TYPE 1 DIABETES
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December 15, 2017

Members of the Senate H.E.L.P. Committee *by email*
United States Senate
Washington, D.C. 20510

RE: Full Committee Hearing on The Cost of Prescription Drugs: An Examination of The National Academies of Sciences, Engineering, and Medicine Report "Making Medicines Affordable: A National Imperative"

Dear H.E.L.P. Committee Chairman, Ranking Member, and Committee Members:

In the past year, the Senate H.E.L.P. Committee held three hearings on drug pricing. As Sen. Alexander pointed out during the December 12 hearing, senators' attention to the drug pricing crisis during the nomination hearing for Alex Azar might allow that to be considered a fourth drug pricing hearing. These four hearings have taken place during a year when senators' constituents have been crying out under the burden of paying skyrocketing out-of-pocket costs for prescription drugs they need to manage medical conditions—and in the case of people with type 1 diabetes, whom T1DF specifically represents, paying just to stay alive.

Four full committee hearings, seven distinguished experts, the former president of Eli Lilly, four industry lobbyists and a pro–value pricing 'patient advocate' (funded almost exclusively by the Laura and John Arnold Foundation) participated as witnesses in these hearings. The result, to date, has been a bipartisan agreement that the system is 'very complicated' and that additional hearings might be required to understand why list prices for rebatable brand name and specialty drugs are ever-increasing. T1DF begs to disagree.

- CMS and Congress know exactly what amount of the large rebates currently received by plan sponsors is being passed through to plan members and beneficiaries under Medicare Part D via reduction of the drug price at the point of sale (short answer: none).[1]

[1] The Medicare Part D cost-sharing crisis was finally formally acknowledged on November 16, 2017: "The proposed rule includes a Request for Information soliciting comment on potential policy approaches for applying some manufacturer rebates and all pharmacy price concessions to the price of a drug at the point of sale. We would use ideas and comments provided in response to the Request for Information to evaluate and consider proposals for rulemaking." https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-11-16.html

- CMS and Congress know that third-party payers and insurers are receiving, as general revenues, the vast majority of the manufacturer rebates negotiated by PBMs (about 90% on average, about 99% under Medicare Part D, up to 100% under pass-through contracts with large employer plans).[2]

- CMS and Congress know that for many medical conditions such as cancer (oncology class), therapies are in fact extremely expensive. These patients are not facing a cost-sharing crisis.[3]

- CMS and Congress know that the current cost-sharing crisis burdens a specific group of patients with certain chronic medical conditions that require the continuous use of relatively cheap to manufacture but heavily discounted rebatable specialty/brand drugs such as analog insulin (10ml vial: less than $5 to produce; supra-competitive U.S. net price around $55—about twice as expensive as European cash prices; U.S. list price over $280).

- CMS and Congress know that people with diabetes have been unfairly singled out and shamed by commercial insurers[4] and others for the cost of insulin and other drugs whose list prices these commercial insurers are in fact cooperating with manufacturers to artificially inflate[5] in order to extract from those people with diabetes larger cost-sharing amounts, far in excess of the actual net cost, to insurance plans, for their treatment.

- CMS and Congress know that commercial insurers have been robbing Peter to pay Paul[6]—making people with diabetes subsidize premiums for people who do not need heavily rebated specialty drugs, as well as using rebates insurers receive for the ostensible purpose of offsetting list prices

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[2] 42 U.S.C. 1320b-23 requires that PBMs disclose rebates received from manufacturers to both insurers and the U.S. government. Reporting inaccurate or misleading rebate information to the U. S. government could subject a PBM to criminal liabilities under the False Claim Act.

[3] As testified by David Mitchell, cancer treatment may cost over $250,000 annually. A cancer patient on such therapy will exhaust their deductible and out-of-pocket maximum in the first month of therapy, irrespective of whether the insurer bases cost-sharing on the drugs' list price or net cost to plan.

[4] See, e.g., Estay Greene, "Why Does Insulin Cost So Much after 95 Years?" Blue Cross Blue Shield of North Carolina, Nov.11, 2016 http://blog.bcbsnc.com/2016/11/why-insulin-cost-so-high/). Accessed Dec. 15, 2017.

[5] Manufacturers and insurers may also negotiate net prices, as suggested by PhRMA representative Lori Reilly during the December 13, 2017, hearing of the Health Subcommittee of the House Energy and Commerce Committee. Such negotiation would explain how even net prices have remained supra-competitive, when compared to launch prices, production costs, and cash prices in international markets.

[6] Insurers' practice of not sharing rebates with patients under Medicare Part D is believed to have caused insurers to mirror this practice in the private sector, possibly to normalize basing plan member cost-sharing on list price. See, e.g. Written testimony of Patricia M. Manzon, Ph.D., on PBM Compensation and Fee Disclosure for the 2014 ERISA Advisory Council, p. 6.

for insulin toward other corporate purposes, including executive bonuses and cash distribution to their shareholders.

- CMS and Congress know that the technology required for delivering point-of-sale net prices under both private insurance and Medicare Part D has existed since at least 2010 and has since been commercially implemented by medium-sized progressive PBMs.

- CMS and Congress know that the resolution of this cost-sharing crisis is first and foremost a matter of political will and moral rectitude. Some insurance premiums may slightly increase in the short run, but this is a necessary price to pay for transparency that is essential to the longterm sustainability of health insurance programs. Removing corporate moral hazard—the type of moral hazard that was at the core of the housing crisis—is now essential to protecting America's public-private health insurance system.[7]

People who use insulin are facing a cost-sharing crisis created by private insurers' benefit design. The cost-sharing crisis may not be the only drug pricing crisis Americans are facing, but the cost-sharing crisis remained the elephant in the room throughout this year's hearings, which have focused anywhere and everywhere but on the problem that is most readily within the federal government's power to solve. Although PBMs and manufacturers are complicit with a reimbursement system from which they derive substantial economic benefits, they are neither its instigators nor its primary beneficiaries. And fixing Medicare Part D does not require a new law; CMS can and should immediately mandate that drugs' negotiated prices be used to assess patient cost-sharing payments as

[7] A fraction of the cost-sharing overpayment under Medicare Part D now accounts for the net profit of the entire health insurance industry.

required under the Medicare Prescription Drug, Improvement, and Modernization Act, also called the Medicare Modernization Act or MMA.[8]

As to private plans managed by insurers/third-party payers, the growing number of ERISA-based class action lawsuits should address their breaches of fiduciary duties towards people with insulin-dependent diabetes and other chronic medical conditions. The federal government neglected its oversight responsibilities toward patients for more than a decade. These lawsuits, which concern the possible misallocation by private insurers of part of the $127 billion in rebates that manufacturers pay annually to gain formulary placement, will ultimately engage the federal government in acknowledging the injury caused by its breach of oversight and thus in compensating those the dual-pricing scheme has injured—a critical matter the H.E.L.P. Committee's hearings also failed to consider publicly.

The current crisis, as experienced by patients, is a cost-sharing crisis: these costs are being borne by patients at the end of the complete drug-pricing channel that begins with manufacturers and ends at the insurers who create benefit designs that determine patient payment. The H.E.L.P. Committee's hearings failed to acknowledge insurers' refusal to pass market access and formulary rebates, negotiated and passed through by PBMs to insurers/third-party payers, on to patients. This failure continued even during the nomination hearing for Mr. Azar, who has explicitly and publicly described the injury to patients. Mr. Azar has already admitted that at the other end of Lilly's reimbursement contracts "a significant number of people who already paid premiums for their health insurance then

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[8] "The MMA requires sponsors to provide their enrollees access to negotiated prices." Department of Health and Human Services, Office of Inspector General, "Accuracy of Part D Plans' Drug Prices on the Medicare Prescription Drug Plan Finder," July 2009, p. 2. T1DF notes that instead of quoting the section of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (P.L. 108- 73), the Office of the Inspector General quotes CMS's regulation, 42 CFR 423.100, which makes use of negotiated price at the point of sale discretionary, thus perpetuating the misrepresentation regarding Part D members' actual entitlement to negotiated price. MMA Section 101 stipulates, under 1860D–1(a)(1), that "a part D eligible **individual**" is entitled to obtain qualified prescription drug coverage as described in section 1860D–2(a). Section 1860D–2(a) stipulates that "the sponsor or organization **shall provide enrollees with access to negotiated prices** used for payment for covered part D drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing or an initial coverage limit" and that "[n]egotiated prices **shall take into account** negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs." In December of 2004, the Congressional Research Service summarized Part D cost-sharing requirements as follows: "Coverage offered by a PDP plan sponsor or a MA-PD entity will be required to provide beneficiaries with access to negotiated prices. Access must be provided even when no benefits were payable because of the application of cost-sharing or an initial coverage limit. Negotiated prices are to take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered Part D drugs, and include dispensing fees." CRS Report available at: https://royce.house.gov/uploadedfiles/overview%20of%20medicare.pdf

end up paying more than their insurer does for a medicine" (Manhattan Institute, 11/2016). As of December 2017, the Senate H.E.L.P. Committee has yet to acknowledge this fact.

Since the FTC investigation of Medco in 2003 and the subsequent 2003 class action filed by Hagens Berman on behalf of Community Catalyst's Prescription Access Litigation fund and third-party payers, the range of PBMs' retained rebates has been broadly known. The percentage of rebates retained by PBMs peaked at about 40 to 60% in 2002 and then dropped to about 18% in 2008, when Hagens Berman withdrew its California rebate pass-through lawsuit. It is public knowledge that CVS and Express Scripts currently keep, on average, about 10% of the price concessions paid by manufacturers, as confirmed by Credit Suisse, U.S. government agencies (e.g. CMS/OIG) and other experts. As to Medicare Part D, a recent investigation by the Office of the Inspector General concluded that PBMs retain only 1% of negotiated rebates and thus pass 99% of their value to plan sponsors.[9]

We can thus trace these rebates to the doors of commercial insurers, and we believe commercial insurers account for these payments as general revenues. AHIP alleges that they are being used for lowering premiums. We don't know. The only other certainty we have regarding this cost-sharing crisis is that commercial insurers are unfairly blaming people with insulin dependent diabetes for the unintended consequences and perverse incentives of a dual-pricing system that commercial insurers have been working to their own corporate advantage under private plans, ACA plans, and Medicare Part D. **Clarifying what happens to the remaining 90% of the rebates reportedly passed through to commercial insurers on plans as a whole (and the remaining 99% of rebates reported passed through to plan sponsors under Medicare Part D) —and countering the insurance industry's public messaging against the very class the pricing scheme has injured—should thus have been the primary purpose of 2017's Senate drug pricing hearings.**

The H.E.L.P. Committee failed, after a year-long investigation, even to arrive at a meaningful public definition of the different causes of patient injury by therapeutic class (the injury depends on the specific market dynamic and drug channel related to that therapeutic class). Instead, the Committee consistently sidestepped the reality that the actions of insurers also "affect what patients pay" and that insurers' decisions regarding patient cost-sharing and allocation of the passed-though rebate amounts insurers receive is a critical element in "making medicines affordable"—and also in making medicines unaffordable.

While the H.E.L.P. Committee carefully avoided any meaningful investigation of insurers' (and, by association, the federal government's) role in the current cost-sharing crisis during the several-month-

[9] Written testimony of Patricia M. Manzon, Ph.D., on PBM Compensation and Fee Disclosure for the 2014 ERISA Advisory Council, p. 6.

long time span in which these hearings have taken place, CMS has been working on a proposed rule that finally acknowledges the need to close the cost-sharing loophole it allowed insurers to carve out for themselves in 2005, despite explicit legislative mandate that Medicare Part D beneficiary cost-sharing be based on "negotiated price" as defined by MMA (the price of the drug, net all manufacturers' rebates and other price concessions). In the 14 years since the Medicare Prescription Drug, Improvement, and Modernization Act was enacted in 2003, insurers have continued to base patient cost-sharing on unrebated list prices rather than the mandated negotiated price—and have blamed the resulting inflated drug price at the point of sale on people with diabetes and, paradoxically, on Medicare Part D itself.[10]

We hope that the Committee will begin the new year by tackling the cost-sharing crisis people with diabetes are actually facing, the perverse incentives and dual-pricing reimbursement system that have created it, and the system's corollary harmful consequences for the uninsured. As of December 2017, the general workings of the prescription drug distribution channel, and its pricing system, are well known. As stated in CMS proposed rule CMS-4182-P, the the key issue to address, going forward, is insurers' failure to apply "**some [or all] manufacturer rebates and all pharmacy price concessions to the price of a drug at the point of sale**" and to pass the full value of those rebates (negotiated price) to the individual plan member who actually purchases the rebated drugs.

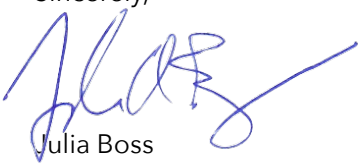
The Committee's work should also address the uninsured, whose numbers are likely to increase as the result of legislative and policy changes driven by the current Congress. They deserve equal protection, under the law, from the predictable effects of the current dual pricing reimbursement regime that commercial insurers have so deftly taking advantage of. In the absence of Congressional action, some form of relief should derive from T1DF's three class actions. These actions, assuming they can survive the current consolidation process, will address, for people with type 1 and other insulin-dependent diabetes, the nature and scope of the injury manufacturers, PBMs, and insurers have caused to patients who purchased highly rebated insulin, test strips and glucagon and were forced to pay-cost sharing based on their drugs' unrebated acquisition costs, rather than the net cost to plan (for private insurance) or negotiated price (Medicare Part D) or were forced to pay the high cash price that is a byproduct of reimbursement contract negotiations (uninsured).

[10] Medicare Part D was conceived as a public-private partnership for the very purpose of preventing the U.S. government from having a direct role in price setting. The price negotiation role was to be fulfilled by commercial insurers and their PBM contractors, and the benefits passed to members in the form of a lower negotiated price. As early as 2004, 'patient' organizations allied to or supported by commercial insurers initiated a blame-shifting campaign to cover for expected insurer-manufacturer price gouging resulting from CMS's 2005 rule.

To guide your ongoing investigation, we attach below a more detailed statement on the prescription drug cost-sharing issues currently before the Committee. We hope H.E.L.P. Committee members will approach this statement with all due consideration the insurers' role (and the role of their PBM agents) in the cost-sharing crisis, in addition to the role of manufacturers that has already received much public attention, and that you will do so in full awareness that the lives of Americans with type 1 diabetes have been placed in direct danger by what T1DF believes to be accounting fraud on a massive scale.

Again, T1DF thanks the Chairman, Ranking Democratic Member and other members of the Senate H.E.L.P. Committee for their attention to the concerns of your constituents with type 1 and other insulin-dependent diabetes. Please don't hesitate to contact us if we can be of any assistance. Your staff can reach me at 541.257.8878 (PST) or julia.boss@t1df.org.

Sincerely,



Julia Boss
President

About T1DF The Type 1 Diabetes Defense Foundation is a nonpartisan Oregon-based 501(c)(3) nonprofit dedicated to advancing equal rights and opportunities for Americans with type 1 and other forms of insulin dependent diabetes. T1DF accepts no funding from the pharmaceutical, medical device, pharmacy benefit management, or insurance industries or from any organization they fund. We support regulatory frameworks in which manufacturers compete directly on innovation and price to consumers and where drug channel actors can engage in open and efficient price arbitraging, without price discrimination and asymmetries of information.

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U.S. Senate H.E.L.P. Committee 2017 Hearings on Drug Pricing:

Obfuscating the U.S. Cost-Sharing Crisis?

How patients with insulin-dependent diabetes forced by commercial insurers, with CMS complicity, to overpay for 'deep-discount' rebated insulin are subsidizing premiums and bailing out America's public-private health insurance partnership.

Charles P. Fournier, JD

Julia A. Boss

Type 1 Diabetes Defense Foundation

December 15, 2017

About T1DF The Type 1 Diabetes Defense Foundation is a nonpartisan Oregon-based 501(c)(3) nonprofit dedicated to advancing equal rights and opportunities for Americans with type 1 and other forms of insulin dependent diabetes. T1DF accepts no funding from the pharmaceutical, medical device, pharmacy benefit management, or insurance industries or from any organization they fund. We support regulatory frameworks in which manufacturers compete directly on innovation and price to consumers and where drug channel actors can engage in open and efficient price arbitraging, without price discrimination and asymmetries of information.

The 2017 H.E.L.P. Committee hearings on drug pricing: An unfinished business?

The H.E.L.P. Committee had the tools to work from industry structure and cash flow to the patient injury and its remedies, but decided not to expose insurers' role.

As suggested by the H.E.L.P. Committee's titles, the apparent intent of these hearings was to first identify the problem in the drug-pricing and payment channel; to then identify the harmful consequences of the current system for individual patients who need to use prescription drugs; and then to establish patient-centered solutions.

Such solutions might include attention to patent issues for patients who need extremely costly innovative therapies and are seeing delays to market for new therapies; attention to copay clawback issues for patients who are being modestly overcharged on drugs that are available at a lower cash price than their insurer asks as a copay; and, for patients whose lives depend on deep discount rebated drugs like insulin, cost-sharing based on net cost to plan rather than a much higher unrebated price.

The Committee gathered a considerable body of experts to answer nearly any question its members might have posed on the actual workings of the drug-pricing channel, and to tell committee members where the money goes when manufacturers pay heavy rebates to PBMs and insurers. These industry experts and lobbyists included:

- Dan Mendelson, President of Avalere Health
- Allan Coukell, Senior Director of Health Programs, Pew Charitable Trusts
- Paul Howard, Ph.D., Senior Fellow and Director of Health Policy, Manhattan Institute
- Gerard Anderson, Ph.D., Professor of Medicine, Johns Hopkins University School of Medicine
- Lori M. Reilly, Executive Vice President, Pharmaceutical Research and Manufacturers of America (PhRMA)
- Chester "Chip" Davis, Jr., President and CEO, Association for Accessible Medicines
- Elizabeth A. Gallenagh, Sr. VP Government Affairs and General Counsel, Healthcare Distribution Alliance
- Mark Merritt, President and CEO, Pharmaceutical Care Management Association (PCMA)

- Thomas E. Menighan, BSPharm, MBA, ScD(Hon.), FAPhA, Executive Director and CEO, American Pharmacists Association
- Norman Augustine, Chair Of Committee On Ensuring Patient Access To Affordable Drug Therapies, National Academies of Sciences, Engineering and Medicine
- David Mitchell, President and Founder, Patients for Affordable Drugs[11]
- Dr. Douglas Holtz-Eakin, President, American Action Forum
- and, if we may add him, Alex Azar, formerly President, Lilly USA, and currently nominee for Secretary of Health and Human Services.

In multiple hours of hearings, these industry experts and lobbyists collectively delivered less meaningful information on the rebating system and the actual injury to patients than Mr. Azar alone did in brief remarks at the Manhattan Institute's panel on "Prescription For Value - Keeping Innovation Affordable For Patients" held in New York on November 3, 2016.[12]

Actors with deep background knowledge were not invited to testify.

To be able to ask the right questions, the H.E.L.P. Committee might have begun with a hearing focused on the individuals and organizations that have been or currently are intimately involved with this prescription drug cost-sharing crisis. These individuals and organizations include:

- The **Centers for Medicare and Medicaid Services**, obviously, and its Office of the Inspector General. The current cost-sharing crisis is intimately connected to MMA, the CMS rule-making process, and related enforcement (or, as the case may be, non-enforcement) decisions.

[11] Although Patients for Affordable Drugs (P4AD) introduced itself to the public in January 2017 as a grassroots patient organization, we consider it to operate as a representative of the pro-value pricing Laura and John Arnold Foundation. LJAF has disclosed on its website a $500,000 grant to P4AD at the organization's start-up, and we believe LJAF remains its primary funder. P4AD's website states, "we do not seek contributions from patients," and it is unclear whether P4AD has registered in any state to do so. We thus regard Mr. Mitchell principally as a lobbyist. T1DF's characterization of Patients for Affordable Drugs as a lobbying organization does not in any way diminish the value of Mr. Mitchell's personal testimony as a cancer patient.

[12] Transcript available at https://www.manhattan-institute.org/html/prescription-value-keeping-innovation-affordable-patients-9342.html. Accessed Dec. 14, 2017.

- **Patient groups** who are suing for disclosure of net price/net cost to plan or any other patient organization that is not funded by industry. The obvious challenge for Congress here would be to find a group that has not been coopted by one or more of the major industry players – pharmaceutical companies; PBMs; insurers and allied organizations such as unions and other third-party payers; or a policy agenda foundation such as the Laura and John Arnold Foundation.

- **Experts on deep-discount rebates** and dual pricing reimbursement contracting, which is most relevant to brand name and specialty prescription drugs. For example, economist **Lawrence W. Abrams**, Ph.D., has written extensively on the PBM business model, including the pass-through of rebates negotiated on behalf of insurers. Wharton School professor **Patricia Danzon**, Ph.D., is an expert in the economics of health care, the biopharmaceutical industry, and insurance, who has written on PBMs' management of manufacturer rebates. **Yale University's National Bureau of Economic Research's Health Economics Program**, directed by Michael Grossman,[13] studies economic models of the determinants of health and the determinants of the cost of medical care. NBER's Health Insurance and Health Care Programs consider the effects of medical care and key determinants of access—including health insurance—addressing issues including the organization of insurance markets and the role of insurers in rebate negotiations.

- **The litigation fund**, attorneys, and expert witnesses who have been intimately involved in the decade-long litigation campaign, on the behalf of third-party payers (TPPs), that has resulted in the current manifestation of the dual-pricing system:[14]

    - **The Prescription Access Litigation fund** managed by Community Catalyst from 2001 to 2013. PAL represented over 130 organizations, including many third-party payers, and filed over 30 class actions on drug pricing. PAL has been described as the largest coalition of health care advocacy groups that fight illegal, loophole-based overpricing by pharmaceutical companies. Wells Wilkinson, as the Director of Community Catalyst's former Prescription Access Litigation project from 2008 to 2013, apparently negotiated

[13] A complete description of the NBER Healthcare Program and its extensive scholarship on Medicare Part D, role of insurers in rebates negotiation and drug costs is available at: http://www.nber.org/programs/hc/hc.html. Accessed Dec. 14, 2017.

[14] The impact of litigation on the evolution of rebate pass-through contracting and diminution of PBMs' retained rebate share has been recognized by experts. See, e.g. Written testimony of Patricia M. Manzon, Ph.D., on PBM Compensation and Fee Disclosure for the 2014 ERISA Advisory Council, p. 6.

consumer interests in several million dollar class action settlements, and advocated for consumer protections in various legal, regulatory and congressional settings.[15]

- Attorneys **Steve Berman and Thomas Sobol** (Hagens Berman Sobol Shapiro LLP). These attorneys filed many of PAL's drug pricing class actions, including the 2003 rebate pass-through and 2012 copay coupon putative class actions filed on behalf of third-party payers in several states, including California and New Jersey. Tom Sobol has also acted as lead counsel to the Prescription Access Litigation fund for over a decade.[16]

- **Aaron Kesselheim**, JD, MD, MPH, as an expert witness in health economics,[17] worked closely with Hagens Berman on several PAL drug pricing class actions filed on behalf of third-party payers. As a member of the PAL advisory board, he has an intimate knowledge of the many issues and loopholes that have developed during the past decade in regard to drug-channel pricing and the actors who have benefited from the system at patient expense. Dr. Kesselheim's scholarship, currently partially funded by a $748,445 grant from the Laura and John Arnold Foundation, focuses on the high cost of prescription drugs, including insulin. He is also a member of the Yale-based Coalition for Affordable Insulin Working Group,[18] along with Dr. Kasia Lipska and Gregg Gonsalves, the latter of whom is also co-director of the Laura and John Arnold Foundation–funded Collaboration for Research Integrity and Transparency Program (CRIT). Dr. Kesselheim is a prolific writer and frequent speaker on the subject of high drug prices[19] and legal

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[15] See https://www.communitycatalyst.org/about/people/wells-wilkinson. Accessed Dec. 15, 2017.

[16] https://www.linkedin.com/in/thomassobol/ and https://www.hbsslaw.com/attorneys/partner-executive-committee/thomas-m-sobol-partner. Accessed Dec. 15, 2017. Information contained in these profiles does not appear to be current. They represent that Mr. Sobol currently serves as lead counsel to the Prescription Access Litigation project (PAL). PAL was apparently dissolved sometime in late 2013 or early 2014, as confirmed to T1DF by Community Catalyst.

[17] E.g. IMS Health Inc. v. Ayotte, U.S. Court of Appeals, 1st Circuit (No. 07-1945), decided Nov. 18, 2008, http://caselaw.findlaw.com/us-1st-circuit/1470126.html. Accessed Dec. 14, 2017.

[18] Dr. Kesselheim is now the Irving S. Ribicoff Visiting Associate Professor of Law at the Yale Law School (https://law.yale.edu/aaron-kesselheim), where LJAF-funded CRIT is co-located with the Global Health Justice Partnership.

[19] E.g. "Reining in Prescription Drug Prices," The Brookings Institution, May 2, 2017, https://www.brookings.edu/wp-content/uploads/2017/05/20170502_prescription_drugs_transcript.pdf (accessed Dec. 15, 2017) and "Outcomes-Based Pharmaceutical Contracts: An Answer to High U.S. Drug Spending?" The Commonwealth Fund, http://www.commonwealthfund.org/publications/issue-briefs/2017/sep/outcomes-based-contracts-high-drug-spending (accessed Dec. 15, 2017).

strategies to promote access to medicines.[20] Dr. Kesselheim has also been a featured speaker at the functions of America's Health Insurance Plans (AHIP), the national association whose members, union health plans, employer plans, private health insurers and other third party payers, provide coverage for health care and related services.[21] Mr. Kesselheim has appeared as a witness in front of several Congressional committees including this Senate committee in 2014,[22] the House Oversight and Government Reform Committee, and more recently the House Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law[23] and the Subcommittee on Health of the House Energy and Commerce Committee.[24]

Dr. Kesselheim, Mr. Sobol, Mr. Berman, and Mr. Wilkinson have all been intimately involved with the rise of deep discount rebating and the adoption of pass-through contracting during the period starting in 2003 and leading up to this year's Senate H.E.L.P. Committee hearings. They would have been able to explain the litigation projects through which payer groups sued PBMs to obtain access to rebates concurrently with the implementation of Medicare Part D (rebate pass-through contracts now deliver an estimated 90% on average of manufacturer reimbursements directly to insurers, and a reported

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[20] See e.g. "Legal Strategies to Promote Access to Medicines" roundtable announcement, AU News, American University, Washington, DC, Feb. 2, 2008: http://augcluster.american.edu/AU/media/mediarel.nsf/608575dac58ec4a785256869007c9cba/3d05fa2b21076aba852573e1007f1f78?OpenDocument. Accessed Dec. 14, 2017.

[21] Dr. Kesselheim's AHIP speaker profile can be found at https://www.ahip.org/speaker/aaron-kesselheim-md-jd-mph/. Accessed Dec. 14, 2017.

[22] Subcommittee hearing on "Why Are Some Generic Drugs Skyrocketing In Price?", Nov. 20, 2014. Transcript at: https://www.help.senate.gov/hearings/why-are-some-generic-drugs-skyrocketing-in-priced. Accessed Dec. 15, 2017.

[23] "Antitrust Concerns and the FDA Approval Process," July 27, 2017, https://judiciary.house.gov/hearing/antitrust-concerns-fda-approval-process/ (accessed Dec. 15, 2017). See also https://sites.duke.edu/ielizziedevitt/files/2017/04/Judiciary.Antitrust-Reform-and-FDA.Memo_.pdf (accessed Dec. 15, 2017).

[24] "Examining Medical Product Manufacturer Communications," July 17, 2017. https://energycommerce.house.gov/hearings/examining-medical-product-manufacturer-communications/ Accessed Dec. 15, 2017.

99% to Medicare Part D plan sponsors), as well as the interplay between pass-through contracts, coupon copay and insurer/third party payers' net cost to plan.[25]

These experts in insurer litigation, pass-through contracting and rebatable specialty/brand drug pricing would have been in a position to testify before the Committee with greater specificity, for example, than a patient advocate like Mr. Mitchell, whose former professional experience with public policy advocacy and public relations firm GMMB has made him an expert in political messaging but not an expert on the complex subject of drug pricing and reimbursement contracting. Bringing in such experts as Dr. Kesselheim, Mr. Sobol, Mr. Berman, and Mr. Wilkinson would have enabled senators to understand how insurers and third-party payers actually capture and retain a significant portion, if not all,[26] of rebates and other reimbursements from manufacturers, and even from copay coupons, via their audited PBM pass-through contracts.

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[25] In 2012, Steve Berman's client AFSCME DC37 reportedly already had a pass-through contract with OptumRx. The TPP plaintiffs, Hagens Berman's clients, in other 2012 coupon copay cases may also have had pass-through contracts with their pharmacy providers, as suggested by the AFSCME case. See Mark McAndrew, "The Future of Drug Coupons and Co-Pay Cards – Part 2," *Managed Market Access,* Nov. 5, 2014, https://www.managedmarketaccess.com/2014/11/the-future-of-drug-coupons-and-co-pay-cards-part-2/ (accessed Dec. 14, 2017), and "Consumer Groups File Class Action Over Copay Coupons, Allege Bribery and Fraud," *AIS Health,* Mar. 30, 2012, https://aishealth.com/archive/ndbn032312-02 (accessed Dec. 15, 2017). Hagens Berman has thus a detailed understanding of rebate/copay coupon pass-through contracting. In September 2014, the Office of Inspector General (OIG) issued a report, a special advisory bulletin, and a podcast on this topic. The OIG report concluded that despite efforts by the drug manufacturers sponsoring such coupons to carve out federal health care beneficiaries from such programs, some of the coupons were nonetheless used by Medicare Part D beneficiaries, and reimbursed by Medicare. In the special advisory bulletin, the OIG, however, placed the responsibility for ensuring that copay coupons do not violate the antikickback statute solely with the drug companies that issue copay coupons. See Jamie K. Wolszon, "RICO Challenges to Drug Co-Pay Programs Fall Like Dominoes: Another Federal Court Judge Dismisses RICO Claim," *FDA Law Blog,* Oct. 6, 2014, http://www.fdalawblog.net/2014/10/rico-challenges-to-drug-co-pay-programs-fall-like-dominoes-another-federal-court-judge-dismisses-ric/. Accessed Dec. 15, 2017.

[26] For example, on December 13, 2017, Mark Merritt, President and CEO, Pharmaceutical Care Management Association, confirmed to the Health Subcommittee of the House Committee on Energy and Commerce, under questioning from Rep. Diana DeGette, that large employer plans now receive 100% rebate pass-through (Recording at 1:55:08 https://energycommerce.house.gov/hearings/examining-drug-supply-chain/ – accessed Dec. 15, 2017). CVS also publicly acknowledged in 2016 and 2017 that its retained rebate was on average 10%, i.e. that 90% of the value of the rebates is "passed back to clients." See, e.g. "CVS Health PBM Clients Achieved Lowest Prescription Drug Trend in Four Years, Despite Rising Drug Prices," CVS Health, March 15, 2017, https://cvshealth.com/newsroom/press-releases/cvs-health-pbm-clients-achieved-lowest-prescription-drug-trend-four-years. Accessed Dec. 15, 2017.

The central role of commercial insurers in this cost-sharing crisis was in fact obfuscated.

Sins of omission can be hard to trace and quantify, especially if the matter at hand is identifying motives rather than simply examining actions. Here the H.E.L.P. Committee's omission is its failure to investigate the role of commercial insurers.

On February 27, 2017, President Trump praised on Twitter the leading U.S. health insurance companies for "[providing] great healthcare to the American people."[27] In remarks to insurance industry representatives that same day, President Trump recognized that he was talking to the leaders of current healthcare delivery system, "the biggest of the big," i.e. the "*people [who] know that better than anybody*."[28] Where the money is going in deep discount rebating is a question these "biggest of the big" leaders in the U.S. health care system can and should answer. The Committee's hearings, however, never addressed this crucial missing link: what are insurers and other TPPs doing with the rebate dollars that industry observers now tell us those insurers/TPPs predominantly capture?

Even without such additional experts as those we mentioned above, the H.E.L.P. Committee has had enough firepower in the room to answer this big-money question—and yet failed to ask the only questions that would have delivered to the American people the answers they deserve. At the end of the third (or, by Sen. Alexander's count, fourth) drug pricing hearing, Sen. Alexander and Sen. Murray were still refusing to acknowledge the elephant in the room: the money trail stops at the doorstep of most insurers. Neither the hearings nor NASEM's report ever addressed the full journey of the drug price rebates that leave manufacturers by the billions and yet never reach patients in the form of lower individual cost-sharing based on rebated drugs' actual net cost to insurance plan.

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[27] https://twitter.com/realDonaldTrump/status/836261209540288513

[28] "THE PRESIDENT: You are the big ones. You are the biggest of the big, right? [Laughter.] That's very impressive… Obamacare forced providers to limit the plan options they offered to patients and caused them to drive prices way up. Now, a third of United States counties are down to one insurer, and the insurers are fleeing. You people know that better than anybody…" "Remarks by President Trump in Listening Session with Health Insurance Company CEOs," White House briefing, February 27, 2017, https://www.whitehouse.gov/briefings-statements/remarks-president-trump-listening-session-health-insurance-company-ceos/ Accessed Dec. 15, 2017. The President's remarks were made during a meeting with representatives of leading insurance companies, including Blue Cross and Blue Shield of North Carolina, Aetna, Humana, Florida Blue (BCBS plans in the state of Florida), the Blue Cross Blue Shield Association (108 million members), Independence Blue Cross/Independence Health Group, Anthem (40 million members), Cigna Corporation, UnitedHealth Group (120 million members), and Kaiser Foundation Health Plan/Kaiser Permanente (11.7 million members).

We heard questions during Tuesday's hearing and hearings earlier in the year regarding partial manufacturer-only transparency (R&D costs, methods for determining list prices, and so on). We heard vague comments on the opaque dealings of PBMs. We did not hear anything on the corresponding absence of transparency from insurers. We did not hear about the size and percentage of rebates insurers receive, where this rebate money goes after it is passed through to third-party payers and insurers, who controls it, or why insurers and third-party payers report unrebated acquisition prices or list prices to consumers as "plan cost" in cases where net cost to plan is actually substantially lower.[29] This situation is all the more dystopian given that rebate pass-through is the very innovation upon which the political compromise allowing Medicare Part D was built.

[29] We do know, however, based on the pass-through pharmacy agreements released in the 2012 AFSCME case mentioned above, that copay coupons are credited against the price of the drug paid by PBMs on behalf of insurers. Based on circumstantial evidence, we also know that some insurers who receive the value of copay coupons at the point of sale still report to consumers the full list price as "plan cost."

Where is the manufacturer rebate money going?

PBMs as the enabling cost-management mechanism of Medicare Part D.

Since Medicare Part D was first on the drawing board, negotiated rebates from manufacturers have been a cornerstone of the proposal and a critical element for achieving broad bipartisan consensus. In 1993, in the report describing the health security act, the Clinton administration put pass-through rebating at the center of the administration's strategy to contain the cost of the prescription drug benefit program and thus to secure the goodwill of a Republican Congress:

> Under reform, with the addition of prescription drug coverage, Medicare will become the world's largest purchaser of drugs. And, the Medicare program will use its negotiating power to get discounts from the pharmaceutical companies. In addition, with competing health plans trying to become more efficient, more and more buyers will use the same successful negotiating techniques. (Health Security 1993, 55)[30]

The initial plan was for Medicare to enter into direct rebate contracts with manufacturers.[31] Many in Congress were, however, opposed to any form of price control or the direct involvement of a government body in the business of setting drug prices. The idea of a stand-alone drug benefit that relies on a private partnership for delivery of the services emerged between 1999 and 2003. It mirrored the original Medicare program's use of private insurers for contracting out Part A's and Part B's claims payments and other functions. The idea then was to create a buffer between health care providers and the regulatory reach of the government so as to preempt opposition from small-government Republicans. Medicare Part D was to deliver on the program's promise indirectly, via insurers' pharmacy benefit managers (PBMs)[32] and the cost-saving mechanisms they were already using in 2003, such as formularies, volume and market access discounts, and utilization review.

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[30] Oliver et al, "A Political History of Medicare Prescription Drug Coverage," *The Milbank Quarterly* 82:2 (2004) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690175/pdf/milq0082-0283.pdf, pp. 301–02. Accessed Dec. 15, 2017.

[31] Id. (citing (Ford et al. 1994, 75–6)).

[32] Insurers' PBMs were considered a part of the "market," and were thus to protect the "market" from the supposedly disrupting influence of a government agency.

Without the development of PBMs and without Congress's actual knowledge of the price reduction benefits of the PBMs' price discount negotiation power, policymakers ideologically inclined to distrust direct government intervention would not have agreed to the viability of this public-private partnership approach. This concept was tried out in July 2001, when the Bush administration proposed a plan for Medicare beneficiaries to buy prescription drugs at discounted prices through private pharmacy benefit managers. The firms endorsed by the Medicare program would negotiate prices with manufacturers and **pass along the savings to their cardholders.**[33] This rebate pass-through approach was preferred to the reimbursement scheme then used by Medicare Part B. As Thomas Scully, administrator of the Centers for Medicare & Medicaid Services, testified, "*It is clear that Medicare's payment system for those covered drugs, based on* ***average wholesale price,*** *is seriously flawed.*"[34]

In 2003, the Medicare reform bill initiated a partisan debate over the roles of government and private industry in delivering health care and the role of government in setting drug prices. Insurance companies had also opposed prior attempts to shift liabilities to them. There were no data to assess whether these plans would be profitable. Yet, in order to be successful, the Medicare Part D program needed the immediate and nationwide availability of drug-only private insurance plans. These uncertainties were traded off against two key cost-control characteristics: a substantial gap in benefits for individuals with high drug costs (the "donut hole"),[35] and **the use of private pharmacy benefit managers** in lieu of direct government price negotiation.[36]

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) was enacted as Public Law 108–173 in December 2003. MMA required, and still requires, that plan sponsors use as the basis of beneficiary cost sharing payment the 'negotiated price.' The negotiated price is defined by MMA[37] as the drug's price net of "*negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations*."

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[33] Id, p. 307.

[34] Id, generally.

[35] In 2017, once the beneficiary and her plan have spent $3,700 on covered drugs, she is in the "donut hole" coverage gap and may pay up to 40% of the plan's stated cost for covered brand-name prescription drugs.

[36] Oliver et al, generally. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690175/pdf/milq0082-0283.pdf

[37] We note that, as part of the proposed rule issued on May 16, 2008, CMS amended the definition of "negotiated prices." We will not discuss the implication of this modification in this statement; this statement is solely focused on the central role of PBMs and thus deep discount rebating in the Medicare Part D fabric. We note, however, that from 2004 on, insurers lobbied to alter, in the public discourse, the general understanding of Medicare Part D's "negotiated prices" to the point that PBMs such as CVS Caremark currently report that the purpose of the regulation is to reduce the Part D sponsors' drug costs – not the drug costs of the Part D individual members. (See, e.g., CVS Form 10-K, Annual Report for the year ended December 31, 2008.)

The Medicare prescription drug benefit was thus designed to provide Medicare beneficiaries immediate assistance through reduced drug costs, both from expanded insurance coverage and from being able to access **negotiated drug prices** when the beneficiary is responsible for the cost of the drug (i.e., during the initial deductible period and the coverage gap, or "donut hole").[38] PBMs, the private-sector mechanism for delivering lower net/negotiated drug prices to elderly Americans, were thus central to the political deal-making between Republicans and Democrats. Representatives and senators from both parties hoped the PBMs would deliver these much-needed benefits to their constituents in order to make Medicare Part D a success.

Congress and the Bush administration also knew that, prior to 2003, PBMs had profited from their intermediary position but had not passed on these savings to the purchasers or beneficiaries—and many policymakers were ready to reconsider, prior to Medicare Part D's 2006 effective date, government price controls if the PBMs failed to deliver the savings promised under drug discount cards.[39] It became a political imperative to force PBMs to pass through a larger share of the rebates to plan sponsors. It was also a practical imperative in order to make stand-alone Medicare Part D plans financially attractive and thus entice the support of private insurance companies.

Prior to 2003 (and possibly in anticipation of the enactment of Medicare Part D), Express Scripts had started to increase its rebate-retention rate (the part of the rebates it keeps) from 31.5% in 2000 to 38.0% in 2002.[40] As of 2002, Express Scripts was thus passing, on average, about 62% of the formulary access and performance rebates to its insurer clients. While the company's rebate-retention rate was then trending upwards, this appears to have been in an effort to "capture a larger piece of a shrinking pie," as the volume of rebatable drugs was decreasing.[41]

As of 2003, government and public knowledge of PBM rebates was already extensive.[42] It was public knowledge that pharmaceutical manufacturers paid rebates to PBMs based on some combination of a

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[38] Jonathan Blum, "A History of Creating the Medicare Prescription Drug Benefit," Avalere Health, August 2006: http://www.npcnow.org/system/files/research/download/history_creating_medicare_partd.pdf. Accessed Dec. 15, 2017.

[39] Oliver, p. 307.

[40] Lawrence Abrams, "Estimating the Rebate-Retention Rate of Pharmacy Benefit Managers," http://www.nu-retail.com/rrr.pdf (accessed Dec. 15, 2017), p.1, citing Securities and Exchange Commission, Form 10-K, Express Scripts, Inc. for the year ending December 31, 2002.

[41] Abrams, p.8.

[42] See, e.g., John Richardson, Health Strategies Consultancy, Health Care Hearings, p. 23–24 (PBMs "can be paid through administrative fees, share of rebates, or some combination."). See also Health Care Hearings, June 26, 2003. http://www.ftc.gov/ogc/healthcarehearings/030626ftctrans.pdf.See also http://www.ftc.gov/ogc/healthcarehearings/03062526agenda.htm.

percentage of a reference price, achieving certain specified sales or market share targets, and preferred placement of certain drug products on the PBM's formulary. These rebates were either entirely passed through to the group health plan sponsor, retained by the PBM, or shared between them depending on the specifics of the contract between these parties.[43]

In 2003, U.S. government (e.g., Federal Trade Commission) and private interests associated with or funded by third-party payers used the legal system to force an industrywide adoption of PBM rebate pass-through contracts, impose audit rights over those contracts, and reduce the PBM's share of retained rebates. In early 2003, the FTC targeted MedCo Health Solutions, then the second largest PBM.[44]

Following in the steps of the FTC, Hagens Berman[45] (Thomas Sobol and Steve Berman), on behalf of the Prescription Access Litigation (PAL) project and the American Federation of State County and Municipal Employees (AFSCME), AFL-CIO, filed suit against the four largest PBMs – Advance PCS, Express Scripts, MedCo Health Solutions, and Caremark Rx. The defendants together controlled more than 80 percent of the PBM market. The lawsuit alleged that these PBMs "reaped billions of dollars in illegal profits by steering health insurers and health care consumers into reliance on more costly drugs. The complaint also charge[d] that the four PBMs have negotiated rebates from drug manufacturers and discounts from retail pharmacies – **but haven't passed those savings on to health plans and consumers.** Instead they've used those savings to secure exploitative profits. In addition, the complaint charge[d] the PBMs developed a pricing system based on the Average Wholesale Price (AWP), widely considered an inflated 'sticker' price set by the drug manufacturer."[46]

Express Scripts' prior disclosure of its retained rates was involuntary—it was the product of an accounting adjustment required by a change in accounting standards. Under pressure from both the FTC and Hagens Berman's lawsuit, Medco Health Solutions, at the time the second largest independent pharmacy benefit manager, became on October 28, 2004, the first PBM to voluntarily

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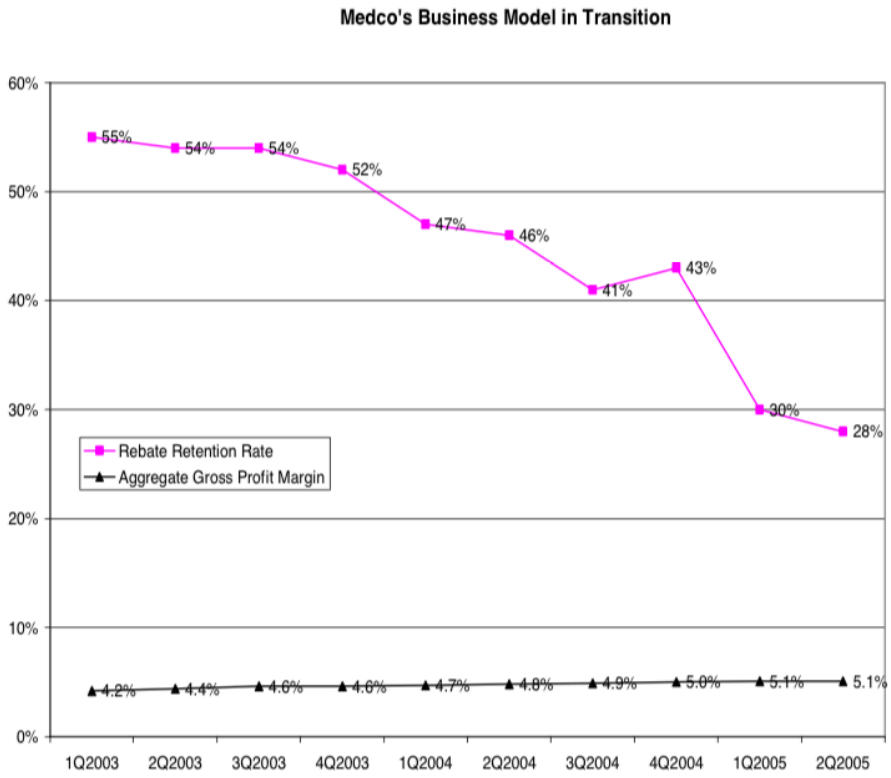
[43] FTC Office of Policy Planning, Bureau of Competition, and Bureau of Economics to California Assembly Member Greg Aghazarian, Sept. 4, 2004, https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf. Accessed Dec. 15, 2017.

[44] B. Martinez, "U.S. Is Joining Lawsuit that Says Medco Put Profits before Patients," *Wall Street Journal,* Jun. 24, 2003, A1.

[45] The fact sheet and copy of the complaint have since been deleted from the website of Hagens Berman and the case has been sealed.

[46] Community Catalyst press release: "Pharmacy Benefit Managers Charged with Inflating Prescription Drug Prices; Lawsuit Alleges Secret Deals between PBMs & Pharmaceutical Companies," March 18, 2003.

disclose its rebate retention rate: 40.5%. In the nine months following this initial disclosure, Medco reduced its rebate retention rate to 28.1%.[47]

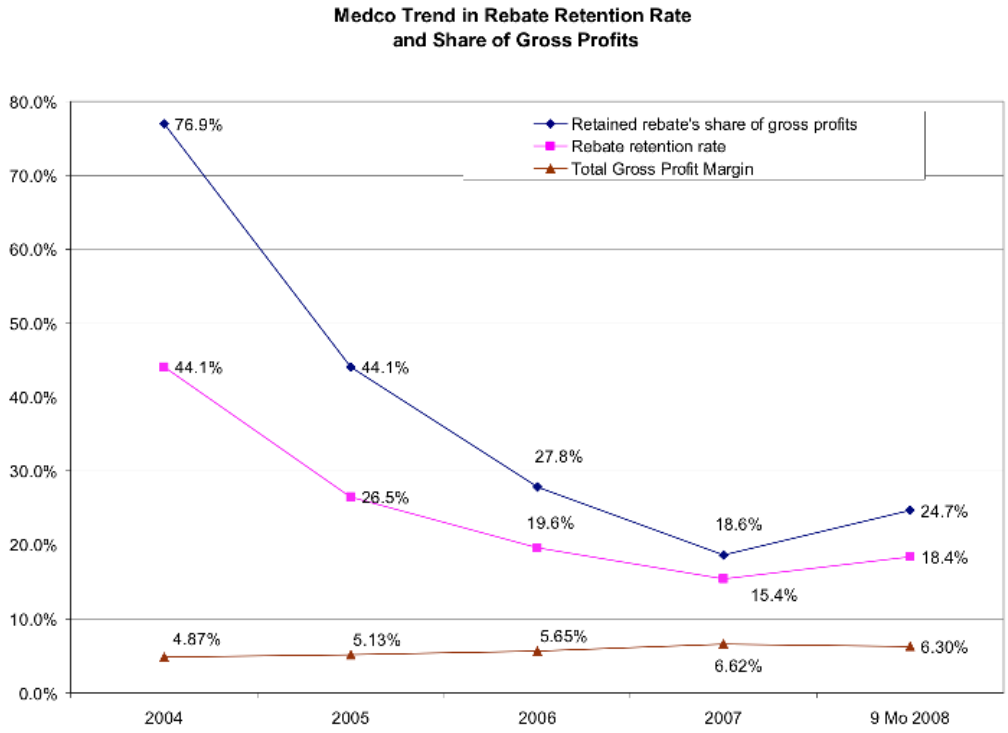


Graph: Lawrence W. Abrams, "Quantifying Medco's Business Model: An Update."

[47] Lawrence W. Abrams, "Medco's Transition to a Transparent Business Model," Sept. 5, 2005, p.1, 3–4 and fn. 2: Medco Health Solutions, 2004 Analyst Day Presentation, "Momentum and Growth for 2005," Nov. 11, 2004, slide show available at http://media.corporate-ir.net/media_files/NYS/MHS/presentations/MHS111104.pdf, pp. 79–80. Accessed Dec. 15, 2017. Graph source: Abrams, "Medco's Transition." This section will rely heavily on the work of Dr. Abrams, one of few authors to publish extensively on this topic on a website readily accessible to patients and patient advocates (i.e. not paywalled). We applaud Dr. Abrams' decision to make his findings available on a public blog, and we summarize some of his conclusions here in the interest of the greater public good. We apologize for any apparent excessive reliance on Dr. Abrams' work.

By 2007, Medco had reduced its rebate retention rate to 15.4%.[48] A market analyst calculated that retained rebates, which in 2004 contributed to 71.4% of total gross profits, only contributed to 18.6% of gross profits in 2007.[49]

More plans and employers were negotiating contracts that include provisions for sharing rebates between the PBM and the plan, and required audit rights that allowed them to verify whether they received the payments for which they had contracted.



Graph: Lawrence W. Abrams, "Quantifying Medco's Business Model: An Update."

Greater transparency and downward pressure on rebate retention also led to a change in the PBM business model. While retained rebate amounts contributed a small share of the PBMs' revenues, the

[48] The other component of the PBMs' 'opaque' revenues, the so-called retail reimbursement "spread"—the difference between client-to-Medco reimbursements and Medco-to-pharmacy retailer reimbursements for prescriptions dispensed at retail—only contributed 4.2% of Medco's overall gross profits.

[49] Abrams, "Quantifying Medco's Business Model: An Update," p.8, http://www.nu-retail.com/Update_2007-8_Medco_Business_Model.pdf. Accessed Dec. 14, 2017.

source and 'intensity' of these rebates had changed. Unit margins for brands based on averages across all therapeutic classes failed to document the emergence of the increased profitability of a new class of highly "rebatable" specialty and brand name drugs.[50]

In 2005, the FTC documented empirical evidence of the variability of rebates paid by Pharma:

> *"Regardless of the PBM category, a majority of these payments were derived from a limited number of brand drugs. The data show that, in 2003, each of PBMs' top 25 brand drugs (in terms of total rebates received) accounted for approximately 71% of its total pharmaceutical payments, on average*."[51]

In 2008, Dr. Abrams gave a name to this new phenomenon, which directly resulted from the success of the PAL litigation campaign in support of rebate pass-through contracting: *deep discount rebating in competitive oligopolistic market* – an economic anomaly that is not predicted by usual economic models. In the context of the insurance market, the rebatability of a therapeutic class, according to Dr. Abrams, does not really begin when a single brand drug faces competition from new, "me-too" brand drugs. It begins when a biosimilar or generic becomes available. For example, the rebatability of the statin class did not begin with the introduction of Crestor to compete with Lipitor and Zocor. Statin rebates really took off only when Zocor lost patent protection and its generic, Simvastatin, became a threat to Crestor and Lipitor.[52]

It follows from this theory of rebates that trends in gross rebates received follow the ebb and flow of competition facing blockbuster brand drugs from generics and biosimilars, but not me-too brands. Basically, the growth and decline in rebates paid on behalf of blockbuster drugs mirrors the transition of a therapeutic class from monopolistic (no rebates) to oligopolistic (high/deep discount rebates) to competitive (low rebates).[53]

The increasing competitive pressures in the PBM industry and assertiveness of insurer clients caused Caremark and other PBMs to share with clients an increasingly larger portion of rebates and/or

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[50] Abrams, "Quantifying Medco's Business Model: An Update," p.26.

[51] Abrams, "Quantifying Medco's Business Model: An Update," p. 27, citing Federal Trade Commission, "Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies," September 2005, p.48. Available at http://www.ftc.gov/os/2005/09/index.htm#6.

[52] Abrams, "Quantifying Medco's Business Model: An Update, p. 27.

[53] The analog insulin market, comprised of a small number of biosimilar drugs and three manufacturers, is currently oligopolistic. As predicted by the Abrams rebating model, analog insulins are subject to 'deep discount/high rebate' in excess of 70% of list price.

discounts received from pharmaceutical manufacturers.[54] As of 2010, the use of pass-through rebate contracting had become prevalent.[55] Rebate retention that accounted for about half Medco's profits in 2004 had, on average, decreased to about 20 percent in 2008.[56] In 2009, Medco rebate retention dropped to 13.7% and continued to slide. In 2011, MedCo rebate retention was 12.2%.[57]

This transition to complete "pass-through" pricing was actively supported by Congress and the insurance lobby.[58] **When the Affordable Care Act imposed pass-though pricing for PBMs participating in state exchanges starting in 2014,** the use of pass-through pricing versus "lock-in" pricing had already spread throughout the private and public sectors.[59] "CMS concluded that pass-through pricing models prevented additional profits from being generated by the PBM at the expense of beneficiaries and the taxpayer. As a result, over the last few years more and more state agencies have been demanding transparency as well."[60]

A recent national survey of plans that elected a rebate-sharing pass-through model concluded that the median rebates received by the plans were 80% to 93% of manufacturer rebates on prescriptions filled at retail pharmacies.[61] Congress, and by extension the U.S. Senate H.E.L.P. Committee, can easily

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[54] CVS Annual Report, Form 10-K, Annual Report for the fiscal year ended December 31, 2008.

[55] Brian N. Anderson and Robert Cosway, "Effective Contracting with Pharmacy Benefit Managers: Protecting a plan sponsor's resources," *Health Watch* Feb. 2010, document attached to webinar "Negotiating Pharmacy Benefit Contracts," October 24, 2012, https://aishealth.com/sites/all/files/file_downloads/c2p36f_102412.pdf. Accessed Dec. 14, 2017.

[56] Martin Sipkoff, "PBMs' Rebate Income Threatened By Lawsuits and Move to Generics—A recent court settlement may affect the way the PBM industry makes profits, but could it also lead to higher drug costs?" *Managed Care Magazine,* March 2008, citing Adam J. Fein, president of Pembroke Consulting, Inc., a management advisory and business research firm. https://www.managedcaremag.com/archives/2008/3/pbms'-rebate-income-threatened-lawsuits-and-move-generics. Accessed Dec. 15, 2017. Hagens Berman/PAL rebate pass-through lawsuit was withdrawn by Hagens Berman in September 2008.

[57] Medco Health Solutions FY2011 10-K fillings accessed through SEC EDGAR Database on December 15, 2017. Medco merged with Express Scripts in 2012. Express Scripts discontinued Medco's disclosure. On September 29, 2017, the Securities and Exchange Commission, Division of Corporation Finance, directed Express Scripts to provide separate disclosure of receivables from pharmaceutical manufacturers (rebates).

[58] "Government, Plans Focus on PBM Transparency to Control Costs," April 16, 2010, issue of AIS's biweekly newsletter, *Drug Benefit News*. Available as attachment at https://aishealth.com/sites/all/files/file_downloads/c2p36f_102412.pdf.

[59] E.g. "An Eight-Point Plan to Transparent Pharmaceutical Contracting," Sept. 21, 2012, issue of AIS's biweekly newsletter Drug Benefit News ("(4) Rebates and other remuneration are 100% auditable to the NDC level and must be passed through to the plan."). Available at https://aishealth.com/sites/all/files/file_downloads/c2p36f_102412.pdf

[60] "Government, Plans Focus on PBM Transparency to Control Costs," citing Kevin Nagle, then president and CEO of Envision Pharmaceutical Services, Inc.

[61] Pharmacy Benefit Management Institute, 2013–2014 Prescription Drug Benefit Cost and Design Report.

confirm this result: Under Section 6005 of the Affordable Care Act, PBMs are required to disclose the aggregate amount of rebates, discounts or price concessions passed through to plan sponsors, for the two types of plans listed in the statutes, to the Secretary of the Department of Health and Human Services.[62]

By 2012, it seems that employer plans[63] were catching up with other sectors of the insurance industry in terms of adopting 100% pass-through pricing and aggressive financial and audit terms.[64] The use of pass-through rebate pricing was prevalent in other sectors. For example, AFSCME DC 37, one of the union plans that joined PAL's litigation campaign against copay coupons in 2012, reportedly had a rebate pass-through contract with OptumRx.

On December 13, 2017, Mark Merritt, President and CEO, Pharmaceutical Care Management Association, confirmed to the Health Subcommittee of the House Committee on Energy and Commerce, under questioning from Rep. DeGette, that large employer plans now receive 100% rebate pass-through.[65] **CVS**[66] **and Express Scripts**[67] **have publicly acknowledged in 2016 and 2017 that their rebate retention was on average 10%, i.e. that 90% and 89%, respectively, of rebate value is "passed back to clients**" and that the insurers/TPPs unilaterally decide how to apply these rebates. Since 2011, the difference between pre-rebate costs (known as gross costs) and post-rebate costs (known as net costs) has grown so that the "gross-to-net bubble" is now worth approximately 10% of all Pharmacy spend– or about $127 billion annually.[68]

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[62] Congress expressly did not permit the disclosure of PBM-specific information to the states or any other party.

[63] As of 2013, only 6% of larger employer plans reported capturing no rebates. The mean and median employer shares of drug rebates were 60% and 80% for retail dispensed drugs. See Written testimony of Patricia M. Manzon, Ph.D., on PBM Compensation and Fee Disclosure for the 2014 ERISA Advisory Council, pp. 6, 10. By late 2017, PCMA's Mark Merritt told the House's Health SubCommittee of the Energy and Commerce Committee that large employer plans were receiving 100% of rebates.

[64] E.g. "NW Prescription Drug Consortium Sought Clarity When Pooling States' Rx Purchases," Sept. 21, 2012, issue of AIS's biweekly newsletter *Drug Benefit News.* Available at https://aishealth.com/sites/all/files/file_downloads/c2p36f_102412.pdf

[65] Recording at 1:55:08 https://energycommerce.house.gov/hearings/examining-drug-supply-chain/

[66] E.g. "CVS Health PBM Clients Achieved Lowest Prescription Drug Trend in Four Years, Despite Rising Drug Prices," CVS Health, March 15, 2017, https://cvshealth.com/newsroom/press-releases/cvs-health-pbm-clients-achieved-lowest-prescription-drug-trend-four-years. Accessed Dec. 15, 2017.

[67] "Express Scripts CEO addresses drug pricing 'misinformation,'" *St. Louis Today,* Feb. 17, 2017, http://www.stltoday.com/business/local/express-scripts-ceo-addresses-drug-pricing-misinformation/article_8c65cf2a-96ef-5575-8b5c-95601ac51840.html. Accessed Dec. 15, 2017. This is apparently the first time since their acquisition of Medco in 2012 that Express Scripts has disclosed its rebate retention.

[68] Adam Fein, "Will CVS Health's Point-of-Sale Rebates Deflate the Gross-to-Net Bubble—and Disrupt the PBM Business?," June 15, 2017. Available at: http://www.drugchannels.net/2017/06/will-cvs-healths-point-of-sale-rebates.html. Accessed Dec. 14, 2017. The "gross-to-net rebate bubble" is a description coined by Adam Fein.

In contrast to generic Rx fills by retail drugstores, PBMs do not markup, or earn a "spread margin" on, brand Rx ingredient costs, however measured and wherever filled. When a brand/specialty drug is rebatable, PBMs prefer the drug with the highest list price, i.e. the drug that will generate the highest rebate retention amount. For example, in the Hepatitis C Virus Drug Therapeutic Class, the two largest PBMs, CVS Caremark and Express Scripts (ESRX), are reported to have a history of making the HCV therapeutic class a "winner-take-all" proposition, persuading competing companies to choose a high list price to be in a position to offer a "deep discount" rebate to gain exclusivity in the HCV therapeutic class.[69] According to Express Scripts, the use of an exclusionary formulary coupled with deep discount rebating on a smaller class of specialty/brand drugs could deliver **an additional $2.5 billion** in manufacturer rebates to the PBM in 2018.[70]

Do deep discount rebates on brand/specialty drugs drive skyrocketing list prices?

The transparency movement began in the Spring of 2003, when Congress decided to make pass-through rebating the cornerstone of the Medicare Part D public-private partnership with insurers and PBMs. The legislated emphasis on rebating resulted in a growing divergence between the list prices for brand drugs (gross) and the prices manufacturers receive after deductions of rebates paid to PBMs and their insurer/TPP clients (net).

(1) The "basis" for collecting rebates today, i.e. rebatable specialty drugs, is a much narrower class of drugs than was the case ten years ago when small-molecule drugs were included in the basis for rebates.

(2) PBMs today must derive a majority of their gross profits from this smaller rebatable base, while maintaining a transparent rebate retention rate at 10% on average.[71] This pressure results in increasing divergence between gross (or list) price and rebated (net/negotiated) price for the drugs that are treated as rebatable. This growing divergence has come to be known as the "gross-to-net rebate bubble."

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[69] Lawrence Abrams, "Was CVS's Formulary Exclusion of Mavyret a Violation of Antitrust Laws?" October 15, 2017, http://nu-retail.com/mavyret-antitrust/. Accessed Dec. 15, 2017.

[70] Adam Fein, "What's In, What's Out: The New 2018 CVS Health and Express Scripts Formulary Exclusion Lists (Plus: A Sneak Peek From Prime)." Available at: http://www.drugchannels.net/2017/08/whats-in-whats-out-new-2018-cvs-health.html. Accessed Dec. 15, 2017.

[71] See generally, Lawrence Abrams' discussion of the correlation between rebates and list price at: http://nu-retail.com/merck-data/. Accessed Dec. 15, 2017.

(3) Insurers prefer highly rebated drugs and have kept the value of the resulting net prices confidential, with the active support of other drug channel actors.

Several reports have been issued on the correlation between high list prices and high rebates. Most of these, undertaken by drug channel actors, deny the existence of a correlation.[72] Dr. Abrams, on the other hand, using data from Merck, found a **significant positive correlation coefficient ratio of .653** between annual brand drug list price inflation and annual rebates rates that Merck had negotiated with PBMs. The PBM-sponsored study showed no correlation. The key for reconciling these differences, says Dr. Abrams, revolves around the choice of sample: the sample used in the PBM-sponsored study was not limited to rebatable drugs and thus was 'smoothed out' with non-rebatable drugs. Price changes for non-rebatable drugs should obviously show no correlation with rebates.[73]

Using a different modeling approach and data supplied by the drug company Merck, Dr. Abrams went through a step-by-step sequence based on how PBMs and drug companies might negotiate the parameters of a rebate deal today under a fixed rebate retention rate at 10%. The outcome of such constrained negotiations reproduced a gross-to-net price bubble.[74] **Dr. Abrams concluded that under the current set of constraints, net and list prices will continue to diverge but at a constant rate.**[75] Resolution of the gross-to-net rebate bubble and high list prices for insulin thus requires a broad restructuring of the current pricing system, incentives and constraints.

What are insurers hiding?

According to the most recent QuintilesIMS report, as discussed by Adam Fein, the total value of pharmaceutical manufacturers' off-invoice discounts, rebates, and other price concessions has more than doubled over the past five years, from $59 billion in 2012 (pass-through contracting) to $127

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[72] According to Express Scripts: "For some prescription drugs, rebates provide a discount to employers and plan sponsors who allow easier access to a medication that has marketplace competition. Rebates do not raise drug prices, drug makers raise drug prices, and they alone can lower them." Available at: http://lab.express-scripts.com/lab/insights/industry-updates/sharing-smarter

[73] Available at http://nu-retail.com/merck-data/.

[74] Abrams, "Blame Pharmacy Benefit Managers (Not Pharma) For Driving Drug Price Inflation, Sept. 13, 2017. Available at: http://nu-retail.com/drug-price-inflation/. Accessed Dec. 15, 2017.

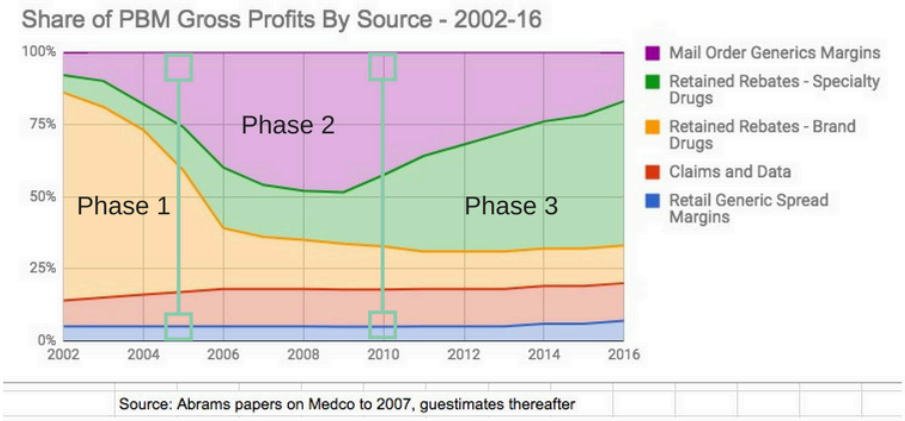
[75] "Blame Pharmacy Benefit Managers (Not Pharma) For Driving Drug Price Inflation."

billion in 2016 (deep discount, exclusionary formulary).[76] In 2016, the year-on-year increase amounted to $11 billion—or about 84% of the insurance industry's net income of $13.1 billion.

Dr. Abrams, who in 2003 coined the term "rebate retention rate," assessed that this gross-to-net bubble was initially fueled by PBMs' need to replace a declining trend in gross profits from mail order and shrinking rebatable generic prescription base. Around 2010, they experienced another substantial loss of gross profit as payers were imposing pass-through contracting. PBMs must today derive a majority of gross profits from a shrinking pool of rebatable specialty drugs while maintaining a transparent rebate retention rate at 10% on average. That additional loss has been fully offset by the use of exclusionary formulary and deep discount rebates. List prices for rebatable drugs—including insulin—have skyrocketed as a result. **And thus an ever-shrinking percentage of patients with a narrowing subset of chronic conditions are being asked to generate the same profits that formerly came from the entire base of the U.S. prescription drug market.**

1. up to 2005 – reliance on retained rebates from small molecule brand drugs;
2. 2005 – 2010 – reliance on mail order generic Rx margins;
3. 2010 – present – reliance on retained rebates from specialty drugs.

Below is Dr. Abrams' graph estimating the distribution of PBM gross profits over the past 15 years:[77]



Graph: Lawrence W. Abrams, "Blame Pharmacy Benefit Managers (Not Pharma) For Driving Drug Price Inflation."

[76] Adam Fein, "New Data Show the Gross-to-Net Rebate Bubble Growing Even Bigger." http://www.drugchannels.net/2017/06/new-data-show-gross-to-net-rebate.html. Accessed Dec. 15, 2017. Deep discount rebates associated with rebatable specialty/brand drugs are the largest component of the bubble.

[77] Abrams, "Blame Pharmacy Benefit Managers (Not Pharma) For Driving Drug Price Inflation," September 13, 2017. Available at: http://nu-retail.com/drug-price-inflation/

What happens next?

While there is in fact sufficient information to track rebate dollars—in broad general terms—to the doors of payers, payers themselves are refusing to be subject to any form of transparency and accountability.[78] As a result, all statements regarding the insurers' actual use of the 90%–100% of the rebates they evidently receive—including claims by payers or AHIP that rebates are used to reduce premiums on Medicare Part D, ACA, or any other plan—can only be speculative, or cannot be confirmed by members of the public. Once classified as general revenue, insurers can apply the rebates amounts as they see fit—plan drug costs, other plan costs, corporate expenses, CEO bonus or shareholder distributions.

Variable net pricing/rebating

More concerning, recent statements would suggest that the injury caused to consumers might be much larger than initially assessed. Rebates are apparently not constant; they vary depending on the plan member's benefit design—in other words, a drug may be cheaper to the plan during phases when the member must pay significant cost-sharing out of pocket. Net prices apparently decrease (i.e. rebates increase) when a member pays out-of-pocket. According to PCMA, this variable net pricing scheme generates $29 billion in rebate payments. In fact, the PCMA figure is calculated based on the assumption of a 33% pass-through rate. Knowing that the actual effective pass-through rate to insurers is closer to 90%, the cost-sharing over-payment could actually amount to **$58 to $79 billion** for Medicare Part D alone.[79]

Under variable net pricing/rebating, manufacturers may actually sell their drugs at a lower net price when a Medicare Part D beneficiary is in the donut hole. But instead of assisting plan beneficiaries by then basing their cost-sharing on the lower net price, it appears that plan sponsors keep the additional

[78] For example, the recently enacted SB17 in California guarantees the confidentiality of all insurer disclosures while subjecting manufacturers to an asymmetrical regime of selective disclosure biased toward the reporting of list price increases (with no offsetting information regarding net cost to plans that might be remaining stable, or even decreasing).

[79] CMS assessment, available at: http://www.drugchannels.net/2017/11/will-cms-pop-gross-to-net-bubble-in.html.

rebate and may thus receive a windfall.[80] The share of the $127 billion (gross-to-net bubble) generated by drug rebates may in fact be larger than initially expected – possibly **$102 billion or more.**

The Medicare Part D cost-sharing crisis.

When Congress passed MMA (Medicare Part D) in 2003, rebates and other price concessions were expected to be passed through to members at the point of sale, i.e., when a prescription is dispensed, in the form of a low negotiated price. But in 2005 CMS relaxed this absolute requirement and in its final rule gave plan sponsors the flexibility to chose the most practical rebate sharing mechanism.

CMS might have expected, in making its 2005 final rule, that rebates would be partially reflected in the negotiated price at the point of sale; CMS did not, however, suggest an alternative mechanism nor an auditing mechanism should the sponsor decide not to include all rebates at the point of sale. It is unclear at this point whether CMS intended this situation to be transitory in order to give private insurers an additional incentive to participate as well as more time to implement the required IT infrastructure.[81] If CMS expected private insurers to voluntarily comply with MMA, that is definitely not what has happened.

As early as 2004, commercial payers began to message that Medicare Part D's lack of direct negotiation power should receive the blame for the anticipated increase in drug prices. And the temporary fix included in the CMS 2005 final rule was never corrected. As Adam Fein has pointed out, "Under current rules, therefore, Part D sponsors may have weak incentives, and, in some cases even no

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[80] Sarah Karlin-Smith, "Part D Proposal Doesn't Touch Pharma," https://www.politico.com/newsletters/prescription-pulse/2017/11/20/part-d-proposal-doesnt-touch-pharma-027829 (The drug industry would also benefit from a global shift toward patients paying net/negotiated price because lower out-of-pocket costs would mean fewer patients wind up in the Part D donut hole, where drugmakers must offer bigger discounts. The Pharmaceutical Care Management Association, citing CMS estimates, notes that plans applying rebates at the point of sale would raise premiums "by up to $28 billion and taxpayer costs by up to $82 billion over the next decade. Such a requirement would also create a windfall for drugmakers, who would pay up to $29 billion less in donut-hole discounts.")

[81] Medicare Part D is under the constant threat of losing commercial insurers, as Dr. Fein recently reminded us: "Some plan sponsors may drop out of the Part D program. As [Dr. Fein notes in his] analysis of preferred pharmacy networks in the 2018 Medicare Part D plans, the total number of plans has already declined, from 1,169 in 2014 to 782 in 2018." Adam Fein, "Will CMS Pop the Gross-to-Net Bubble in Medicare Part D With Point-of-Sale Rebates?" Available at: http://www.drugchannels.net/2017/11/will-cms-pop-gross-to-net-bubble-in.html. Accessed Dec. 14, 2017.

incentive, to lower prices at the point of sale or to choose lower net cost alternatives to high cost-highly rebated drugs when available."[82]

In 2006, plan sponsors decided they would base the so-called 'negotiated price' on the brand-name prescription drug's list price (reduced by small price concessions received from the pharmacy network), not on the drug's net price after rebates, i.e. the true negotiated price intended by MMA.[83] Insurers and other TPPs replicated the same rebate-capture mechanism for their private plans, and eventually for ACA plans as well. The result is the current cost-sharing crisis, where consumers are forced by insurers to pay inflated list prices instead of the much lower net or negotiated prices that represent the drugs' actual costs to the insurance plan/TPP/Medicare Part D plan sponsor.

Can manufacturer rebates be shared with plan members at the point of sale?

90% to 100% of the rebate amounts received by large employer plans, large insurers and union plans are now reportedly retained by these third-party payers as general revenues and used for corporate purposes in complete opacity.[84] The next question is obviously whether these rebates could be passed back to consumers at the point of sale. The answer is yes.[85] The technology has existed for several years and has already been commercially implemented by mid-size progressive PBMs offering complete end-to-end transparency.

Established in 2001, Envision Pharmaceutical Services (EnvisionRxOptions) is a national, full-service pharmacy benefit management (PBM) company. EnvisionRxOptions, now part of the RiteAid group, was founded on a commitment to provide full transparency and disclosure in the PBM marketplace.

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[82] Adam Fein, "Will CMS Pop the Gross-to-Net Bubble in Medicare Part D With Point-of-Sale Rebates?" Drug Channels Nov. 21, 2017, http://www.drugchannels.net/2017/11/will-cms-pop-gross-to-net-bubble-in.html. Accessed Dec. 15, 2017.

[83] CMS has been publicly reporting that "Beneficiaries' cost-sharing is calculated based on the drug price at the point-of-sale" without clarifying that this "price at the point-of-sale" is the full list price rather than the required 'negotiated price.' See, e.g.: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html

[84] "The majority of rebates Express Scripts receives from drug makers (nearly 90%) are paid by Express Scripts to employers and plan sponsors." Adam Fein, June 30, 2017. Tweet available at https://t.co/MEYlHbSOtH.

[85] IT network management is an integral part of the services provided by PBMs. The integration of PBM, pharmacy and insurance networks already allows for real-time benefit management at the point of sale. See, e.g. written testimony of Patricia M. Manzon, Ph.D., on PBM Compensation and Fee Disclosure for the 2014 ERISA Advisory Council, p. 1.

Envision states that it employs a transparent, pass-through business model in which 100% of earned rebates, discounts, and incentives are instantly credited at the point of sale to customers.[86]

It has also been reported that Express Scripts also offers a POS benefit design called SmartShareRx. It doesn't appear that Express Scripts is actively marketing this solution.[87] Express Scripts disclosed in a recent earnings conference call:

> *"We collaborated with several key health plan clients to launch SmartShareRx, which enables patient and drug-specific rebates to be offered to our PBM members at the point of sale. For payers, our SmartshareRx solution gives them enhanced flexibility to offer plan designs that match their growth and patient engagement strategies."*[88]

Express Scripts' marketing material for its pass-through point-of-sale solution uses the example of Humalog:

> "*Consider the cost of Humalog® (insulin lispro): over the past seven years, the list price for this medication has increased dramatically, yet the net cost has remained relatively constant.*[89] *Without PBMs, and specifically without Express Scripts, plan sponsors would have paid exponentially more for their prescription drugs… The majority of rebates Express Scripts receives from drug makers* ***(nearly 90%) are paid by Express Scripts to employers and plan sponsors*** *who pay for the pharmacy benefit. These employers and plan sponsors negotiate whether they will keep the whole rebate or allow Express Scripts to retain a small portion of the rebates.* ***Employers and plan sponsors also decide how to use the discounts provided by rebates****…* "[90]

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[86] http://www.businesswire.com/news/home/20131203005586/en/Envision-Pharmaceutical-Announces-Acquisition-Laker-Software. Accessed Dec. 14, 2017. We cite EnvisionRx as one example among others. T1DF has no commercial relationship with this entity or with any other PBM.

[87] Fein, "Will CVS Health's Point-of-Sale Rebates Deflate the Gross-to-Net Bubble—and Disrupt the PBM Business?" http://www.drugchannels.net/2017/06/will-cvs-healths-point-of-sale-rebates.html. Accessed Dec. 15, 2017.

[88] Second Quarter 2017, Financial Results, Earnings Conference Call, July 26, 2017. Available at: https://expressscriptsholdingco.gcs-web.com/static-files/e41855f1-01a8-445c-aa11-307850486cc4

[89] In fact, per an October 2016 *Wall Street Journal* article by Denise Roland and Peter Loftus ("Insulin Prices Soar While Drugmakers' Share Stays Flat," Oct. 7, 2016) the list price for Lilly's Humalog insulin drug was at that time more than twice that of the drug's 2011 price, but its **net price had declined.** See http://www.drugchannels.net/2017/03/drug-channels-news-roundup-march-2017.html and https://www.wsj.com/articles/insulin-prices-soar-while-drugmakers-share-stays-flat-1475876764. Accessed Dec. 15, 2017.

[90] "Sharing. Smarter." Express Scripts, June 29, 2017. http://lab.express-scripts.com/lab/insights/industry-updates/sharing-smarter. Accessed Dec. 15, 2017.

Express Scripts provides further detail regarding this new program in a written clarification to its Form 10-K for the year ended December 31, 2016.[91] As Dr. Abrams explained in an email to T1DF, PBMs have an accurate estimate in real time of rebates due from manufacturers at the time of brand fill at list price, either at the retailer or the mail order point of sale. When the consumer fills a prescription, "a signal is triggered to Express Scripts' accounting system in [St Louis] to generate an accrual of rebate due from Pharma as a % of list price. This means that Express Scripts has the capability of generating an accurate signal from their internal accounting systems back to the retail pharmacy [point of sale] terminal to adjust copay as a % of **net price** instead of gross price."[92]

Conclusion: a cost-sharing crisis.

We have reviewed in this first section the key role of rebate pass-through in Medicare Part D, the litigation and government actions that led to the widespread use of rebate pass-through contracts, the increasingly small share of retained rebates that PBMs keep (instead passing through nearly all reimbursements and price concessions to insurers/TPPs, who may also receive reimbursements directly from manufacturers), and the resulting economic trends that have amplified deep discount rebating on a decreasing subset of rebatable drugs—a phenomenon that has been described as a "gross-to-net" drug pricing bubble.

These trends have directly caused the **list prices** of a small subset of rebatable specialty/brand name drugs, including analog insulin, to skyrocket while their **net prices**, although much lower than list, remained insulated from downwards competitive pressure. Commercial insurance companies and other third-party payers have taken advantage of this phenomenon by basing cost-sharing on list rather than net price. The crisis we are facing is thus an insurance benefit design/cost-sharing crisis.

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[91] https://www.sec.gov/Archives/edgar/data/1532063/000095013817000610/filename1.htm and http://www.businessinsider.com/sec-looks-into-express-scripts-rebates-from-pharmaceutical-firms-2017-12

[92] Email Lawrence Abrams to Charles Fournier, Dec. 11, 2017.

Diagnosing the U.S. cost-sharing crisis

In this section we will briefly review the impact of the cost-sharing crisis on insured and uninsured patients. Since Congress has not yet acknowledged that the crisis even exists, we will not develop this section in great detail at this point. The matters we outline below will be further addressed when the basis of the injury to these individuals has finally been acknowledged by Congress.

Actors.

U.S. Government – Reliance on a public-private partnership model for the delivery of Medicare and certain Medicaid services has apparently destabilized the regime of regulatory checks and balances that would ordinarily operate between the private and public sectors. Since 2006, the federal government has been aware of Medicare Part D sponsors' failure to abide by the MMA requirement to use 'negotiated' (net) drug prices as the basis of members' cost sharing.

Manufacturers – Manufacturers are deriving substantial profits from Patient Assistance Programs ('rebates' off list prices for participating patients, who are by definition low-income, are much smaller than the deep discounts provided to commercial insurers, resulting in unconscionable supra-competitive profit to manufacturers). Some dominant actors have also taken advantage of the anti-competitive nature of exclusionary formulary to deny competitors market access and receive supra-competitive net prices. Competition on rebating, and not on net prices and the intrinsic qualities of the pharmaceutical product, has stifled innovation. Drug companies are accomplices, and they do obtain additional profits from the dual-pricing scheme.

PBMs – PBMs have been enablers and enforcers of the network of confidentiality agreements that have kept the net price of analog insulin confidential for decades. They have also driven the skyrocketing list price increases in order to maintain or increase gross rebate revenues from a shrinking pool of rebatable specialty drugs. The recent shift to PBM-controlled exclusionary formulary based on financial rather than medical considerations, and the explosion in rebating it generated, is a growing existential threat for the type 1 diabetes community.

Insurers, Large Employer Plans,[93] **Third Party Payers** – Aetna, Anthem, Cigna, Humana and UnitedHealth Group – the top five for-profit insurers – cumulatively collected $4.5 billion in net earnings in the first three months of 2017. The industry's net income rose to $13.1 billion, a year-on-year increase of 46%.[94] Part of this income comes from the insurance industry's large and increasing share of the rebates and other price concessions paid by manufacturers to PBMs and passed through to payers—but not to patients. Assuming a low average pass-through rate of 85%, then 100% of the insurance industry's profit, and more, would now derive from manufacturer rebates kept by insurers and other TPPs while individual patients are overcharged.

The greatest injury to insured patients with chronic medical conditions such as diabetes is the cost-sharing crisis.

Insured patients who have extremely expensive medical conditions such as cancer (with annual treatment cost mounting into six figures) will immediately hit out-of-pocket maximums, whether insurers calculate patient cost-sharing in terms of list price or lower net cost. The list/net cost-sharing crisis thus primarily concentrates its injury on patients with chronic conditions who use heavily rebated drugs such as insulin. These insured plan members move through even extremely high deductibles and out-of-pocket maximums year after year, hitting maximums that many of them would not meet at all—or would meet much later in the plan year—if they were correctly paying insurers' net cost to plan for prescription drugs like insulin.

Because the H.E.L.P. Committee has, to date, failed to acknowledge that rebates are being returned to insurers, they have evaded the key injury to consumers: when reimbursements negotiated "to reduce the price of drugs" are being returned to insurers, these are not being used to reduce individual patient cost-sharing.

For Medicare Part D beneficiaries, the Committee offered no explanation of the cost-sharing practice that is already required under MMA—i.e. that negotiated price, as defined in the legislation, should already be passed through to patients. The Committee did not ask why CMS, 14 years after passage of the MMA in 2003, is now seeking comment on how to implement its longstanding legal mandate to

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[93] While small employer plans behave more like individuals, i.e. contract for PBM services via a health plan administrator, over 65% of large employer plans contract directly with a PBM. See, e.g., written testimony of Patricia M. Manzon, Ph.D., on PBM Compensation and Fee Disclosure for the 2014 ERISA Advisory Council, p. 3.

[94] http://money.cnn.com/2017/06/15/news/economy/health-insurers-profits-obamacare/index.html.

pass through net negotiated price. Why no question from the Committee, during hearings dedicated to the high price of drugs to American consumers, regarding this crucial disclosure from CMS?

We have now a system where individuals with chronic conditions such as insulin-dependent diabetes are, in addition to the heavy financial, social and medical burden of their medical condition, additionally being forced to subsidize the premiums of other Americans who use no or different prescription drugs—via overpayments on a massive scale, to the amount of $29 to $79 billion per year.

Whether the most vulnerable, uninsured Americans are fairly treated should be the litmus test for any health care pricing system.

Uninsured Americans are, meanwhile, exposed to skyrocketing unrebated prices, which are rising fueled by demands from insurers and PBMs (whose retained rebate share depends on rebate size) for ever-increasing rebates. Because the H.E.L.P. Committee did not touch the impact of the dual-pricing system in general, it could not explore the indirect harmful impacts on the uninsured of a system that generates very high list prices as a byproduct of rebate negotiations. **Nor could it address how manufacturers benefit from the insurer-generated rebate negotiation system when they sell to consumers who do not have insurance (selling at a supra-competitive list price, and taking unconscionable profit in particular relating to patient assistance programs that sell to the poorest of uninsured patients at prices much higher than net prices insurers pay)**.

Any viable solution to the prescription drug-pricing crisis must convey the same or an equivalent benefit to the uninsured; otherwise we are simply kicking much higher healthcare costs farther down the field, paying for ER visits and eventually a Medicare system full of patients with longterm complications that could have been avoided with early affordable access to needed medication. Real reform of the drug pricing system must acknowledge the unfair burden that the current system places on the most vulnerable people in the U.S.—those who can't afford insurance, don't qualify for insurance, or have somehow fallen through the cracks even though they technically qualify for Medicaid. Everything about the politics of 2017, not least the tax bill currently under consideration, indicates that this population is likely to grow. This population must be protected, not further abused under a new set of labels.

Potential solutions that have been offered to protect the insured—value-based pricing, outcomes-based reimbursements to payers, lower co-pays for all instead of cost-sharing—remain insurance-based solutions. People who don't have insurance have no individual negotiating power: high cash prices at the pharmacy are collateral damage of a market where manufacturers secretly compete on the size of rebates, thus inflating the cash price that the uninsured have no choice but to pay.

T1DF doesn't advocate for a specific health care system solution. We do argue that the current hybrid system is putting uninsured people with diabetes in an unsustainable position. The U.S. can have single-payer system with no patient cost-sharing. Or we can have a free market that's free in countless ways were not seeing now. What the U.S. cannot afford is the current system.

Americans with diabetes should no longer be lied to and shamed.

We've spent all of 2017 having a national conversation about health insurance based on misinformation: insurers led us to believe that they, the insurers, pay unrebated list price for prescription drugs. No one on either side of the political aisle wants suddenly, in a live-streamed hearing in December of 2017, to draw public attention to the reality: Congress has looked the other way on consumer fraud for a decade in order to obtain private insurer cooperation in two successive public-private partnerships, Medicare Part D and the ACA. At this point, the goal of many is to distract the public with a focus on manufacturers, while in the background corporate stakeholders come up with a Medicare Part D fix that never acknowledges the overcharging scandal. In this goal of distraction, the interests of Congress, insurers and value-pricing advocates like the Laura and John Arnold Foundation are systematically aligned.

Overcharging on the scale we've seen for insulin can only happen if the public doesn't know the numbers involved—and it can only be brought under control quietly if the patients with the largest injury have lost their right to sue. While Americans are still looking at their pharmacy claim statements that show unrebated list prices as "plan cost," industry actors were making a last-ditch effort in this week's House Committee on Energy and Commerce's Health Subcommittee hearing on drug pricing to convince us that the injury to the few is so inconsequential as to be beneath Congressional attention, and that the injury to the few is justified by a general benefit to everyone else.

Obviously, that's not how insurance is supposed to work—we're not supposed to rob Peter who buys insulin so we can modestly reduce Paul's premium. This is definitely not how Medicare Part D was

supposed to work as it was enacted in 2003. And even the small general benefit is, for diabetes, illusory: if you force rationing of insulin by overcharging, you'll increase both short term and long term costs to the overall health care system.

The injury to people with diabetes who use insulin is even more insidious. This group of Americans has been shamed for years via public statements from insurance industry actors that plans pay list price for insulin, and that paying list price for insulin is a factor driving up premiums for everybody else. Insurers and other TPPs have, in other words, been **using net price to pay and list price to blame.** Consider, for example, this November 2016 remark in a blog post by Estay Greene, the director of pharmacy programs at Blue Cross and Blue Shield of North Carolina (emphasis added):

> *"Can consumers do anything to help control the cost of insulin? Or are they just plain out of luck?… Still, climbing insulin prices affect everyone, even people who don't use insulin.* ***We all pay for expensive drugs through higher insurance premiums.*** *This underscores the urgency of [people with diabetes] adopting healthy lifestyles and using health care wisely."*[95]

A person with diabetes who finds out tomorrow that he's been paying three times the net cost of his insulin to his insurance plan will be outraged—that could mean thousands of dollars of overpayment in a single year. But the lie, perpetuated by insurance executives and their public relations apparatus, might also cost him access to health insurance, period. This unconscionable scapegoating of a vulnerable population—particularly *the scapegoating of a population who are currently being overcharged by their insurers for a lifesaving drug*—must stop. We had hoped the Committee would deliver this message to the American public.

[95] Estay Greene, "Why Does Insulin Cost So Much after 95 Years?" Blue Cross Blue Shield of North Carolina, November 11, 2016 http://blog.bcbsnc.com/2016/11/why-insulin-cost-so-high/)

Conclusion

Rebating on insulin has accelerated in the same years that we saw Medicare Part D implemented (a voluntary program, for both seniors and insurers). It truly exploded when the Affordable Care Act delivered a captive market to insurers and payers enforced strict pass-through contract terms. Misinforming the public about prescription drug spending has been central to insurers' effort to profit from the ACA while publicly describing themselves as its victims. There's a paradox here: insurers need the ACA's anti-discrimination mandate in order to perpetuate the fraud T1DF alleges in our lawsuits on insulin, glucagon, and test-strip overpricing. But they also need to blame the ACA to deflect public attention from the actual injury insurers are committing against people with diabetes. The message has been (1) that the ACA's anti-discrimination mandate "forces" insurers to keep people with diabetes in their plans, which in turn (2) "forces" increased premiums because list price for insulin is high (and net price is never mentioned), and then people with diabetes are blamed for the premium increases.

Along the way, opponents of the ACA have gone even farther. Consumers on high-deductible ACA policies devastated by out-of-pocket payments for insulin? The ACA is "failing to keep down the cost of drugs." ACA premium hikes, which insurers tell us are caused by rising list prices for prescription drugs? Opponents say drug spending on people with pre-existing conditions must be driving up ACA premiums for the healthy. In 2017 we've seen the supposed impact of insulin list price on premiums used to argue that people with diabetes should pay much higher premiums, or should be pushed into the deep end of a "high risk pool."

What if we replayed 2017's national conversation on health insurance with full public knowledge that insurers don't pay list price for drugs? What if we replayed those conversations about premiums and high risk pools and individual mandates knowing that an insurer actually makes a large profit every time a person on a high-deductible ACA plan buys a vial of insulin? What if we started asking why the drug prices Medicare Part D members are forced by plan sponsors to pay are not based on the true negotiated price? What if we started asking where $127 billion dollars in annual drug rebates is actually going?