remuneration for the sale of PHI, or if PHI used or disclosed for marketing will involve financial remuneration	Copy to individual
		disclosures of My Information after the date my notice of revocation is received by United Therapeutics and not to any uses or disclosures made prior to that date.")	not be affected if I refuse to sign this authorization")	services provided by United Therapeutics")	disclosed pursuant to this authorization")	remuneration from UT in exchange for disclosing my information and/or using my information to contact me with communications about UT products and other patient support services.")	
Shared Solutions	Y	Y ("my cancellation will not apply to any information already disclosed pursuant to this Authorization.")	Y ("I understand that my treatment, payment for treatment, insurance enrollment, or eligibility for insurance benefits will not be directly affected if I do not sign this Authorization.") ("I understand my consent is not a condition of purchase.")	Y ("However, if I do not sign this Authorization, I may not be able to receive Program services.")	Y ("I understand that once my information is disclosed, it may be subject to redisclosure by the recipients and no longer protected by federal privacy law.")	Y ("for which the third party service provider may receive financial remuneration from the manufacturer of your medication")	Y

APPENDIX II (4): OTHER FEATURES

PSP name	Allowance to limit release of specific sensitive information	Section on use of de-identified or aggregated information	Policy for disclosure outside of the PSP/access program	Comments on when PHI will be destroyed	Other defensive language
myAIM	N	N	N	N	
My Source	N	N	N	N	
BETAPLUS	N	N	N	N	
Access Solutions	N	N	N	Y ("If I reside in California, I also have the right to request that Genentech and/or the Genentech Patient Foundation delete my PII, although deletion is not required under certain circumstances.")	
Horizon Patient Services	N	N	N	N	
Shared Solutions	N	N	N	N	
Amgen Assist 360: Amgen Nurse Navigator Program	N	N	N	N	
None	N	N	N	N	Separate Marketing Authorization with specification of limits on sale of marketing data. ("I understand that Harmony will not sell or transfer my personal data to any unrelated third party for marketing purposes without my express permission.")
Oncology Together	N	N	N	N	Y (Additional certifications and authorizations: Personalized patient support opt-in; Pfizer PAP certification, attestation, and privacy disclosure; patient consent to receive communications; patient authorization for electronic income verification)
Xelsource	N	N	N	N	Y
		But, in Pfizer's online privacy policy: "We may aggregate and/or de-identify data about visitors to our Site and use it for any purpose, including product and service development and improvement activities."			
Xembify Connexions	N	N	N	N	

PSP name	Allowance to limit release of specific sensitive information	Section on use of de-identified or aggregated information	Policy for disclosure outside of the PSP/access program	Comments on when PHI will be destroyed	Other defensive language
<i>EntyvioConnect</i>	N	Y ("I understand that employees of the Companies only use my Protected Health Information for the purposes described herein, to administer the EntyvioConnect Patient Support Program or as otherwise required or allowed under the law, unless information that specifically identifies me is removed.")	N	N	
Acthar Patient Support	N	Y in a separate consent section: authorizing Mallinckrodt "to use my information that cannot identify me for scientific and market research"	N	N	
CORE (Comprehensive Oncology Reimbursement Expertise) Program	N	N	N	N	Y ("I agree that the Program and its affiliates, agents and representatives shall not be liable for any damages, of any kind, without limitation, in connection with my receiving Product assistance, benefits, or services provided by the Program.") Also, this form contains an especially lengthy physician agreement
XENAZINE Information Center	N	N	N	N	N
Assist (Access Solutions and Support Team)	N	N	N	N	N
Shared Solutions	N	N	N	N	N

-
- ⁱ Aline Bourdin et al., *Promoting Transitions of Care, Safety, and Medication Adherence for Patients Taking Fingolimod in Community Pharmacies*, 76 AM. J. HEALTH-SYSTEM PHARMACY 1150 (2019).
- ⁱⁱ Aline Bourdin et al., *Satisfaction and Experiences of Patients Taking Fingolimod and Involved in a Pharmacy-Based Patient Support Program in Switzerland – A Qualitative Study*, 20 BMC HEALTH SERVS. RSCH. 1 (2020).
- ⁱⁱⁱ Florian Lenz & Lutz Harms, *The Impact of Patient Support Programs on Adherence to Disease-Modifying Therapies of Patients with Relapsing-Remitting Multiple Sclerosis in Germany: A Non-Interventional, Prospective Study*, 37 ADVANCED THERAPEUTICS 2999 (2020).
- ^{iv} Jane Roche, Yvonne McCarry & Karen Mellors, *Enhanced Patient Support Services Improve Patient Persistence with Multiple Sclerosis Treatment*, 8 PATIENT PREFERENCE & ADHERENCE 805 (2014).
- ^v Sean Wharton et al., *Real-World Persistence with Liraglutide 3.0 mg for Weight Management and the SaxendaCare® Patient Support Program*, 6 OBESITY SCI. & PRAC. 382 (2020).
- ^{vi} David T. Rubin et al., *Impact of a Patient Support Program on Patient Adherence to Adalimumab and Direct Medical Costs in Crohn's Disease, Ulcerative Colitis, Rheumatoid Arthritis, Psoriasis, Psoriatic Arthritis, and Ankylosing Spondylitis*, 23 J. MANAGED CARE & SPECIALTY PHARMACY 859 (2017).
- ^{vii} Masayo Sato et al., *Effect of a Patient-Support Program on Once-Daily Teriparatide Adherence and Persistence in the Japan Fracture Observational Study (JFOS)*, 13 ARCHIVES OSTEOPOROSIS 1 (2018).
- ^{viii} Zaza Katsarava et al., *Adherence and Cost in Multiple Sclerosis Patients Treated with IM IFN Beta-1a: Impact of the CARE Patient Management Program*, 15 BMC NEUROLOGY 1 (2015).
- ^{ix} Einav Srulovici et al., *Is Patient Support Program Participation Associated with Longer Persistence and Improved Adherence Among New Users of Adalimumab? A Retrospective Cohort Study*, 35 ADVANCED THERAPEUTICS 655 (2018).
- ^x John K. Marshall, et al., *Canada's Study of Adherence Outcomes in Patients Receiving Adalimumab: Three-year Results from the COMPANION Study*, 40 CLINICAL THERAPEUTICS 1024 (2018).
- ^{xi} John K. Marshall et al., *Impact of the Adalimumab Patient Support Program's Care Coach Calls on Persistence and Adherence in Canada: An Observational Retrospective Cohort Study*, 40 CLINICAL THERAPEUTICS 415 (2018).
- ^{xii} Anne-Marie Landtblom et al., *RebiQoL: A Randomized Trial of Telemedicine Patient Support Program for Health-Related Quality of Life and Adherence in People with MS treated with Rebif*, 14 PLOS ONE 1 (2019).
- ^{xiii} H.H. Samawi et al., *Real-World Use of Trifluridine/Tipiracil for Patients with Metastatic Colorectal Cancer in Canada*, 26 CURRENT ONCOLOGY 319 (2019).
- ^{xiv} Fang Liz Zhou et al., *Impact of a Structured Patient Support Program on Adherence and Persistence in Basal Insulin Therapy for Type 2 Diabetes*, 6 BMJ OPEN DIABETES & RSCH. CARE 1 (2018).
- ^{xv} Alan C. Moss et al., *Impact of a Patient-Support Program on Mesalamine Adherence in Patients with Ulcerative Colitis – A Prospective Study*, 4 J. CROHN'S & COLITIS 171 (2010).
- ^{xvi} Jelena Drulovic, *The Impact of Betaplus Program on Patient Treatment Satisfaction with Interferon Beta-1b in Multiple Sclerosis: Multicentric Cross-Sectional Survey in the Western Balkan Countries*, 11 MULTIPLE SCLEROSIS & RELATED DISORDERS 56 (2017).

-
- ^{xvii} Carlo Pozzilli et al., *Supportive Strategies to Improve Adherence to IFN Beta-1b in Multiple Sclerosis – Results of the BetaPlus Observational Cohort Study*, 307 J. NEUROLOGICAL SCI. 120 (2011).
- ^{xviii} Diana Brixner et al., *Patient Support Program Increased Medication Adherence with Lower Total Health Care Costs Despite Increased Drug Spending*, 25 J. MANAGED CARE & SPECIALTY PHARMACY 770 (2019).
- ^{xix} Diana Brixner et al., *Participation in an Innovative Patient Support Program Reduces Prescription Abandonment for Adalimumab-Treated Patients in a Commercial Population*, 13 PATIENT PREFERENCE & ADHERENCE 1545 (2019).
- ^{xx} Louis Bessette et al., *Impact of the Adalimumab Patient Support Program on Clinical Outcomes in Ankylosing Spondylitis: Results from the COMPANION Study*, 5 RHEUMATOLOGY & THERAPY 75 (2018).
- ^{xxi} Filip Van den Bosch et al., *Impact of Participation in the Adalimumab (Humira) Patient Support Program on Rheumatoid Arthritis Treatment Course: Results from the PASSION Study*, 4 RHEUMATOLOGY & THERAPY 85 (2017).
- ^{xxii} Neeraj Narula et al., *Impact of Adalimumab Patient Support Program's Care Coach Calls on Clinical Outcomes in Patients with Crohn's Disease in Canada: An Observational Retrospective Cohort Study*, 1 J. CANADIAN ASS'N GASTROENTEROLOGY 191 (2018).
- ^{xxiii} Jennifer Jones et al., *BioAdvance Patient Support Program Survey: Positive Perception of Intravenous Infusions of Infliximab*, MANAGED CARE, Feb. 2017, at 41.
- ^{xxiv} Matthias Freidel et al., *Acceptance of the Extracare Program by Beta Interferon-Treated Patients with Multiple Sclerosis: Results of the Explore Study*, 47 J. NEUROSCI. NURSING E31 (2015).
- ^{xxv} Chris L. Pashos, Lael S. Cragin & Zeba M. Khan, *Effect of a Patient Support Program on Access to Oral Therapy for Hematologic Malignancies*, 69 AM. J. HEALTH-SYSTEM PHARMACY 510 (2012).
- ^{xxvi} Janice L. Jones et al., *Assessing the Role of Patient Support Services on Adherence Rates in Patients Using Glatiramer Acetate for Relapsing-Remitting Multiple Sclerosis*, 16 J. MED. ECON. 213 (2013).
- ^{xxvii} Thomas Kohlmann et al., *The Impact of a Patient Support Program for Multiple Sclerosis on Patient Satisfaction and Subjective Health Status*, 45 J. NEUROSCI. NURSING E3 (2013).