



**OREGONIANS FOR
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August 24, 2018

HB 4005 Rulemaking Advisory Committee
Oregon Department of Consumer & Business Services
Division of Financial Regulation
350 Winter St. NE
Salem, OR 97309

By Email to: Jesse.E.OBrien@Oregon.gov

Re: HB 4005 Rulemaking Advisory Committee / Mark Griffith's Comments to the Joint Task Force on Fair Pricing of Prescription Drugs, August 21, 2018

Committee Members,

On August 21, 2018, a member of this HB 4005 Rulemaking Advisory Committee ("Committee"), Mark Griffith, filed a public comment with the Joint Task Force on Fair Pricing of Prescription Drugs ("Task Force") that disputes the relevance of the Task Force's ongoing deliberations as they relate to the work of this Committee. It is reasonable to assume that Mr. Griffith acted on behalf of the Committee or with its implied consent.¹ I am therefore replying to the Committee.

Mr. Griffith's letter misrepresents the substantive contribution of Dr. Neeraj Sood and disparages the work of the Task Force members.²

Mr. Griffith downplayed the relevance of Dr. Sood's discussion of rebate pass-through to the overlapping scope of this Committee.³ By characterizing the cost factors the Task Force might be prepared to find significant to the prices paid by Oregonians for pharmaceutical products as "on the fringes of the issue," Mr. Griffith seems to prepare the ground for this Committee to overlook the recommendations of the Task Force in the event that the Task Force should progress from its preliminary identification of benefit design (absence of rebate pass-through) as a cost factor worthy of evaluation to a final determination that insurers' failure to pass through rebates to consumers is the most significant cost factor driving most list price increases on brand prescription drugs.

¹ Mr. Griffith should, among other issues, be asked to clarify whether he made his comments to the Task Force as a representative of this Rulemaking Advisory Committee or on behalf of the public and private payers that funded the HB 4005 coalition—a coalition represented on the Committee by Courtney Helstein, Strategies 360 Director of Government Affairs.

² Mr. Griffith's letter is available at: <https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/150048>.

³ Review of health insurance rate assessment rules (Section 5(1)(d)); identification of the factors that contributed to the price increase (Section 2(3)(c)).



In response to the Committee/Mr. Griffith’s intervention in the Task Force on August 21, I have attached to this letter relevant slides from Dr. Sood’s Powerpoint presentation to the Task Force, a partial transcription of his oral comments (including Q&A with Moda Health’s Robert Judge—another member of this Committee⁴) and OR4AD’s substantive comments filed with the Task Force on August 22, 2018 (including Credit Suisse’s industry analyses of drug prices and rebate trends). These documents are directly relevant to Mr. Griffith’s representations and to the Committee’s Request for Information (RFI) regarding the interplay between rate review and rebate pass-through. OR4AD will substantively respond to this RFI and address other procedural issues related to the membership of the Committee under separate cover.

Dr. Sood’s presentation did not, as Mr. Griffith alleges, show that “the primary driver of the high cost of prescription drugs remains the list price [*sic*] set by manufacturers.” Slide 14 of Dr. Sood’s presentation documents that the key driver of the “cost of prescription drugs” to insured consumers has been the ever-expanding size of rebates that manufacturers pay to health insurers, via their PBM agents (accounting, on average, to 57% of list price in 2014 and 70% to 80% of analog insulins’ list prices in 2018), but that payers do not pass through to consumers in many benefit designs. Dr. Sood specifically discussed the fact that health insurers capture almost all manufacturer rebates—PBMs retain only a small percentage, now reported, on average, at 5%—but health insurers fail to use these rebates to offset the prescription drug “cost-sharing” payments they exact from individual beneficiaries.⁵ Dr. Sood’s key recommendation was therefore to “[m]andate pass-through of discount to consumer [to ensure] that consumers get the benefit of rebates.”⁶ Dr. Sood’s work also documents that non-creative intermediaries—health insurers and pharmacy networks, not drug manufacturers—are the health care actors with the greatest excess profits.

Mr. Griffith, in addition to misrepresenting Dr. Sood’s recommendations, disparaged the work of the Task Force as “nibbling around the edges” and characterized the policy proposals under consideration by the Task Force (and, by extension, OR4AD’s substantive comments) as being “on the fringes of the [prescription drug prices] issue.”

⁴ During the August 21 meeting of the Task Force, Mr. Judge also raised issues directly related to the scope of the Committee, i.e. (1) actuarial standards, (2) impact of manufacturer rebates on costs to plan and (3) benefit design. Mr. Judge asked the Task Force to stipulate that an insurer’s benefit design always decreases costs to members. The Task Force rejected the stipulation. It is well established that payers’ rebate-capture scheme inflates coinsurance payments and contributes to premium inflation when premium rate increases are based on gross pharmacy claims expenses, before rebate offset, as directed by NAIC’s reporting data model. See, e.g., <https://www.t1df.org/news/2017/12/15/t1df-letter-to-us-senate-cost-sharing-crisis>; <https://www.t1df.org/news/2018/4/19/t1df-president-files-motion-in-support-of-pbminsurer-track>.

⁵ Dr. Sood assumed that payers capture 90% of manufacturer rebates, an assumption consistent with Credit Suisse’s assessment in 2016. In 2018, payers reportedly capture, on average, between 94% and 98% of manufacturer rebates (see attached).

⁶ Slide No. 43, Recommendation three. Available at: <https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/150027>.



Insurers' rebate capture (and related refusal to pass rebates through to consumers) is at the core of both "the [prescription drug prices] issue" and the impact of drug costs on premium rates. Mr. Judge's comments in the August 21 Task Force meeting regarding actuarial assessment of premium rates (and rebate pass-through—specifically, "it's a lot of dollars going to a very small set of prescriptions") and Mr. Griffith's comments regarding Dr. Sood's presentation paradoxically point to a crucial overlap between the Task Force and the HB 4005 Rulemaking Advisory Committee regarding Section 5 of HB 4005. The attached OR4AD comments, issued to the Joint Task Force On Fair Pricing of Prescription Drugs on August 22, 2018, are thus directly relevant to Section 5 of HB 4005 and hence to the work of this Committee.

Section 5 of HB 4005 concerns "information regarding drugs reimbursed by the insurer under policies or certificates issued in [Oregon]."⁷ Most of these drugs are generics. Some of these drugs are brand drugs subject to deep discount rebates paid by manufacturers for placement on payers' exclusionary formularies. The 'cost' of these drugs to insurers, and to the plan, is thus the net cost after subtracting rebate offset (and any other discount or price concession by other name) from claims expenses. In aggregate, such rebates now amount to about \$150 billion annually in the U.S.

Since rebates collected by Oregon health insurers amount to substantial sums ("a lot of dollars") as stated by Mr. Judge, then any actuarial assessment based on unrebated pharmacy claims expense—as well as any insurer cost reporting under HB 4005 based on unrebated pharmacy claims expense—is fundamentally flawed and injurious to patients (inflated drug costs), to other plan members (inflated premium rates) and to uninsured Oregonians (inflated cash prices, inflated OPDP discount card prices).

Oregon statutes and regulations do not, however, define 'net cost to plan.' Insurance regulations do not clarify the basis of premium rate assessment and excessively rely, via incorporation by reference, on NAIC's standards, model laws and processes. In order to fulfill the mandate of HB 4005, if the presence of substantial rebates would generate a flawed assessment of the actual cost of a prescription drug to insurers (and thus the proper impact of that drug's cost on health plan premiums), then the starting point for rulemaking on insurer reporting under HB 4005 must be (1) a definition of 'cost,' (2) a review of insurers' discriminatory practice of using unrebated claims expense as the basis for patient payment and premium rate actuarial assessment, and (3) a review of the 'incorporation by reference' framework upon which insurance regulation in Oregon is currently predicated.

Mr. Griffith's recommendation that "any changes to existing insurance regulation [should] be limited to the bare minimum necessary to implement 4005's additional requirements"⁸ seems thus to express (1) a fundamental

⁷ HB 4005, Section 5, Clause (1).

⁸ <https://dfr.oregon.gov/help/committees-workgroups/Documents/prescription-price-transparency/20180817-comments-OSPIRG.pdf>.



misunderstanding of the regulatory issues raised by HB 4005 and (2) a partisan position that promotes the current practices of “the coalition [of public and private payers] in support of HB 4005” (no rebate pass-through to consumers, coinsurance based on list prices, premium rate assessment based on unrebated/gross pharmacy claims expense), and is hence **entirely contrary to consumers’ interest**. It is also self-serving: OSPIRG has been intimately involved in health insurance rate review over several years; a finding that Oregon insurers have been falsely representing ‘cost’ in this process would significantly undermine OSPIRG’s credibility and its claim to work as an independent watchdog in relation to the health insurance industry.

Mr. Griffith clearly does not speak as an advocate for Oregon consumers when he argues to preserve current insurance rate review practices that OR4AD has argued are exploitative to the point of potentially constituting consumer fraud or otherwise potentially violating state and federal law protecting persons with pre-existing medical conditions and protected disabilities.

Regards,

Charles Fournier, J.D.

Director

Oregonians for Affordable Drug Prices Now

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Exhibit List

- A Dr. Sood’s Slides for Presentation to the Task Force on August 21, 2018
- B Partial Transcript of Dr. Sood’s Presentation to the Task Force on August 21, 2018
- C OR4AD Comment to the Joint Task Force On Fair Pricing of Prescription Drugs (August 22, 2018)



EXHIBIT A

USC Price

Sol Price School of Public Policy

USC Schaeffer

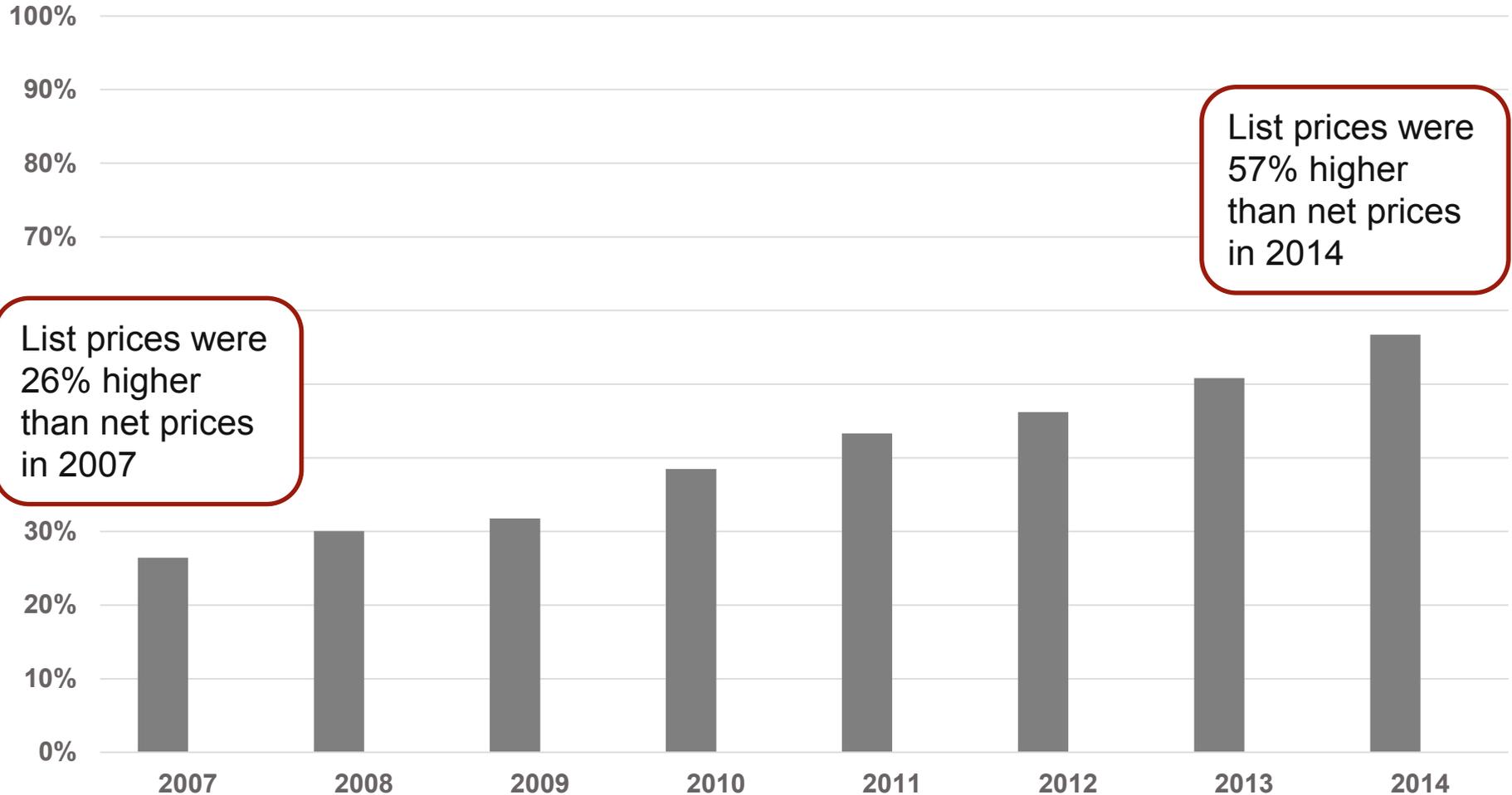
Leonard D. Schaeffer Center
for Health Policy & Economics

Improving Drug Price Transparency

Neeraj Sood, PhD

*Vice Dean for Research and Professor, USC Price School of Public Policy
Strategic Advisor to the Director, USC Schaeffer Center*

Rebates are rising but are consumers benefiting?



List prices were 26% higher than net prices in 2007

List prices were 57% higher than net prices in 2014

Step four: Get disclosures from top 3 PBMs/payers

1. What is the average price per script paid to pharmacies?
2. What is the average rebate per script paid to health plans?
3. What is the rebate received from manufacturers?
4. What is the fee received from manufacturers?
5. What is the pharmacy reimbursement received from health plans?
6. What is administrative fee received from health plans?

Step five: Get disclosures from health plans

1. What is the average price per script paid to PBMs?
2. What is the average rebate per script received from PBM?
3. What is the pharmacy reimbursement paid to PBMs?
4. What is administrative fee paid to PBMs?

Recommendation three: Mandate pass-through of discount to consumers

- Ensures that consumers get the benefits of rebates



EXHIBIT B



Partial transcript: Neeraj Sood presentation to Joint Interim Task Force on the Fair Pricing of Prescription Drugs, 8/21/18

From audio download available at: http://oregon.granicus.com/MediaPlayer.php?clip_id=25011

Slide references in the table are to Dr. Sood's powerpoint slides, available here: <https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/150027>

Time	Speaker	Transcription
1:34	Neeraj Sood (See slide 41, "Rebates misalign incentives.")	"I'm assuming that the PBM keeps only 10% of the [manufacturer] rebates and passes 90% of the rebates back to the health plan. . . . The cost of the drug to the health plan is the retail price less whatever money it got from the PBM as rebates. "



Time	Speaker	Transcription
1:37	<p>Dr. Sood</p> <p>(See slide 43: “Recommendation three: Mandate pass-through of discount to consumer - Ensures that consumers get the benefit of rebates”)</p>	<p>The last recommendation is that if you really cannot move to a discount model and that proves to be difficult, maybe a step there is to mandate a pass-through of the discounts or of the rebates to consumers. So uh, basically what’ll happen is that as far as consumers are concerned when they are paying a coinsurance or they are paying a copay that should reflect the actual price of the drug net of rebates and not the list price of the drug. [Aside from unidentified speaker in the Task Force room: “I understand this is all your fault.”]</p> <p>Again, the rationale here is that you know the PBM market is highly concentrated. What PBMs say is this is actually good for consumers because if a PBM represents more lives they have more bargaining power to negotiate lower prices with manufacturers and pharmacies.</p> <p>But market power is two-sided. So this is true that they will negotiate lower prices with manufacturers and pharmacies, but they also have more market power relative to health plans. So it’s unclear whether they are [going to] pass on these lower prices to health plans or whether they are just [going to] keep these lower prices as higher profits for themselves. And in turn, health plans themselves might have market power. So it’s unclear how much of the savings are passed from the PBM to the health plan. And if the health plan has market power, then it is unclear how much of the savings are passed from the health plan to the beneficiary.</p> <p>So one way of making sure that some of these savings are being passed to the beneficiary is by making sure that the beneficiary never pays based on the list price of the drug, beneficiary is always paying based on the price net of rebates for the drug. So if you are in a high-deductible health plan you are not paying the list price of the drug, which might be \$100, you’re actually paying the price net of rebates, which might just be \$50 or \$40.</p>



Time	Speaker	Transcription
2:07	Robert Judge	<p>“Recommendation number 3, can I ask, [interjection from Task Force Moderator Sam Imperati: “Go for it!”] where you’re mandating pass-through discount to consumers, I wonder if you’ve given thought to the fact that, you know, roughly, you know, 2.3% of prescriptions that are dispensed have rebates associated with them so it’s a lot of dollars going to a very small set of prescriptions that are dispensed in the marketplace and the individuals who get those are a relatively smaller suit—uh, group of individuals—so you’re really maximizing the savings to individuals by passing rebates down to that individual [who] is buying the drug but you’re not um, kind of, helping consumers uh, uh, en masse. Uh . . . And so . . . Is . . . is . . . is that purposeful in how you’re thinking about this, giving optimum savings for consumers on specific drugs, uh, [Dr. Sood interjects: Yes] and letting every other consumer kind of deal with the market as they deal with the market?”</p>
2:08	Dr. Sood	<p>Yes, so I think that is purposeful. Because I think the other way to look at the current system is you are taxing . . . Suppose you are a cancer patient and the list price of the drug is \$100,000, but the actual cost of acquisition of the drug is \$20,000. If you are asking the cancer patient to pay \$100,000 for the drug because all of us who are on the health plan can have a lower premium, I don’t think that’s fair. So if the cancer patient is buying the drug they should pay what it truly costs to get that drug.</p> <p>So if the true cost was \$20,000, I think that particular patient should get the entire benefit of that, not everybody else in their health insurance pool. Because what you’re doing then is just taxing patients who buy drugs and helping everybody else. So this in substance is saying it’s reverse taxation. You’re taxing sick people so that people who are healthy who just pay premiums are [going to] benefit from the discounts.</p> <p>And plus I think that this makes the discounts more transparent. So what might be happening is the difference in price— it’s not that we are getting that back as lower premiums. It’s basically the health plan is keeping that as higher profits.</p> <p>So what this ensures is that the patients who are actually using the drugs benefit from their lower prices and that these discounts are not kept by health plans as profits but actually given to consumers.</p>



EXHIBIT C

OR4AD Report to the Joint Task Force on Fair Pricing of Prescription Drugs (August 22, 2018)



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August 22, 2018

Oregon Legislative Assembly
Joint Task Force on Fair Pricing of Prescription Drugs
Oregon State Capitol
900 Court Street NE
Salem, Oregon 97301

Re: Task Force's Failure to Address "Prices Paid by Oregonians for Pharmaceutical Products"

Dr. Hargunani, Mr. Stolfi, and Task Force Members,

Inaccurate Task Force Roster

First, please note that Jon Bartholomew and John Santa are still inaccurately described as representing "Consumer" stakeholders in Table 4, page 9 of the Executive Summary of the Transaction and Transparency Survey filed by the Staff of this Task Force. This inaccurate representation should be corrected and the ongoing breach of HB 4005's Section 11(2)(D)(v) remediated.

- Mr. Bartholomew's employment as an AARP lobbyist precludes him from representing consumers on this Task Force.¹ AARP is a joint-venture partner of UnitedHealthcare. AARP derives 40% of its total revenues from Medicare plans. AARP has control over these plans' benefit designs and directly profits when those plans use list (unrebated) prices of prescription drugs as the basis for calculating beneficiaries' payments in Medicare Part D. AARP cannot represent consumers on issues that directly impact its principal source of revenues.
- Dr. Santa is similarly conflicted in relation to the health insurance lobby. He is a provider, and healthcare providers are the primary targets of his Open Notes project. Providers depend on insurance companies for inclusion within provider networks, and providers negotiate their fees with insurers. It is also noteworthy that the Open Notes project's primary funders include the

¹ See Exhibit E for a more detailed exposé of AARP's conflicts of interest, including UnitedHealthcare's involvement as defendant in active drug pricing lawsuits filed by an Oregon-based nonprofit.



Cambia Health Foundation, the corporate foundation of insurer Cambia Health Solutions.² Dr. Santa's provider status and Open Notes affiliation, among other issues,³ directly conflict him from representing consumers on any pricing matter—such as health plan misrepresentation of “plan cost” in benefit design—where consumers' interest is adverse to insurers'. Dr. Santa thus cannot represent consumers on this Task Force, which is uniquely focused on drug prices paid by Oregonians.

The roster of the task force must be amended to reflect the stakeholders (insurers, providers, OHPB/OHA) who are actually represented by Mr. Bartholomew and Dr. Santa.⁴

Furthermore, Dr. Santa also seems to participate in this task force as a liaison for the Oregon Health Policy Board's Oregon Sustainable Drug Costs Committee created in November 2017 (and referred to as the “High Cost Drugs Committee”). His relationship to OHPB/OHA may again conflict Dr. Santa from acting as a consumer representative on this Task Force. The relationship between the HB 4005 task force and the Oregon Sustainable Drug Costs Committee chartered by the Oregon Health Policy Board under its authority in ORS 413.016 in November 2017⁵ must also be clarified.

² Cambia is now represented in Salem by former Strategies 360 Vice President Vince Porter. <https://www.linkedin.com/in/vince-porter-0353515/>.

³ See <https://www.opennotes.org/about/partners-supporters/funders/> and <http://www.cambiahealthfoundation.org/about/overview.html>. Open Notes partners with another insurer-funded project originally incubated by The Foundation for Medical Excellence (<https://tfme.org/officers/>): We Can Do Better. Currently incorporated as a tax-exempt Oregon nonprofit, We Can Do Better acts as the “lead convener of the Northwest Open Notes Consortium” servicing about 10 health systems, including Kaiser Permanente Northwest, all three regions of Peace Health, Legacy Health, OHSU, Providence Health & Services, Adventist Health, and Samaritan Health Service. We Can Do Better seems then to use revenues generated from these ‘health systems’ to sponsor Allies for a Healthier Oregon (<https://www.wecandobetter.org/what-we-do/aho/>)—a forum used by AARP (Jon Bartholomew) and others to coordinate legislative agendas and lobbying strategies/actions with other health care organizations such as OSPIRG (Jesse O'Brien).

⁴ We brought AARP's conflict to the attention of this Task Force and Gov. Brown on July 18, 2018 (Exhibit E, also available at: <https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/149724>). No remedial action has apparently been taken. Since Dr. Santa is equally conflicted due to his status as provider, his extensive business dealings with the insurance lobby, and his OHPB/OHA affiliation, Gov. Brown's administration remains in breach of its duty to name to the Task Force individual(s) representing consumers per HB 4005's Section 11(2)(D)(v).

⁵ See, e.g., <https://www.oregon.gov/oha/OHPB/Documents/High%20Cost%20Drugs%20Committee%20Charter.pdf>. Since May 2018, The Oregon Health Policy Board has ceased to report on the status of the Oregon Sustainable Drug Costs Committee. The update on the committee's activities, originally scheduled for the July 10 meeting, has been deleted from the agenda. Since February 2018, no OHPB meeting minute has documented the status and activities of its “High Cost Drugs Committee.”



Task Force’s Failure to Address “Prices Paid by Oregonians for Pharmaceutical Products”

Second, this task force has already passed its mid-term mark but has yet to issue a detailed work plan that outlines its mandatory scope—i.e. the prices paid by Oregonians. To achieve a report that delivers tangible benefit to Oregonians and meets the requirements of HB 4005, the Task Force must now curtail its scope and cease to engage in directionless exploration of “flow of money constructs.”⁶

This Task Force now has only 4 weeks and a single meeting remaining to finalize its scope, identify specific prices ‘paid by Oregonians,’ develop substantive solutions and draft a report. In practical terms, there is no time to engage in theoretical or academic review of the general pharmaceutical supply chain, international pricing models, and other esoteric considerations that are wholly outside the scope of this Task Force and the jurisdiction of the State of Oregon.

Task Force members⁷ are required to issue a report no later than November 1, 2018, which “must contain a cost-effective and enforceable solution that exposes the cost factors that negatively impact prices paid by Oregonians for pharmaceutical products.”⁸

HB 4005 thus mandates that the scope of the Task Force meet 4 tests:

- **Timeliness:** HB 4005 was passed on an **emergency basis** to address an immediate price/access crisis caused in no small part by the State of Oregon’s failure to implement the Oregon Prescription Drug Program and its point-of-sale net price transparency mandate for discount card holders.
- **Enforceability:** The solutions recommended by the Task Force must be **enforceable**.⁹ A solution is enforceable only when the state has plenary or, at a minimum, shared jurisdiction over it. All matters obviously preempted by Federal laws (patents, Medicaid, Medicare, interstate commerce) are outside the scope of this Task Force and need not be discussed.
- **Practicality:** The matters considered by the task force must lead to “**cost-effective and enforceable solutions**”—i.e. practical solutions.¹⁰ Mandating rebate pass-through in the OPDP discount card program is obviously cost-effective and practical; mandating point-of-sale rebate pass-through in all health plans offered to Oregon consumers is cost-effective and practical; transforming the entire U.S. pharmaceutical industry and distribution network is neither. This practicability standard creates a tension with the broader goal to “develop a strategy to create transparency for drug prices across the entire supply chain of pharmaceutical products,”

⁶ Prof. Sood’s presentation scheduled on August 21, 2018, focuses on “flow of money constructs” and “transparency around the flow of funds in the pharmaceutical system.”

⁷ In addition to 4 legislators, the Governor was to appoint 14 individuals including consumer representatives. HB 4005, Section 11(2)(c)(D)(v).

⁸ HB 4005, Section 11(10).

⁹ HB 4005, Section 11(10).

¹⁰ HB 4005, Section 11(10).



including (though not limited to) insurers.¹¹ This task force should have already addressed and reconciled these conflicting requirements.

- **Proximity:**¹² The scope of the Task Force report is exclusively focused on “prices **paid by Oregonians** for pharmaceutical products.” The Task Force does not have the discretion to refocus its report on “flow of money constructs,” unless there is a proximate impact on prices paid by individual Oregonian consumers. For example, the characterization of unrebated pharmacy claims expenses by health insurers as “plan cost” proximately causes an artificial inflation of premium rates, coinsurance payments and copayments—prices paid by over 90% of Oregonians. The OPDP discount card program’s failure to pass rebates through to individuals in the form of transparent net prices also proximately impacts the prices paid by the uninsured as well as the prices paid by enrollees in Medicare Part D and private insurance plans.

The scope of the Task Force is thus unambiguous: the “prices paid by Oregonians for pharmaceutical products.” The Task Force’s implementation agenda should have been straightforward: (1) identify these prices ‘paid by Oregonians’; (2) identify the factors that ‘negatively impact’ these prices and the actors who are controlling them; and (3) outline the practical strategies that would increase price transparency and reduce the prices paid by Oregonians for prescription drugs within the scope of Oregon’s regulatory authority.

In order to meet the practicability, proximity and enforceability factors, the Task Force must limit its focus to issues over which the State of Oregon has full direct control or current statutory oversight/regulatory authority: discount card programs (OPDP, NACo), private insurance benefit design (rebate pass-through), pharmacies’ point of sale fees and possibly 340B prices and Medicare Part D (via legal challenge or by bolstering the competing OPDP discount card program).

The Oregonians primarily impacted by high drug prices for brand drugs are the uninsured and the underinsured—people on individual health plans (either ACA Marketplace or ACA-compliant policies sold off-exchange) or employer plans that have high deductibles and/or prescription drug cost-sharing based on stated “plan cost.” The uninsured pay cash (U&C) pharmacy prices; prices determined by the Oregon Prescription Drug Program’s Discount Card

¹¹ Section 11(3).

¹² The requirement of proximity is critical to keeping this Task Force focused on solving an immediate medical crisis currently experienced by the most vulnerable Oregonians, rather than becoming a policy antechamber for corporate lobbyists (such as Jon Bartholomew) who are bound to only pursue the profit-maximizing interests of their clients and venture partners. Many cost factors “across the supply chain” (e.g. manufacturer R&D, production and advertising costs, PBMs’ negotiation of rebates and discounts, wholesaler fees) lie outside the state’s jurisdictional control or are subject to the dormant commerce clause of the U.S. Constitution; most manufacturers are foreign corporations engaged in interstate commerce; all prescription drug production takes place outside Oregon (and much of it takes place outside the United States). Transparency across the physical supply chain, moreover, won’t reveal “cost factors that negatively impact prices paid by Oregonians” for the brand drugs and biologics like insulin with high or rising list prices that are of primary pricing concern to patients and were thus the primary focus of HB 4005. Insulin production costs and average rebate amounts are already public information, although most insurers do not disclose the rebates insurers obtain in their reporting to individual consumers. Many of these supply-chain factors impact payers’ net costs, but the Oregonians who are most deeply impacted by high brand drug prices do not typically pay prices indexed on insurers’ net cost. The exclusive focus on the Task Force should be on the current and practical interplay between ‘prices paid by Oregonians’ and these factors, not on esoteric discussions of obscure patent law theories or far-reaching industry reform projects.



program; prices determined by other Prescription Drug Discount Cards (including the NACo program promoted by some Oregon counties); and prices offered by Oregon-based 340B hospitals (“covered entities”). Underinsured Oregonians pay all or a percentage of “plan cost” as reported to them by their insurers.¹³ These Oregonians are the primary stakeholders of this Task Force, and the prices they pay should be the exclusive focus of its report.

We here identify eight (8) prices that Oregonians pay for brand drugs,¹⁴ along with the key actionable cost factor(s) that now negatively impact(s) prices paid by Oregonians in each category. Once the prices paid by Oregonians have been identified, the analytical framework—upon which a “strategy to create transparency for drug prices” can be developed—naturally flows from the report’s statutory scope.

The “**prices paid by Oregonians** for pharmaceutical products” that meet HB 4005’s tests of timeliness, practicability, enforceability and proximity comprise:

- **Retail Pharmacy “Usual & Customary” or Cash Prices; Hospital Pharmacy Prices:** The U&C or cash price is the price set by a retail pharmacy for a cash transaction, i.e. a transaction without the involvement of a third-party payer. This price is the ingredient cost or actual acquisition cost of the brand drug plus the pharmacy’s mark-up (dispensing fee and profit). When a consumer purchases a drug without insurance or discount card (OPDP, CVS Caremark’s NACo card), the dispensing fee is solely within the discretion of the retail or hospital pharmacy. In both cases, dispensing fees are widely inflated, often resulting in payments to pharmacies that are equivalent to or larger than the actual net price of the drug obtained by the manufacturer.

Actionable cost factor — Retail pharmacies’ inflated dispensing fees significantly increase the total U&C or Cash Price paid by uninsured Oregonians. Actual ingredient cost is publicly available via weekly posted updates of the Oregon Average Actual Acquisition Cost (OAAAC); but cash prices often aren’t disclosed to the consumer at the point of sale until payment is tendered. Inflated cash prices also appear to be broadly similar in local markets, suggesting lack of effective competition between retail pharmacies.

On the supply side, the Task Force could seek more formal disclosure of pharmacists’ U&C prices and mark-up percentages. Regulations and fiduciary obligations could also prevent retail pharmacies from

¹³ Medicare Part D beneficiaries similarly pay based on prices determined by Part D Plan Sponsors, but we will assume for the Task Force’s purposes that federal jurisdiction effectively preempts state jurisdiction regarding Medicare, Medicaid, and Veterans Administration coverage.

¹⁴ For the purpose of this analysis, we do not consider a small fixed copay a “price.” Percentage coinsurance is, however, pegged to the figure payers represent to the patient as a price or cost to plan. A payer’s designated “plan cost” is thus a price for the purpose of this analysis. We will focus on brand drugs, where year-on-year increases to list prices have drawn national and local attention and where there is no transparency to consumers on net prices obtained by institutional payers. Rebating in the brand drug channel now amounts to \$134 billion annually nationwide, per IQVIA’s “Medicine Use and Spending in the United States” review of 2017 spending. <https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022>.



invoicing vulnerable patients for pharmaceutical drugs at inflated prices wholly disconnected from the pharmacies' actual net acquisition costs.

*On the demand side, immediate implementation of **rebate pass-through in OPDP's Discount Card Program** would reduce the number of Oregonians exposed to inflated cash prices for brand drugs. These two approaches—U&C price control (fiduciary obligations) and rebate pass-through in the OPDP discount card program—are not mutually exclusive. The latter solution (rebate pass-through in the OPDP discount card program) could be immediately implemented; it is therefore superior as it also meets the timeliness, enforceability and practicability tests of HB 4005.*

A similar approach should govern pharmaceutical prices at hospital pharmacies. For example, mark-up fees should be capped at or below the average dispensing fees at retail pharmacies. Hospital pharmacies could also be required to follow the OPDP rebate pass-through model and to make pharmaceuticals available at the lowest possible cost to patients (including manufacturer rebates).

Patients, especially those admitted to hospitals on an emergency basis, are captive consumers. They have no ability to negotiate prices and are severely limited in their ability to refuse treatment. By virtue of the nature of their hospital admission, they are compelled to enter into commercial transactions without symmetry of information or bargaining power. Similarly, patients can't procure the pharmaceutical products used during inpatient procedures through other pharmacies. Since free market conditions (symmetry of pricing information, price arbitrage) do not apply to such in-hospital drug purchase transactions, they should be regulated under the State's broad mandate to protect vulnerable consumers, to prevent discrimination against classes of people with disabilities (jointly protected under the Americans with Disabilities Act) and to discourage price gouging of captive patients.

A structural approach could include imposing fiduciary obligations on the relationship between hospital pharmacists and patients. Fiduciary obligations can be imposed in relationships in which one party, the fiduciary, is in a position to take advantage of the other party, called the beneficiary, principal, or "entrustor,"¹⁵ and in which the interests of the entrustors that are at stake are important to society and sometimes vital to the entrustors' welfare.¹⁶ Access to affordable drugs saves lives and reduces the overall healthcare costs ultimately born by Oregonian taxpayers. The Task Force should recognize that hospital pharmacies have an inherent fiduciary relationship with their patients. It is may also be important to Oregon to impose on retail pharmacies similar fiduciary obligations.

¹⁵ There is no generally accepted term for the weaker party in a fiduciary relationship. Frankel coined the term "entrustor." Tamar Frankel, *Fiduciary Law*, 71 CALIF. L. REV. 795, 800 n. 17 (1983). Rodwin proposes "fiducie." Marc A. Rodwin, *MEDICINE, MONEY, & MORALS: PHYSICIANS' CONFLICTS OF INTEREST* 181 (1993).

¹⁶ D. Gordon Smith calls these interests "critical resources." D. Gordon Smith, *The Critical Resource Theory of Fiduciary Law*, 55 VAND. L. REV. 1399, 1402 (2002). Paul Miller calls them "significant practical interests." Paul B. Miller, *Justifying Fiduciary Duties*, 58 MCGILL L. J. 1014 (2013).



Furthermore, fiduciary obligations would provide a legal basis for nullifying current “gag clauses” and other contractual restraints on information flows included in pharmacy contracts.¹⁷ Fiduciary obligations would also preclude pharmacies from entering into any other form of contractual relationships that would be similar in effect to gag clauses.

Summary

Retail Pharmacy “Usual & Customary” or Cash Prices

	Timeliness	Enforceability	Practicability	Proximity	
OPDP Discount Card (Rebate Pass-Through)	Green	Green	Green	Green	Best
Fee Cap (Statute)	Red	Green	Green	Green	2 nd
Fiduciary Obligations (Statute)	Red	Green	Green	Green	
Fee Disclosure (Regulation)	Red	Green	Green	Light Red	

Gag Clauses

	Timeliness	Enforceability	Practicability	Proximity	
Fiduciary Obligations (Statute)	Red	Green	Green	Light Red	Best
Specific Ban (Statute)	Red	Light Green	Green	Light Red	2 nd

¹⁷ Oregon is one of few remaining states not to have recently passed any legislation governing PBM/payer transparency and pharmacy gag clauses. See http://www.ncsl.org/Portals/1/Documents/Health/Pharmacist_Gag_clauses-2018-14523.pdf.



Hospital Pharmacy Prices

	Timeliness	Enforceability	Practicability	Proximity	
Lowest Available Price, OPDP (Statute)	Red	Green	Green	Green	Best
Fiduciary Obligations (Statute)	Red	Green	Green	Green	2 nd
Fee Cap (Statute)	Red	Green	Green	Orange	
Fee Disclosure (Regulation)	Red	Green	Green	Orange	

- 340B Pricing:** Safety-net hospitals (“covered entities”) in the federal 340B program¹⁸ obtain prescription drugs at rebated prices. This discount is supposed to enable these safety-net hospitals to better serve low-income, uninsured patients who fill prescriptions at the hospitals’ pharmacies. But no part of 340B Subsection (a)(5) actually requires that eligible patients directly benefit from low 340B prices. This federal program has weak oversight, and federal guidance does not direct how 340B hospitals must use manufacturer discounts to benefit patients. Nationally, some hospitals offer prescription drugs they obtained with 340B rebates to patients at prices at or below the rebated prices; others do not. There are currently about four dozen 340B covered entities in Oregon.¹⁹ The state would have jurisdiction over how state-regulated nonprofits use 340B drug rebates.

Actionable cost factor – A recent national United States Government Accountability Office (GAO) report found that 57% of hospitals did not offer prescription drug prices reflecting 340B discounts/rebates to

¹⁸ Section 340B of the Public Health Service Act.

¹⁹ <https://www.340bhealth.org/files/OR.pdf>.



low-income uninsured patients.²⁰ This Task Force should recommend a review of Oregon nonprofits that are 340B “covered entities,” to determine whether the state’s safety-net hospitals are making prescription drugs available to Oregon’s poorest patients at prices reduced by the full amount of 340B discounts and rebates from manufacturers.

OHA requires that 340B covered entities or their contracted agents that fill Medicaid patient prescriptions with drugs purchased at the discounted 340B prices must bill Medicaid for the actual acquisition cost.²¹ OHA has created no equivalent regulation mandating that an eligible patient (not enrolled in Medicaid) be similarly billed for the actual 340B acquisition cost.²² Oregon also caps the dispensing fee of all 340B pharmacies to \$14.30 per claim.²³ A similar cap on dispensing fees applies to pharmacy transactions under OPDP, but not to cash transactions between pharmacies and uninsured Oregonians. The 340B program is thus an example, along with Medicare Part D and OPDP,²⁴ where a federal or state government requires, for itself or its public employees, a benefit that it currently denies to individual Oregonians.

Although the State may only have limited jurisdiction over most of the 340B program (and no private right of action against drug manufacturers),²⁵ no part of Section 340B of the Public Health Service Act²⁶

²⁰ <https://www.gao.gov/assets/700/692697.pdf>.

²¹ OHA Pharmaceutical Services Administrative Rulebook Chapter 410, Division 121 (Effective August 15, 2018), 410-121-0150(1), available at: <https://www.oregon.gov/oha/HSD/OHP/Policies/121rb050117.pdf>.

²² The 340B program is managed by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services. HRSA audits primarily focus on internal controls required to prevent diversion and duplicate discounts, including how the covered entity defines whether a patient is considered inpatient or outpatient, HRSA Medicaid Exclusion File designations, and accuracy of a covered entity’s 340B OPAIS record. HRSA does not audit whether eligible patients who receive 340B drugs are invoiced actual 340B acquisition costs. See: <https://www.hrsa.gov/opa/program-integrity/index.html>.

²³ OHA Pharmaceutical Services Administrative Rulebook Chapter 410, Division 121, 410-121-0160(1)(c).

²⁴ In addition to the lowest pharmacy dispensing fees, public employees in Oregon benefit from 100% rebate pass-through and **free** insulin. Individual OPDP card members receive no rebate pass-through. OHA now argues that OPDP, an interstate drug purchasing pool, does not receive any manufacturer rebate for purchasing transactions under a single program — the individual discount card program. See: <https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/149286>.

²⁵ *Astra USA v. Santa Clara County*, 563 U.S. 110 (2011).

²⁶ The 2010 Patient Protection and Affordable Care Act (PPACA), Pub. L. 111–148, 124 Stat. 119, provides for more rigorous enforcement of the price agreements between HRSA and drug manufacturers—not between patients and eligible entities. The PPACA directs the Secretary to develop formal procedures for resolving overcharge claims against drug manufacturers. *Id.*, at 826, 42 U. S. C. A. §256b(d) (3)(A). No provision addresses overcharging of patients by eligible 340B covered entities.



specifically preempts²⁷ the State from concurrently regulating how 340B pharmacies bill patients.²⁸ The State can also revoke the nonprofit status of delinquent entities or impose penalties. An active oversight regime requires periodic audit and reporting. The outcome of these 340B price pass-through audits should be public. A more cost-effective approach to direct control would be to impose fiduciary obligations (and related private cause of action, damages and penalties) on the relationship between hospital pharmacies and 340B eligible patients. Fiduciary obligation would require that the hospital pharmacy pass the 340B prices to eligible patients.

340B Pricing

	Timeliness	Enforceability	Practicability	Proximity	
Fiduciary Obligations to Patients (Statute)	Red	Green	Green	Green	Best
340B Price Pass-through (Statute)	Red	Green	Green	Green	2 nd
340B Price Pass-Through Disclosure (Statute)	Red	Green	Green	Light Green	3 rd
Revocation of Tax Exempt Status (Statute)	Red	Green	Light Green	Red	
Penalty / Fee / Tax (Statute)	Red	Green	Light Green	Red	
Annual Audit & Reporting (Statute)	Red	Green	Light Green	Red	
Price Negotiation with Drug Manufacturers	Federal preemption				n/a

²⁷ Under the modern preemption doctrine, federal law preempts state law only when the two are in actual conflict unless specified otherwise by Congress. Federal law can displace state law when Congress has expressly provided for preemption. Beyond these two cases, however, courts no longer seem to “imply” exclusive federal preemption and seem to allow for concurrent jurisdiction. Moreover, especially in areas of “historic” state powers (such as health and safety regulation), courts reportedly apply a “presumption against preemption” test. <http://www.aei.org/publication/federal-preemption-principles-and-politics/>. Neither the Public Health Service Act nor the Patient Protection and Affordable Care Act addresses the transactions between patients and 340B entities and no preemption provision would prevent states from regulating these transactions. The pharmaceutical purchase transactions between patients and 340B entities may thus be subject to state and common laws, including consumer protection laws.

²⁸ In *Astra USA v. Santa Clara County*, 563 U.S. 110 (2011), the Supreme Court held that Congress vested authority to oversee compliance with the 340B Program exclusively in HHS. The case concerned enforcement of the Pharmaceutical Pricing Agreement (PPA) negotiated by HRSA under Section 340B. This holding is not applicable as 340B does not address patients’ access to 340B pricing and HRSA is not required by Section 340B nor the PPACA to implement formal procedures for resolving overcharge claims between patients and 304B entities.



- OPDP Discount Card Program Prices:** OPDP has a statutory obligation to “[m]ake prescription drugs available at the lowest possible cost to participants in the program as a means to promote health.”²⁹ Under the Oregon Health Authority’s regulatory definition for OPDP, “program price” must include “all applicable manufacturers discounts and rebates.”³⁰ OPDP was created to “allow participants to receive discounted prices and rebates, making drugs available to participants at a lower cost,”³¹ while 2006’s Ballot Measure 44, expanding the program, was advanced as an opportunity for any underinsured or uninsured Oregonian to benefit from “the same bulk purchasing power that the big insurance companies have when they negotiate lower prices with the drug companies.”³²

Actionable cost factor — OPDP’s failure to pass manufacturer rebates, discounts, and price concessions through to individual card holders³³ is the primary cause of the current price/access crisis in Oregon. The Task Force should recommend a complete audit of the OPDP program (including discount card program and state employee plans OEGB and PEBB). If current OPDP third-party administrator Moda Health is unable or unwilling to negotiate manufacturer rebates and price concessions and pass those rebates and price concessions through to OPDP discount card members (as required by statute and OPDP regulation of Program Price), then this Task Force should recommend termination of Moda Health’s TPA contract, and replacement by a fully transparent PBM (such as Ventegra—a California Benefit Corporation—or Navitus Health) contracted to deliver net rebated prices—true “lowest possible cost”—to OPDP discount card members.

OPDP Discount Card Program Prices

	Timeliness	Enforceability	Practicability	Proximity	
100% Rebate Pass-through to Individual Discount Card Holders (Regulation)	Green	Green	Green	Green	Best
Terminate Moda’s TPA; re-bid to Transparent PBMs	Red	Green	Green	Green	2 nd

²⁹ ORS 414.312(2)(b).

³⁰ The OHA here broadly defines rebates to include all “payments or discounts whether retrospective or not, including promotional or volume-related refunds, incentives or other credits however characterized, pre-arranged with pharmaceutical companies on certain prescription drugs, which are paid to or on behalf of OPDP or a designated entity, and are directly attributable to the utilization of certain drugs by members.” 431-121-2000(17) and (18).

³¹ <https://www.oregonlegislature.gov/lpro/summleg/2003SummaryOfLegislation.pdf>.

³² <https://www.t1df.org/news/2018/5/21/t1df-statement-to-oregons-joint-interim-task-force-on-fair-pricing-of-prescription-drugs>.

³³ <https://www.t1df.org/news/2018/6/7/t1df-asks-oregon-gov-kate-brown-to-deliver-lowest-possible-cost-to-opdp-discount-card-holders>.



	Timeliness	Enforceability	Practicability	Proximity	
Investigation of Moda Health & OHA: Breach of OPDP Law, Misrepresentations, Breach of Consumer Protection Laws, Breach of Fiduciary Duties, Breach of ADA & State Law Protecting People with Disabilities					3 rd
Rebate Pass-Through Audit (Regulation)					

- Commercial Discount Card Program Prices (e.g. NACo Prescription Discount Card) and Direct-to-consumer PBM services (e.g. GoodRx):** Oregonians in counties including Polk, Clatsop, and Yamhill are being enticed by county officials to use the CVS Caremark–managed NACo RX Prescription Discount Card rather than OPDP’s Discount Card.³⁴ Counties may receive, in exchange, a “marketing fee” (about \$1) for each prescription filled, and NaCo’s State Associations may receive an additional fee of about \$0.40 per prescription fill. For analog insulins, NACo prices are about \$20.00 per vial higher than unrebated OPDP prices, e.g. OPDP \$270.71 per vial for Novolog vs. NACo \$293.90.³⁵ These cards are county government–endorsed exploitation of Oregon consumers.

Actionable cost factors — *Prices to NACo discount card holders (1) do not reflect the rebates that manufacturers pay to CVS, and (2) are consistently higher than OPDP prices. The Oregon Department of Justice’s Consumer Protection Division and DCBS Division of Financial Regulation should immediately investigate these products and the relationships between CVS Caremark and local government entities (Counties and Municipalities) that market these products on behalf of CVS Caremark in exchange of*

³⁴ See, e.g., for Polk County: <https://www.co.polk.or.us/ms/naco-county-prescription-discount-card-program>.

³⁵ Commercial discount card programs BlinkHealth and GoodRx also operate in Oregon. These programs offer prices that reflect some manufacturer rebates. As of June 2, 2018, the BlinkHealth price for a 10 ml vial of Humalog was \$178.90; the GoodRx price for Humalog was \$177.87. This Task Force should obviously be asking why public programs offered by the State and by Oregon counties, supposedly in the interest of public health, are charging much higher prices than these commercial entities (as of June 2, 2018, \$263.83 for Humalog in OPDP, and \$293.90 for Humalog via NACo).



marketing fees paid to the County and other inducements (e.g. other undisclosed payments made to NACo and its state chapter).³⁶

The Task Force should also recommend that any Oregon government entity advertising the NACo program be required to disclose to consumers that Oregon residents are also eligible for OPDP’s Discount Card program and may be able to obtain lower prices via the OPDP Discount Card program. Counties and Municipalities that promote the NACo prescription drug discount card on their public websites should be required to post same-page disclosures on those sites of any per-prescription fees or other financial return that participants’ prescription drug transactions generate for the County or for Oregon’s state NACo association (and counties must not be allowed to misrepresent these programs to consumers as “free”).

Since CVS Caremark obtains large manufacturer rebates but its prices to NACo Discount Card holders do not reflect these rebates, the Oregon Department of Justice Consumer Protection Division should also review whether these Counties and Municipalities are co-conspirators in consumer fraud when they describe NACo prescription card prices as “discounted” or “rebated.”

In order to increase transparency and competition among these discount card and mail-order PBM services, the Task Force should consider mandatory price disclosure requirements, e.g. disclosure for each drug of average rebate retention rates (portion of the manufacturer rebates retained by the PBM). Accessibility issues and standard disclosure formats (on the model of mandatory financial disclosure for credit facilities and mortgages) should also be addressed.

Commercial Discount Cards

	Timeliness	Enforceability	Practicability	Proximity	
Rebate Pass-through (Statute)	Red	Green	Green	Green	Best
Investigation of Possible Fraudulent Misrepresentations, Breach of Procurement Laws, Local Officials’ Conflicts of Interest / Malfeasance	Light Green	Green	Light Green	Light Green	2 nd
Disclosure of PBMs’ Actual Rebate Retention Rate per Drug, Benefit Design	Orange	Green	Light Green	Light Green	3 rd
Mandated Disclosure from OPDP to Private Card Holders (Regulation)	Light Green	Green	Light Green	Orange	

³⁶ Under ORS 180.610(5), the Department of Justice is required to investigate allegations of corruption or malfeasance by public officials in Oregon and, where appropriate, coordinate, cooperate and assist in taking legal action.



	Timeliness	Enforceability	Practicability	Proximity	
Mandated Disclosure of Hidden Fees, Marketing Fees Paid to Local Government Entities & State Organizations (Statute)					

- Manufacturers’ patient assistance program (e.g. Lilly Diabetes Solution Center):** Based on preliminary anecdotal reporting from patients, the new Lilly Diabetes Solution Center now offers prices for 10 ml vials of analog insulin Humalog that are very close to net prices (between \$30 and \$60 per vial). The same Humalog vial is sold for \$177 by GoodRx³⁷ and \$269.85 by OPDP.³⁸ These manufacturers’ patient assistance programs are thus a very low priority for this Task Force, as they already offer the best available prices to consumers.

Actionable cost factors — It is now reported that PBMs are passing, on average, up to 98% of the rebates to payers.³⁹ On average, rebates account to 55% of Novo Nordisk’s gross revenue and 49% of Sanofi’s.⁴⁰ Before addressing whether these rebates should be larger and whether manufacturers’ net prices are supra-competitive, the Task Force must first address the fact that these manufacturer rebates are not now used by payers to decrease point-of-sale prices paid by Oregonians and are not now used by OPDP to deliver low net prices to discount card holders. Instead of focusing on manufacturers’ R&D and manufacturing costs—factors wholly unrelated to the prices paid by Oregonians—the Task Force should investigate why private health insurers, mail-order and direct-to-consumer PBMs, discount card programs and OPDP do not offer discounted net prices that are substantially equivalent to the low drug prices offered by manufacturers’ patient assistance programs.

Manufacturers’ patient assistance program

³⁷ https://www.goodrx.com/humalog?form=vial&dosage=10ml-of-100-units-ml&quantity=&days_supply=&label_override=Humalog.

³⁸ <https://mp.medimpact.com/mp/secure/LaunchProductFrameset.jsp>.

³⁹ See, e.g., <https://www.drugchannels.net/2018/01/employers-are-getting-more-rebates-than.html>; <https://www.drugchannels.net/2018/08/new-disclosures-show-cvs-and-express.html> (calculating CVS rebate retention rate as 6% in 2017); <https://www.fiercehealthcare.com/payer/cvs-caremark-express-scripts-pbm-pass-through-cigna-merger>.

⁴⁰ See Exhibit C - Credit Suisse, European Pharma 1Q17 Quarterly Prep Pack (April 18, 2017), page 11, US list prices and rebates.



	Timeliness	Enforceability	Practicability	Proximity	
n/a	No action required				n/a

- Private Health Plan “Plan Cost”**: the prices that insurers and other third-party payers, including self-insured employer plans, report as “plan cost” to health plan members and use as the basis for calculating patient payments when the patient has not met his or her deductible or is responsible for cost-sharing/coinsurance payments calculated as percentage of “plan cost.”

Actionable cost factor – Pursuant to their fiduciary obligations, Health plans’ “plan cost” prices to insured Oregonians must reflect the rebates and other price concessions manufacturers pay to insurers and other third-party payers.⁴¹ Private insurers should be required to disclose to individual health plan members average or estimated net prices actually paid by insurers, taking into account all rebates, discounts, and other price concessions; private insurers operating in Oregon should be mandated to use these net prices as “plan cost” reported to patients; private health plans should be mandated to base all patient payments (pre-deductible or any percentage coinsurance based on cost) on net plan cost.

The Oregon Department of Justice and Secretary of State should investigate whether insurers’ ongoing representation of gross claims expense as ‘cost to plan’ constitutes insurance fraud and the Secretary of State should audit private insurers’ (and OPDP’s) use of manufacturer rebate revenues. The Oregon Department of Justice, in conjunction with the U.S. DOJ Civil Rights Division, should also investigate whether payers’ ongoing rebate-capture scheme and related premium inflation based on gross pharmacy claims expense (see below) is a breach of the Americans with Disabilities Act, the non-discrimination mandate of the ACA, and other federal and state consumer protection and non-discrimination statutes.

⁴¹ For analog insulins such as Humalog and Novolog, insurance companies and large self-insured employer plans now receive rebates in excess of 70% of list price, with Bloomberg recently using SSR Health data to report that Lilly “doesn’t keep even 20 percent” of list price for Humalog insulin. See e.g. Cynthia Koons and Robert Langreth, “What Stands Between Bezos, Buffett, and Dimon and a Health-Care Fix,” *Bloomberg*, February 14, 2018 (<https://www.bloomberg.com/news/articles/2018-02-14/what-stands-between-bezos-buffett-and-dimon-and-a-health-care-fix>). Oregon payers’ failure to use rebates to offset “plan cost” is thus a cost factor that adds about \$200 per vial to the payers’ “plan cost” price that insurers demand many Oregon consumers pay outright and that insurers use as the basis for calculating many other consumers’ percentage coinsurance.



The Oregon Department of Justice should finally investigate past and present insurance regulators’ role in allowing private health insurers to misrepresent the actual cost to plan of the pharmaceutical drugs purchased by the plan members.⁴²

Private Health Plan “Plan Cost”

	Timeliness	Enforceability	Practicability	Proximity	
Fiduciary Obligations to Patients	No action required				n/a
100% Rebate Pass-through (Regulation)	Green	Green	Green	Green	Best
Investigation of Misrepresentations, Breach of Consumer Protection Laws, Breach of Fiduciary Duties, Breach of Insurance Laws, Breach of ACA Nondiscrimination Requirements, Breach of ADA & State Law Protecting People with Disabilities, Breach of Anti-trust Laws	Red	Green	Light Green	Green	2 nd
Annual Rebate Pass-through Audit (Regulation)	Red	Green	Light Green	Light Green	3 rd
Revocation of Tax Exempt Status (Statute)	Red	Green	Light Green	Light Green	
Penalty / Fee / Tax (Statute)	Red	Green	Light Green	Light Green	

- **Health Premium Rates Actuarial Assessment:** Health insurance premiums are within the scope of this Task Force, to the extent that premiums are calculated based on unrebated list prices for prescription drugs.

Actionable cost factor – Mandate that all actuarial valuation of premium rates be based on net costs of prescription drugs to insurer, not unrebated claims expenses. Oregon Department of Justice and Secretary of State should investigate whether insurers’ reliance on gross claims expense as basis for actuarial valuation is a breach of the Actuarial Standards of Practice (ASOPs) stipulated by the Actuarial

⁴² Under ORS 180.610(5), the Department of Justice is required to investigate allegations of corruption or malfeasance by public officials in Oregon and, where appropriate, coordinate, cooperate and assist in taking legal action.



Standards Board. This Task Force should recommend that the state’s insurance commissioner (Task Force co-chair Andrew Stolfi) immediately address the National Association of Insurance Commissioners (NAIC)’s flawed data modeling and mandate that in Oregon pharmacy claims expense must be fully reconciled with rebate/discount offsets prior to reporting and prior to use as cost basis for any actuarial assessment and loss ratio reporting. The Oregon Division of Financial Regulation should deny Oregon’s approval to any health plan where insurers misrepresent unrebated pharmacy claims expense to patients as “plan cost” and should investigate all insurers who have engaged in this practice.

Health Premium Rates Actuarial Assessment

	Timeliness	Enforceability	Practicability	Proximity	
Premium Rate & Loss Ratio Assessments Based on Net Costs to Plans (Regulation)	Light Green	Dark Green	Dark Green	Dark Green	Best
Investigation of Private Insurers & Insurance Commissioner: Misrepresentations, Breach of Consumer Protection Laws, Breach of Fiduciary Duties, Breach of Insurance Laws, Breach of ACA Nondiscrimination Requirements & State Law Protecting People with Disabilities, Breach of Anti-trust Laws	Orange	Dark Green	Light Green	Light Green	2 nd
Investigation of Insurers & Insurance Commissioner: Breach of the Actuarial Standards of Practice (ASOPs) stipulated by the Actuarial Standards Board	Orange	Dark Green	Light Green	Light Green	3 rd
Investigation of Quasi-Regulatory Authority of the National Association of Insurance Commissioner, Financial Reporting Model	Red	Dark Green	Light Green	Orange	



- **Medicare Part D Negotiated Price:** The Medicare Prescription Drug, Improvement, and Modernization Act (MMA)⁴³ included a mandate to base Part D plan design on “access to negotiated prices”⁴⁴ and specified that “negotiated 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.”⁴⁵ A negotiated price is thus a net cost-to-plan or net price.⁴⁶

Actionable cost factor – Plan Sponsors in Medicare Part D base beneficiaries’ payments on CMS’s modified regulatory definition of “negotiated price,” which does not reflect the rebates manufacturers pay to Part D Plan Sponsors. The State of Oregon could sue CMS, on behalf of Oregonians, for its failure to implement the 2003 MMA access to net price. Oregonian individual beneficiaries under Medicare Part D are entitled by federal statute to “access to negotiated prices” that take into account all rebates and price concessions.⁴⁷ More practically, moving the Oregon Health Authority to full implementation of the OPDP Discount Card Program’s required cardholder access to “lowest possible cost” via full rebate pass-through would benefit some seniors.⁴⁸

Under Medicare Part D, net negotiated prices are not confidential information.⁴⁹ Under the MMA, the mechanism for disclosure of rebate and net prices to Part D beneficiaries was the ‘negotiated price.’ Disclosure of net prices was implied in the explicit legislative mandate that Medicare Part D beneficiary cost-sharing be based on “access to negotiated price” as defined by MMA (the price of the drug, net all manufacturers’ rebates and other price concessions). CMS regulation allowed Part D plans to use list prices instead of ‘negotiated price’ as basis for cost-sharing but did not specify an alternative mechanism to give plan beneficiaries access to manufacturer rebates, nor did CMS specify an alternative disclosure

⁴³ Public Law 108–173 108th Congress [H.R. 1] (Dec. 8, 2003), codified under 42 USC 1305.

⁴⁴ Part 1860D-2(d)(1)(A).

⁴⁵ Part 1860D-2(d)(1)(B).

⁴⁶ <https://www.t1df.org/news/2018/01/16/t1df-comment-to-cms-negotiated-price>.

⁴⁷ <https://www.t1df.org/news/2018/01/16/t1df-comment-to-cms-negotiated-price>.

⁴⁸ OPDP’s discount card program, with full rebate pass-through, would effectively compete with private Medicare insurance plans that include Part D benefits, including AARP-United Healthcare co-branded Medicare plans sold in Oregon. This conflict between AARP financial interest and the implementation of rebate pass-through in the OPDP discount card program precludes Jon Bartholomew from representing consumer stakeholders on this issue, among many others, on this Task Force. Because the same conflict exists with Cambia and other private insurers offering Part D benefits, Dr. Santa is equally conflicted from representing consumers on this issue, as on other issues where insurers’ and drug-purchasing consumers’ interests may be adverse.

⁴⁹ The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) uses the exact same definition of ‘negotiated price’ in Section 1860D-31, Medicare Prescription Drug Discount Card and Transitional Assistance Program. Under this Section, Congress mandated disclosure of ‘negotiated prices’ to plan beneficiaries. Disclosure of the negotiated prices under Section 1860D-31 would also disclose the negotiated prices relied upon by standard plan design under Section 1860D-2. Under Part D, negotiated prices are thus public information



standard. As stipulated by CMS, exclusive preemption requires a federal standard.⁵⁰ A State seems to be preempted from requiring full rebate pass-through in Medicare Part D plans. The only option to compel Part D plans to deliver 100% rebate pass-through to patients might be to challenge CMS’s final rule addressing negotiated prices in federal courts and/or to lobby CMS.⁵¹ Since full rebate pass-through is possible under current CMS regulations and Part D rules might not preempt State common law governing fiduciaries, a State could also attempt to enforce Part D plans’ fiduciary obligations to beneficiaries in State courts. On the other hand, no part of the MMA addresses dissemination of rebate and price information outside the Medicare Prescription Drug Discount Card and Transitional Assistance Program. A State could thus mandate that Part D Plans disclose to their beneficiaries the effective net negotiated prices actually paid by the plan.

Medicare Part D Negotiated Price

	Timeliness	Enforceability	Practicability	Proximity	
100% Rebate Pass-through to OPDP Individual Discount Card Holders (Regulation) — Competing State Program	Green	Green	Green	Green	Best
Mandated Part D Plans’ Disclosure of Rebate & Effective Net Prices (to Part D Plans) to Medicare Part D Beneficiaries (Statute)	Red	Green	Green	Light Green	2 nd
File Lawsuit in State Court Against Part D Plans to Enforce Fiduciary Obligations (100% Rebate Pass-Through) to Beneficiaries	Red	Green	Red	Green	3 rd
File Lawsuit Against CMS to Force Implementation of MMA’s Negotiated Price (100% Rebate Pass-through)	Red	Green	Red	Green	

⁵⁰ The MMA includes broad preemption clauses. See, e.g., Section 1860D-12(g) of the MMA, which extends the State preemption provisions under section sections 1854(g) and 1856(b)(3) (regulating Medicare Advantage organizations under Part C— “The standards established under this part shall supersede any State law or regulation”) to Part D plans. CMS interpreted these clauses as creating a presumption of exclusive preemption regarding “the areas where the Congress intended [Part D/CMS] to regulate—such as the rules governing pharmacy access, formulary requirements for prescription drug plans, and marketing standards governing the information disseminated to beneficiaries by PDP sponsors.” 42 CFR Parts 400, 403, 411, 417, and 423 [CMS-4068-F], p. 154. CMS specifically rejected an insurer’s request that “all State laws and regulations (with the exception of State licensing and solvency laws) [be] preempted with respect to MA and Part D plans.” CMS clarified that this was not “the Congress’ intent to do so” and clarified that CMS could not preempt State civil rights laws. The preemption in section 1860D12(g) of the Act is a preemption that operates only when the MMA actually creates standards in the area regulated.

⁵¹ See, e.g., <https://www.t1df.org/news/2018/01/16/t1df-comment-to-cms-negotiated-price>.



	Timeliness	Enforceability	Practicability	Proximity	
Lobby CMS for Implementation of MMA's Negotiated Price (100% Rebate Pass-through)					

Not only is HB 4005 conceptually flawed, but the Task Force it created has to date failed to take any practical steps towards fulfilling its legislated mandate. The Task Force has already expended over half the time from inception to November 1 report delivery deadline, and the co-chairs have not yet even identified any of the ‘prices paid by Oregonians’ its report purports to address.

Even a review by the Washington State Office of Financial Management⁵²—an observer sympathetic to the cost-containment goals of legislation like HB 4005—has noted that the current wave of drug-pricing bills will do little to achieve proponents’ stated goals. The Washington State Office of Financial Management concluded last year that using the massive negotiating power of prescription drug pricing entities like Washington and Oregon's Northwest Drug Pricing Consortium is likely to be far more effective in driving down drug costs to states than the flawed manufacturer-focused reporting requirements of HB 4005.

And yet, this Task Force has thus far refused to address the Northwest Drug Pricing Consortium’s failure to negotiate and pass rebates through to under- and uninsured Oregonians via the OPDP discount card program. It is equally doubtful whether this Task Force, controlled as it is by insurers and AARP and governed by weak “consensus” rules, will “[expose] the cost factors that negatively impact prices paid by Oregonians for pharmaceutical products”⁵³ by examining benefit design in ACA insurer or employer plans or in Medicare Part D.

This Task Force’s failure to address the prices outlined above would render HB 4005 ineffective as a catalyst for price transparency and would, instead, increase stigma against people with insulin-dependent diabetes and other chronic conditions—while leaving them exposed to pricing practices by actors including insurers, OHA/OPDP, and CVS

⁵² https://ofm.wa.gov/sites/default/files/public/publications/prescription_drug_price_transparency.pdf.

⁵³ HB 4005, Section 11(10).



Caremark/Oregon Counties and Municipalities that by any reasonable standard of evaluation must be deemed exploitative.⁵⁴

Oregonians deserve better.

Regards,

Charles Fournier, J.D.

Director

Oregonians for Affordable Drug Prices Now

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Exhibit List

- A CVS, Express Scripts provide a rare moment of transparency on rebate profits (8/10/2018)
- B Prescription Drug Price Transparency Legislation: Review and Recommendations (12/2017)
- C Credit Suisse Pharma Team, European Pharma 1Q17 Quarterly Prep Pack (04/18/2017)
- D New Disclosures Show CVS and Express Scripts Can Survive in a World Without Rebates. Are Plan Sponsors Now the Real Barrier to Disruption? (8/24/2018)
- E Joint Interim Task Force On the Fair Pricing of Prescription Drugs – OR4AD Calls for Resignation of AARP–UnitedHealth Lobbyist from Role as Task Force ‘Consumer Representative’ (7/18/2018)

⁵⁴ <https://www.t1df.org/news/2018/5/21/from-the-eugene-register-guard-march-6-2018-drug-transparency-bill-ignores-role-of-insurers>.



EXHIBIT A

CVS, Express Scripts provide a rare moment of transparency
on rebate profits (8/10/2018)



Payer

CVS, Express Scripts provide a rare moment of transparency on rebate profits

by [Evan Sweeney](#) | Aug 10, 2018 3:07pm



CVS says it will make \$300 million on drug rebates. Express Scripts pulls in \$400 million. (Mike Mozart/CC BY 2.0)

Amid questions about the future of drug rebates, the nation's largest pharmacy benefit managers have provided a rare moment of



Chronic care management at Federally Qualified Health Centers



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difficult to pin down. As recently as June, CVS **told** Department of Health and Human Services Secretary Alex Azar that its PBM, CVS Caremark, passes 95% of rebates to commercial clients and their members.

But during an earnings call this week, CVS Health CEO Larry Merlo told investors the company keeps just 2% of rebates, passing the rest on to clients and consumers. For 2018, the company expects to retain \$300 million of rebates, which amounts to 3% of annual earnings.

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Meanwhile, a **financial disclosure** from Cigna indicates that Express Scripts retains approximately \$400 million per year from rebates and passes on 95% of "purchase discounts, price reductions and rebates" back to clients. Cigna reiterated its support for the merger, noting that the "elimination of rebates does not pose a material threat to the value of Cigna and Express Scripts combination."

In May, Express Scripts **said** it passes 90% of rebates back to clients, in line with **figures** from the Pharmaceutical Care Management Association.

The Office of Management and Budget is currently reviewing a proposed rule that **hints at changes to pharmacy rebates**, prompting questions from analysts about the financial impact that could have for companies like CVS and Express Scripts. This week's numbers were significantly less than Wall Street had previously assumed.

RELATED: Cigna reaffirms support for Express Scripts merger, calling Icahn's views 'shortsighted'

For both companies, which have pushed to downplay any possible changes to the rebate structure, the disclosures are more than a little self-serving. Cigna's disclosure comes as activist investor Carl Icahn issued a **second open letter** urging Cigna shareholders to block the company's merger with Express Scripts. In it, he pointed to a report by Ross Muken and Michael Newshel of Evercore ISI, who estimated that Express Scripts earns closer to \$1.1 billion on rebates. Regulatory changes to the rebate structure, he argued, would hurt the company's bottom line.

In a **previous letter**, he said the merger "may well become one of the worst blunders in corporate history."

CVS, meanwhile, is looking to close its own acquisition of Aetna, a deal that would tighten the PBM market, according to California regulators.

RELATED: California insurance commissioner urges DOJ to block CVS-Aetna merger

But Merlo said the pass-through rates show the industry is benefiting from existing competition and that means insurers will continue to see a large portion of rebates.

"This is a good thing," he said. "It demonstrates that the market techniques used by PBMs do in fact work. And no matter what may happen to the ability to rebate, PBMs will still be needed to drive discounts and cost savings for their clients and members. And the PBM model will continue to evolve as a result."

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Evan Sweeney
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EXHIBIT B

Prescription Drug Price Transparency Legislation: Review and Recommendations (12/2017)

Washington State

Prescription Drug Price Transparency Legislation: Review and Recommendations

A report to the Legislature

As required by Substitute Senate Bill 5883
(Chapter 1, Laws of 2017, 3rd Special Session)



Washington State Office of Financial Management
Forecasting and Research Division
December 2017

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Executive summary

In 2001, prescription drug costs represented 13 percent of the health care cost for an average American family; by 2017, those costs had grown to 17 percent.¹ Given prescription drugs' burgeoning share of health care costs — and the collective outrage over inexplicable price hikes highlighted recently in various media reports — concerns over prescription drug prices have been mounting. Absent any federal initiatives, states are now exploring options to address these rising prices. One such approach has been *price transparency*, which, broadly, requires manufacturers to justify price increases above a set threshold.¹

In 2017, the Washington State Legislature included a proviso in the state budget directing the Office of Financial Management to determine if the newly established all payers claims database (WA-APCD) could be used to initiate such a price transparency process. In that context, the WA-APCD would allow for:

- Reporting of consumer out-of-pocket expenditures for prescription drugs;
- Identification of the most commonly prescribed drugs;
- Annual charges for prescription drugs; and
- Identification of those drugs with charges that are increasing at a higher-than-average rate.

However, transparency in prescription drug costs typically requires manufacturers and, at times, others involved in bringing a drug to market to report detailed financial information on costs for researching, manufacturing, advertising and marketing those drugs. To go beyond the measures now available through the WA-APCD and require such information from manufacturers and, potentially, others would necessitate new or revised legislation.

To that end, this report provides an overview of factors to consider in developing such legislation, beginning with possible metrics for use in monitoring drug prices and including a discussion on how such metrics are surprisingly complicated to identify because what a drug cost varies widely throughout the process of taking it from manufacturer to patient.

The report also highlights the statutes, together with their attendant successes and shortcomings, of four states that recently put forward prescription drug transparency legislation: Oregon, California, Nevada and Vermont. While similar in some regards, they differ in others and collectively provide a set of lessons learned in the development of transparency legislation.

In addition, since the proviso references Canada's drug pricing practices, a review of that system is included. Although Canada is often touted as a potential model system, its prescription drug prices — and the approaches taken to control them — would face a host of challenges, under federal law, if they were to be implemented in the United States.

Although not requested in the proviso, the report provides a brief summary of Washington's current drug purchasing strategy, which focuses more on exercising market forces as a major purchaser than on using transparency to control costs.

¹ Currently, the Washington State Health Care Authority is examining transparency in its Public Employees Benefits Board and Medicaid drug purchasing programs, but these programs do not make manufacturer prices transparent. In fact, a proviso from the current state budget (see [SSB 5883](#), Pages 108–109) requires pharmacy data from the Medicaid managed care plans for reports to the Legislature “without disclosure of proprietary or confidential drug-specific information.”

Below are brief summaries of the report's key findings.

Among the various price metrics, the wholesale acquisition cost (WAC) and average acquisition cost (AAC) are the two most commonly used cost measures. The WAC, which is the most widely used, is akin to the invoice price a dealership pays a car manufacturer. This list price does not reflect any discounts or rebates negotiated between the drug manufacturer and either the wholesaler or the pharmacy benefits manager. A more recently developed measure, the AAC, is based upon surveys of pricing data from independent and chain retail pharmacies and reflects the actual transactional price of drugs. The Centers for Medicare and Medicaid began providing AAC price data on a public website in 2013 for drugs it covers; however, while seemingly extensive, that list is relatively limited.

Most states with enacted or proposed transparency legislation have used the WAC as their metric. In the Oregon proposed bill, the WACs from comparison countries are proposed for use in establishing price thresholds; any increases or new drugs introduced above those thresholds would trigger a justification process involving the reporting of detailed development and marketing costs. Such an approach mirrors, to a degree, that taken in Canada. Although the Oregon bill did not pass out of committee, the span of opposition is worth noting — from patient advocates fearful that specialty drugs would lose coverage, to start-up pharmaceutical companies concerned about excess costs in monitoring and reporting detailed financial information, to drug lobbyists noting the shortcomings of the WAC as an inaccurate cost measure.

California's newly passed legislation, which has garnered much attention, is broad in scope, encompassing any drug with a WAC of more than \$40 per course of therapy and a price increase of more than 16 percent over the course of two years. But the law is also, arguably, shallow in design, ignoring, for instance, negotiated rebates and discounts. In addition, the statute risks signaling wholesalers in advance of a price increase, allowing them to stockpile many drugs slated to increase for resale later at the higher price.

Alternately, Nevada's legislation is narrow in scope, focusing only on diabetes-related drugs, but broad in design, requiring transparency not only from manufacturers but also from pharmacy benefits managers, sales representatives and nonprofit patient advocacy organizations. That legislation is now being challenged in the courts and the legal arguments strike at the root of many transparency initiatives: from the authority to establish patent policy, to the federal Defend Trade Secrets Act, to the Fifth Amendment's Taking Clause, to the Commerce Clause. How well this bill fares under judicial review may have profound effects on current and future transparency laws.

Last, while noteworthy for being the first successfully enacted drug transparency law in the nation, Vermont's statute may, nonetheless, be best known for its lack of impact. As required, the report mandated in this statute focuses on 10 drugs whose WAC had increased by 50 percent or more over the previous five years or by 15 percent or more over the last year. Manufacturers are required to justify these increases in a confidential report to the Office of the Attorney General. That office, in turn, summarizes those justifications in a publicly released report. The broad and vague details in the first final report — with its lack of any real impact — make it a cautionary tale of trying to legislate transparency without risking challenges from manufacturers.

In addition to examining these states' transparency legislation, because the budget proviso also expressed interest in Canadian prescription drug pricing, a summary overview of that country's health care system is provided in this report. Perhaps surprisingly, outside an inpatient setting, prescription drugs are not covered under Canada's universal health care system. (Most Canadians are insured for that component of

their health care through their employer or on their own.) Moreover, even with price-regulated and universally covered patented drugs for inpatients, Canada still has higher drug prices than all the other countries it uses for indexing prices, except for the United States — and for generic drugs, Canadians actually pay more than U.S. citizens. In short, while Canada may model some approaches worth adopting, its system struggles with rising prescription drug costs, too.

In taking such a broad view of the Canadian system, it seems worthwhile reiterating, briefly, the description of Washington’s current prescription drug purchasing strategies, which mirror some aspects of the Canadian system. As outlined in a report submitted to the Legislature last year, [Review of Prescription Drug Costs and Summary of Potential Purchasing Strategies](#), by allying itself with other major purchasers — including Oregon — the state’s process mirrors Canada’s exercising of market forces to better negotiate prescription drug prices.

Transparency has value, but it appears limited in other states under review. Both Nevada and California are now facing legal challenges to their prescription drug price transparency laws; the resolution of those suits is in the courts’ hands. Federal law prohibits states from directly negotiating drug prices and, instead, limits such negotiations to rebates, further affecting states’ opportunities.

Finally, in reviewing transparency of the four states highlighted here as well as others across the country, none has used its APCD (or the program directly responsible for its day-to-day operation) as its transparency reporting entity. Instead, such responsibilities have typically fallen to the state attorney general’s office, the state insurance office, the state health and human services program or the state health planning office. In Washington, consideration could be given to the first three locations, but perhaps the best fit might be in the Office of Financial Management, where the WA-APCD is housed as well as where the health care research and planning functions are conducted.

Introduction

In 2017, the Washington State Legislature passed the state operating budget, Substitute Senate Bill 5883 (Chapter 1, Laws of 2017, 3rd Special Session) that, in part, states:

(5) The office of financial management must perform a legal and policy review of whether the lead organization of the statewide health claims database established in chapter 43.371 RCW may collect certain data from drug manufacturers and use this data to bring greater public transparency to prescription drug prices. Specifically, the review must analyze whether the organization may collect and use manufacturer's pricing data on high-cost new and existing prescription drugs, including itemized production and sales data and Canadian pricing. The office of financial management must report by December 15, 2017, to the health care committees of the legislature the results of the study and any necessary legislation to authorize the collection of pricing data and to produce public analysis and reports that help promote prescription drug transparency.

This report is in response to that request.

As currently written, Chapter 43.371 of the Revised Code of Washington (RCW) would allow for:

- Reporting of consumer out-of-pocket expenditures for prescription drugs;
- Identification of the most commonly prescribed drugs;
- Annual charges for prescription drugs; and
- Identification of those drugs with charges that are increasing at a higher-than-average rate.

The current law would not, however, allow for the collection of pricing, itemized production or sales data from prescription drug manufacturers. Furthermore, prescription drug pricing in Canada is more complex — and decentralized — than perhaps implied by this directive. Canadian pricing lists, as well as price controls, vary by the medicines' patent or generic status, whether the prescription is for a patient in an inpatient or outpatient setting, and the province in which the patient resides.

In fact, chapter 43.371 RCW grants the lead organization the authority to collect claims data only. This authority is, initially, limited to claims data from the state Medicaid program, Public Employees' Benefits Board programs, all health carriers operating in the state, all third-party administrators paying claims on behalf of health plans in this state, and the state Labor and Industries program. However, the director of the Office of Financial Management may expand that authority, by rule, to include the following:

- a. Long-term care insurance governed by chapter 48.84 or 48.83 RCW;
- b. Medicare supplemental health insurance governed by chapter 48.66 RCW;
- c. Coverage supplemental to the coverage provided under chapter 55, Title 10, United States Code;
- d. Limited health care services offered by limited health care service contractors in accordance with RCW 48.44.035;
- e. Disability income;
- f. Coverage incidental to a property/casualty liability insurance policy such as automobile personal injury protection coverage and homeowner guest medical;

- g. Workers' compensation coverage;
- h. Accident-only coverage;
- i. Specified disease or illness-triggered fixed payment insurance, hospital confinement fixed payment insurance or other fixed payment insurance offered as an independent, noncoordinated benefit.

Nevertheless, while no authority is granted for the collection of data pertaining to the manufacturers' prescription drug production or sales data, the claims records in the all payers claims database (WA-APCD) do show the amounts charged and the amount ostensibly paid by the insurer for prescribed drugs. The amount reported as "paid" in the claims data is, however, qualified because it does not take into account rebates, coupons or other cost-related negotiations that may have occurred among manufacturers, pharmacy benefits management entities and insurers. In fact, such challenges in determining true costs and true reimbursements broadly underlie all attempts at bringing transparency to drug costs.

There are, of course, compelling reasons to seek transparency in drug prices. Between 2001 and 2017, prescription drug costs grew from being 13 percent of the health care costs for a typical American family of four to 17 percent. Moreover, although the year-to-year upward trend in prescription drug costs has somewhat abated, the increase in prescription drugs in 2017 — 8.0 percent — is more than twice the overall medical increase of 3.6 percent.ⁱⁱ Of course, widespread reports of skyrocketing prices by pharmaceutical manufacturers, best exemplified by Mylan's EpiPen, have added to the public outcry. Seeking a better understanding of the justifications, or lack thereof, for such price increases is an understandable response.

With that context in mind, this report will first provide definitions of some of the benchmarks used in defining costs, as well as an overview of the flow of drugs from manufacturers to patients and the flow of money back to manufacturers. Next, legislation pertaining to transparency developed by other states will be reviewed. These are Oregon, California, Nevada and Vermont. Canada's health care system will be briefly described and its approach in prescription drug pricing and price controls will be considered. Finally, Washington's current strategy in addressing rising prescription drug prices will be outlined.

Metrics and participants

The Legislature’s interest in collecting and using manufacturer’s pricing data on high-cost new and existing prescription drugs requires a definition of “pricing data.” The common starting point for a prescription drug pricing data is the average wholesale price (AWP). Created in the 1970 for the California Medicaid Drug Program,ⁱⁱⁱ the AWP became, by default, the industry standard. It can be thought of as a close equivalent to the sticker price on a car — essentially the starting point of negotiations between manufacturers and wholesalers or pharmacy benefit managers (PBM) (third-party administrators of prescription drug programs who contract with commercial, self-funded, federal and state health plans) or nonretail providers (hospitals, nursing homes, etc.). AWP has been referred to as “ain’t what’s paid”^{iv} but, in fact, is often the cash price uninsured consumers do pay.^v

While a number of proprietary third-party entities publish the AWP for purchasers’ use, First Data Bank, the original publishers of AWP, and Medi-Span were the two largest. In 2005, private health plan payers filed a class action suit against these publishing entities, contending they had conspired to artificially inflate prices. In 2009, a federal court found in favor of the plaintiffs and essentially called for the rollback in AWP prices for the 1,442 drugs specified in the case. This list eventually expanded to more than 50,000 pharmaceuticals.^{vi} First Data Bank subsequently ceased publishing the AWP in 2011;^{vii} others, however, continue to do so.

With the diminishment of the AWP, the most commonly used benchmark in pharmacy purchasing today is the wholesale acquisition cost (WAC). The two, however, are closely related. If the AWP is the *sticker* price on a car, the WAC approximates the *invoice* price the dealership pays. In fact, a general rule is that the AWP equals the WAC plus a 20 percent increase. What makes the WAC, and the subsequently derived AWP the generally preferable benchmark is that the WAC is defined in federal statute and thus, arguably, is not as easily manipulated as the AWP had been prior to 2009. However, the WAC is still quite limited in specificity and transparency:

The term ‘wholesale acquisition cost’ means, with respect to a drug or biological, the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

- Section 1847A(c)(6)(B) of the Social Security Act

In short, since the WAC is established by the manufacturer — and is neither a transactional price nor transparent in its derivation — it is arguably as susceptible to artificial price increases as the AWP.

Such concerns underlie the recommendations of the American Medicaid Pharmacy Administrators Association and the National Association of Medicaid Directors’ (AMPAA-NASMD) 2009 white paper “Post AWP Pharmacy Pricing and Reimbursement.”^{viii} Instead of the WAC as a replacement pricing benchmark for the AWP, the AMPAA-NASMD recommended the “establishment of a single national benchmark for pharmacy reimbursement “*based on actual acquisition cost data*” (emphasis added). Such a measure, the report notes, would not be the same as the average sales price that is already reported by manufacturers to the Centers for Medicare and Medicaid Services (CMS) and is

essentially limited to injectable or inhalant products. Instead, the report envisions an average acquisition cost (AAC) that could be based upon surveys of invoices from independent and chain retail pharmacies.

Some states, in fact, had already implemented such AAC-like survey systems — although not universal in design — to calculate their maximum allowable costs (MAC), that is, the maximum price to be paid for a multi-source generic drug. However, most states PBMs used different methods for calculating their MACs, and those methods were often confidential or proprietary.

From the perspective of the AMPAA-NASMD, until the establishment of a national AAC-based system, the WAC, together with a more universally defined MAC, could serve as an interim benchmark, notwithstanding the WAC's susceptibility to manipulation and its lack of transparency. Further, the AMPAA-NASMD emphasized the interim nature of this approach and urged CMS to act quickly in developing an AAC-based benchmark.

In 2010, one year after the release of the AMPAA-NASMD white paper, the Journal of Managed Care Pharmacy (JMCP) published an in-depth assessment of potential pricing benchmarks to replace the AWP.^{ix} In doing so, it laid out the 12 criteria, listed below, that such benchmarks should meet:

1. accessible – readily available
2. timely
3. administratively simple and efficient
4. comprehensive
5. durable (not an interim solution)
6. stable (won't produce more litigation)
7. easily understood
8. transparent and unambiguous
9. auditable
10. trustworthy
11. not anticompetitive
12. acknowledges complexity of drug distribution system

The JMCP assessment noted the recommendation of the AMPAA-NASMD but dismissed an AAC-based benchmark for a host of reasons but primarily because, at that time, such a system was not readily available, and initiating one would be complex as well as challenging to maintain with timely, up-to-date data.

However, in 2011, two years after the release of the AMPAA-NASMD white paper, a survey by CMS found that most state Medicaid agencies indicated they wanted a national pricing benchmark using an AAC-based metric. Thus, in the following year, CMS contracted with a public accounting firm to perform a survey of invoices from independent and chain retail pharmacies.^x By the end of that year, CMS posted a set of draft data on its website, and by 2013, the National Average Drug Acquisition Cost was available online.^{xi} These data are updated weekly and monthly, and available at data.medicaid.gov under “drug pricing and payment.”

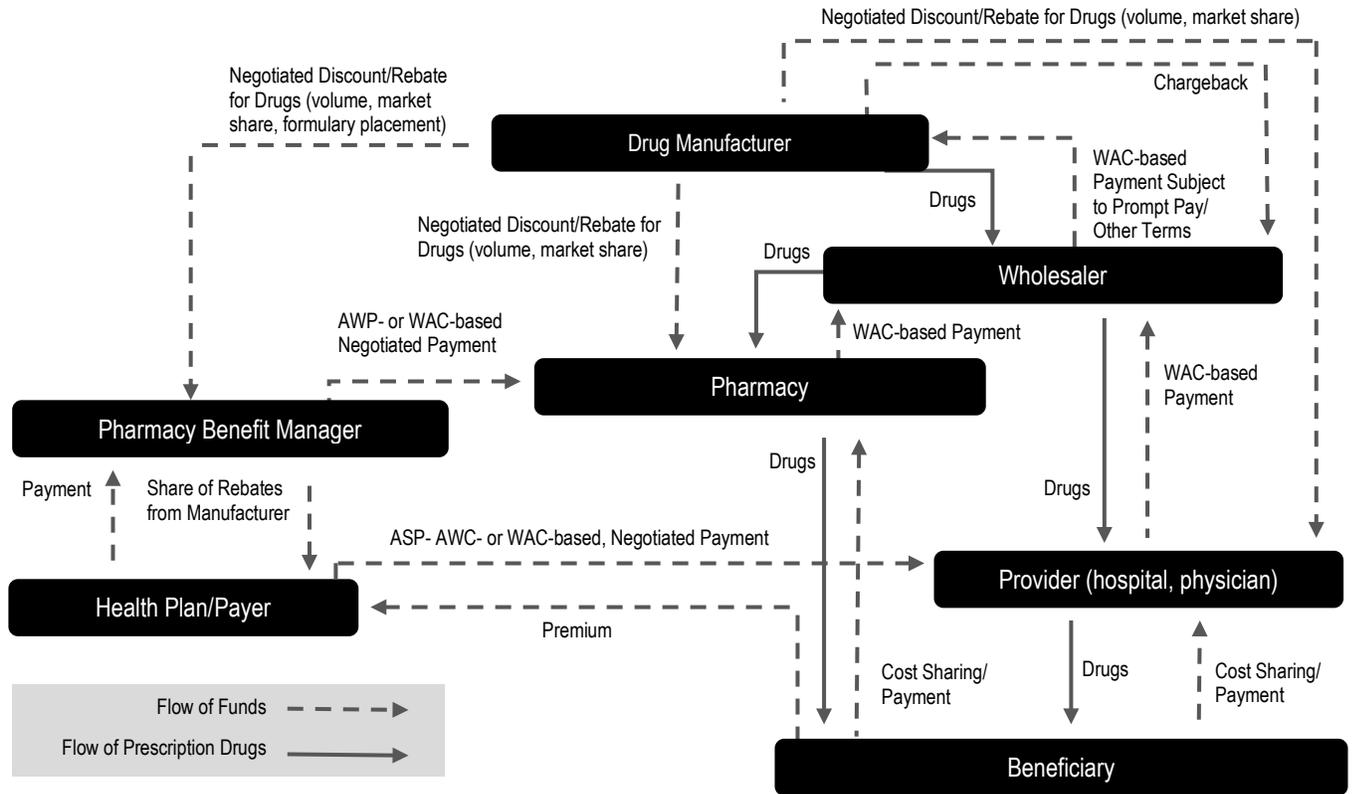
It is worth noting, though, that although the data listed appear comprehensive in scope, they are not. While including brand and generic prescription drugs, as well as over-the-counter ones, the list is limited to only those pharmaceuticals currently covered by CMS. Furthermore, because the prices shown are for the drug ingredients only, the cost for the pharmacy to dispense the medications must be added. Such fees can be as high as \$21 per prescription for rural Alaskan pharmacies, but are generally around \$10 or \$11 for the ACC-based state systems. In AWP- or WAC-based systems, the dispensing fees average around \$5 or less; however, costs for dispensing are offset by the higher reimbursement rates set for the drugs themselves.^{xiii}

It should be further noted that notwithstanding the efforts that have been expended in the development of an AAC-based metric, as of June 2017, 25 states — including Washington — still use either AWP or WAC in benchmarking their Medicaid prescription drug payments. An additional 10 states use AWP, WAC or an AAC-based metric, depending on which are available and/or cost less.^{xiii}

Beyond state and national pricing benchmarks used by each state’s Medicaid program, there are proprietary pricing benchmarks that PBMs, chain or major retail pharmacies, drug wholesalers and commercial health plans may use. The Predictive Acquisition Cost^{xiv} is one such pricing benchmark and describes itself as being transparent, accessible, comprehensive, timely, unable to be manipulated and administratively simple. However, because of its proprietary nature, we could not verify those claims.

In short, “manufacturer’s pricing data” is a somewhat elusive construct that appears to be evolving. Moreover, the complexities and nuances of the various pricing benchmarks arguably constitute only the tip of the iceberg, as may be suggested from the flowchart in Exhibit 1 of the drug distribution and payment model.^{xv}

Exhibit 1 Drug Distribution and Payment Model



AMCP Guide to Pharmaceutical Payment Methods | 2013 Update

While the flow of drugs is straightforward — from manufacturer to wholesaler to pharmacy or provider and then on to the beneficiary or patient — the flow of funds is not. In addition to whichever metric one chooses for establishing a “price,” the true cost may also need to take into account markups added by wholesalers; fees charged by PBMs as well as the discounts, rebates and chargebacks negotiated in return for adding drugs to their formulary and preferred tiers; overhead charges of health plans; and cost-sharing or full payments by beneficiaries plus any premiums they may have paid.

A brief CNBC report, [The Pharma Money Chain](#), provides an overview of this flow of funds using Mylan’s EpiPen as an example. Broadly, for an EpiPen with a list price (AWP) of \$610, Mylan would receive about \$290 in payment, resulting in a substantial profit on what’s estimated to cost, at most, \$30 to manufacture, but still leaving \$320 unaccounted for. Part of that remainder would go to the local pharmacy, the distributor and the PBM — somewhere around \$20 to \$30 each. The majority of the remaining funds would be in the form of a rebate from Mylan to the insurer.

In short, beyond the complexity of establishing a price, there is another layer of complexity pertaining to who profits and by how much.

Transparency legislation in Oregon, California, Nevada and Vermont

Oregon

During the 2017 legislative session, the Oregon Legislature introduced a bill that addressed rising drug costs and transparency. As subsequently amended, [House Bill 2387A](#) made it through the legislative process up to the Ways and Means Committee but was never voted out.

The bill called for the creation of the Oregon Premium Protection Program in the state's consumer protection and business regulatory agency, the Department of Consumer and Business Services. That program would create a price cap limiting prescription drugs charges to the highest price charged to countries in the Organisation for Economic Co-operation and Development. The bill would also require 60-days' notice for any WAC price increase exceeding 3.4 percent over a 12-month period and limit copayment to between \$250 and \$500 per year. If the WAC exceeded the 3.4 percent threshold or if the introductory WAC for a newly FDA-approved drug exceeded \$12,000 per year for a course of treatment, the manufacturer would be required to provide information on the costs for research on the drug's development, including clinical trials, and for research on the drug's safety and effectiveness. Manufacturers would also be required to provide information on costs for manufacturing and marketing as well as for information on projected profit margins and 10-year return on investment). If justification for such prices were not sufficient, manufacturers would be required to refund insurers the difference between the state's cap and their WAC.

Opposition to the bill from Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group representing the pharmaceutical industry, was not surprising. Neither, perhaps, was the opposition from large — and small start-up — biotech companies. But opposition also came from the NAACP, HIV/AIDS advocates and organizations representing individuals with rare or chronic diseases.

PhRMA's concerns included (1) using WAC as an index because it does not capture discounts and rebates; (2) the 60-day advance signaling of a price increase incentivizing stockpiling before an increase and thus allowing subsequent resale at the higher price; (3) the ability of insurers to drop high-price drugs from their formularies without adequate patient notification; and (4) the refunding to insurers without any subsequent refunding to patients.^{xvi}

The biotech industry concerns also included the WAC indexing and the price cap's potential in reducing return on investment and thus discouraging new drug development. Yet the focus appears to be mostly on the "vague, yet complex reporting and compliance requirements" that could lead to civil penalties and further divert resources from development.^{xvii}

Patient advocacy groups argued that the bill protects only insurers, not the patients, and would allow expensive drugs to be dropped from formularies without adequate notice — or viable alternatives — to those in need. They also argued the bill would dampen innovation.^{xviii}

California

One of the largest purchasers of prescription drugs in the nation, California recently enacted [Senate Bill 17](#), which has garnered much attention and differs from other legislation in that it requires reporting from both the health care payers/insurers and the drug manufacturers.

Under the legislation, payers would annually provide a list to the Department of Managed Health Care or the Department of Insurance of the 25 most commonly prescribed drugs, the 25 most-costly drugs in terms of annual spending and the top 25 drugs in terms of increase in year-over-year spending. Using weighted and actuarially adjusted rates, the payers would also report on the impacts prescription drug costs have on each year's premium rates. This information would be made publicly available.^{xxix}

For those drugs with a WAC of more than \$40 per course of therapy and a price increase of more than 16 percent over the course of two years, drug manufacturers would be required to provide a description to the Office of Statewide Health Planning and Development (OSHPD) of the specific financial and nonfinancial factors used to make the decision to increase the WAC of the drug and the amount of the increase including, but not limited to, an explanation of how these factors explain the increase in the WAC. In addition, manufacturers would be required to provide 60-days' advance notice of the planned 16 percent or higher price increase. This information, too, would be made publicly available.

Finally, the law requires manufacturers to report to the OSHPD within three days after release of any new specialty drug that exceeds Medicare's specialty drug price threshold.^{xxx}

Proponents of the legislation contend there is a public need-to-know in rising prescription drug prices, and while no direct mechanisms for limiting costs are included in the statute, the mere act of having to justify such increases may dampen the rising price trend.

Opponents contend that the statute may serve as a stalking-horse for future legislation on price controls.^{xxxi} Some proponents of the law agree.^{xxxii}

But in their opposition to the statute, drug manufacturers point mostly to three shortcomings in the law: (1) The WAC is not representative of the true cost paid by purchasers; (2) As in Oregon, the 60-day notification of a price increase would simply allow wholesalers to stockpile purchases prior to the increase date and resell at higher prices afterwards with no net savings to consumers; and (3) The reporting requirements, as written in law, are vague and, depending upon how they are implemented, may be subject to challenge.^{xxxiii}

Having just been signed into law in October 2017, the potential benefits of, as well as the potential challenges to this law are evolving. In fact, on Dec. 8, 2017, PhRMA filed a suit challenging the constitutionality of this new law.^{xxxiv}

Nevada

To address the rising cost of diabetes-related drugs through price transparency legislation, Nevada enacted [Senate Bill 539](#) in June 2017. Although narrow in its focus, the law is broad in scope. It not only requires transparency from pharmaceutical companies, it also requires transparency from PBMs, sales representatives and nonprofit patient advocacy organizations, with each reporting on financial information pertaining to manufacturing, rebates, sales or donations.^{xxv} However, in September 2017, two pharmaceutical lobbying groups, PhRMA and Biotechnology Innovation Organization (BIO), filed suit in federal court alleging that federal law preempts Nevada's law, which they contend violates the U.S. Constitution.^{xxvi} That suit is pending.

SB 539 requires the Nevada Department of Health and Human Services (NDHHS) to compile a list of prescription drugs considered essential for treating diabetes and prediabetes, such as insulin and biguanidines. For drugs on that list, manufacturers are required to report to NDHHS the following information:

- Costs of producing the drug;
- Total administrative expenditures relating to the drug, including marketing and advertising costs;
- Profit earned by the manufacturer from the drug and the percentage of total profit for the period attributable to the drug;
- Total amount of financial assistance provided by the manufacturer through any patient assistance program;
- Cost associated with coupons provided directly to consumers and for copayment assistance programs, along with the cost to the manufacturer attributable to the coupons and copay programs;
- The drug's WAC;
- History of WAC increases over the preceding five years, including the amount of each such increase expressed as a percentage of the total WAC, the month and year in which each increase became effective and any explanation for the increase;
- Aggregate amount of all PBM rebates provided by the manufacturer for sales of the drug in Nevada; and
- Any additional information prescribed by NDHHS regulation.^{xxvii}

From that list NDHHS will identify a second list of drugs whose WAC has increased by a percentage equal to or greater than either (1) the Consumer Price Index, Medical Care Component (CPI Medical) during the previous calendar year or (2) by twice the CPI Medical during the previous two years. For drugs meeting those criteria, manufacturers will be required to report on each of the factors that contributed to the WAC increase, the percentage of the WAC increase those factors represented and any other information required under rules.

For all the drugs on the first list, PBMs will be required to report on the rebates they negotiated with the manufacturers, including how much of the rebate they passed on to their clients and how much they kept for themselves. Those reports will be broken down by payer type, including Medicare, Medicaid, other government payers, third-party plans and plans subject to ERISA, the Employee Retirement Income Security Act.

Sales representatives will be required to register with the state, and only registered sales representatives will be allowed to market prescription drugs. Sales representatives must then subsequently report to NDHHS

all instances where they had compensated — in any way — a health care provider with anything valued at \$10 or more per instance or \$100 or more over the course of the year. This provision includes all drugs, not just those for diabetes.

Finally, spurred in part by a report in the New England Journal of Medicine, [Conflicts of Interest for Patient-Advocacy Organizations](#), nonprofits will have to disclose any funding they receive from drug companies, PBMs and health insurers.

In their lawsuit, PhRMA’s and BIO’s arguments against SB 539 fall into four categories: the authority to establish patent policy, the federal Uniform Trade Secrets Act, the Fifth Amendment’s Takings Clause and the Commerce Clause.^{xxviii}

Authority to establish patent policy – Article I of the U.S. Constitution, they argue, grants Congress the power “to promote the process of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings,” and Congress, in the 1984 Hatch-Waxman Act, created market and patent exclusivity periods for branded and generic drugs. PhRMA and BIO further note that drug development is an expensive process, citing a finding that 95 percent of experimental medicines fail to be safe and effective.^{xxix} Hence, they argue, although price controls are not explicitly enacted in the Nevada statute, the requirement that manufacturers provide detailed information on why price increases are necessary “in purpose and effect ... punishes manufacturers ... thus restrain[ing] patent holders from setting list prices in a manner that the federal patent laws secure in order to incentivize innovation.”^{xxx}

Uniform Trade Secrets Act – The plaintiffs next argue that the Uniform Trade Secrets Act, which most states (including Nevada and Washington) have adopted, together with the 2016 U.S. Defend Trade Secrets Act (DTSA), would be violated by SB 539 once the NDHHS publishes all the information manufacturers are required to submit. “SB 539 alters the operation of the DTSA — and the laws of every other jurisdiction in the nation — to eliminate trade-secret protection for confidential advertising, cost, marketing, pricing, and production information associated with diabetes drugs.”^{xxxi}

Fifth Amendment’s Takings Clause – Here the plaintiffs argue that SB 539 denies all economically beneficial or productive use of property because it eliminates the trade-secret protections held by manufacturers, a “categorical” taking of property rights. Moreover, even if not deemed categorical per se, it still constitutes a “taking” because of the economic impacts and the reasonable expectations that the company information would remain secret.^{xxxii}

Commerce Clause – Finally, the plaintiffs argue that SB 539 violates the Interstate Commerce Clause that gives the federal government the authority to regulate interstate commerce. By removing the trade-secret protections for manufacturers, none of whom are located in Nevada, SB 539 nullifies the trade-secret laws of every other state and the federal government. Eli Lilly, they cite as an example, is located in Indiana. By exposing that company’s trade secrets, Nevada undermines that company’s ability to promote growth, create local jobs and fuel the local economy in Indiana.

Legislators supporting SB 539 counter that these concerns have either been addressed or assessed and found to be unwarranted, and see the suit as simply a delay tactic. The decision will be the court’s.

Vermont

In June 2016, Vermont became the first state to pass legislation requiring transparency from drug manufacturers. That law, [18 V.S.A. § 4635](#), requires the Green Mountain Care Board, the state health care system's regulatory and planning entity, to each year identify up to 15 drugs on which "significant health care dollars" are spent and for which the WAC has increased by 50 percent or more over the previous five years or by 15 percent or more over the last 12 months. From that list, the Vermont Office of the Attorney General (VOAG) would contact the manufacturers of those drugs and require them to provide a justification for those increases in a "format that the Attorney General determines to be understandable and appropriate."^{xxxiii} That justification may include:

- All factors that have contributed to the WAC increase;
- The percentage of the total WAC increase attributable to each factor; and
- An explanation of the role of each factor in contributing to the WAC increase.

Each year, and in consultation with the Department of Vermont Health Access, the VOAG is required to submit a report to the state General Assembly based upon the information received from manufacturers and to post that report on the VOAG website.

However, in the state law, the information the VOAG receives from the manufacturers is deemed confidential and "exempt from public inspection and copying under the Public Records Act and shall not be released in a manner that allows for the identification of an individual drug or manufacturer or that is likely to compromise the financial, competitive, or proprietary nature of the information."^{xxxiv}

In December 2016, the VOAG issued its first report. For the 2016 fiscal year, the VOAG assessed 10 prescription drugs, ranging in total gross Medicaid spending from \$6.5 million for Abilify, a brand antipsychotic medication, to \$70,000 for permethrin, a generic insecticide used generally in treating head lice. The five-year average WAC increase for Abilify was 55 percent; the one-year average WAC increase for permethrin was 50 percent. The cost estimates included rebates provided by drug manufacturers to the state.^{xxxv}

Doxycycline hyclate, a generic antibiotic used to treat a wide range of conditions from acne to Lyme disease, had the greatest relative increase in WAC: 4,788 percent over the course of five years. Such a dramatic rise may, in part, be attributed to a temporary shortage brought on by the outbreak of Lyme disease in an area, and may also be mitigated by the relatively low initial price. "The retail price of doxycycline increased from about three cents per pill, to more than \$5 per pill over the past 18 months, according to local doctors and pharmacists,"² reported the Vineyard Gazette in September 2015.^{xxxvi} Medicaid's fiscal year spending for doxycycline was \$194,000. Below is the complete listing:

² It may be worth noting that as of August 2017, the price of doxycycline has fallen to \$0.60 per pill according to The New York Times. https://www.nytimes.com/2017/08/08/health/generic-drugs-prices-falling.html?_r=0

Exhibit 2
Identified Drug List per 18 V.S.A. § 4635

Type	Brand Name	Generic Name	Labeler	Therapeutic Class	1 year Avg.	5 year	SFY 2016
					WAC	Avg. WAC	Gross Drug
					% increase	% increase	Spending
Brand	Abilify	Aripiprazole	Otsuka America	Quinolinone Derivatives		55.27%	\$6,500,094
Brand	Lantus	Insulin Glargine	Aventis Pharmaceuticals	Human Insulin		89.83%	\$5,445,451
Brand	Humira	Adalimumab	Abbott Laboratories	Anti-TNF-alpha-Monoclonal Antibodies	27.95%	113.79%	\$4,712,103
Brand	Enbrel	Etanercept	Amgen/Immunex	Soluble Tumor Necrosis Factor Receptor Agents	16.42%	92.73%	\$3,194,725
Brand	Crestor	Rosuvastatin Calcium	Astrazeneca	HMG CoA Reductase Inhibitors	20.75%	75.98%	\$1,759,834
Brand	Epipen	Epinephrine	Mylan Specialty	Anaphylaxis Therapy Agents	32.02%	205.45%	\$1,697,384
Brand	Latuda	Lurasidone HCl	Sunovion Pharmaceuticals, Inc.	Antipsychotics-Misc.	19.80%	99.68%	\$1,149,040
Brand	Prevacid	Lansoprazole	Takeda Pharmaceuticals America	Proton Pump Inhibitors	20.78%	103.32%	\$941,689
Generic	Doxycycline hyclate	Doxycycline Hyclate	Mutual Pharmaceuticals Company	Tetracyclines		4787.61%	\$194,044
Generic	Permethrin	Permethrin	Perrigo Pharmaceuticals	Scabicides & Pediculicides	50.00%		\$69,949

Although not lengthy, the VOAG report focuses in part on the limitations of the metric used — WAC — noting many of the limitations cited above in the section on metrics. Additionally, the report discusses negotiations on favorable positioning of drug formularies: how as WACs increase, the rebates often proportionately increase and how the manufacturer has no control over payers’ decision on patient out-of-pocket expenses under the various prescription pharmaceutical benefit plans.

Concluding with factors commonly mentioned by the manufacturers in making their pricing decisions, the VOAG listed these, in no particular order:

- Cost effectiveness (meaning the economic value to patients given the effectiveness of the drug, compared to other drugs in the same class).
- The size of the patient population for the drug.
- Investments made (including in research and development) and the risks undertaken.
- Creation and maintenance of manufacturing facilities and capabilities, including the ability to address drug shortages caused by production issues.
- Cost of ingredients.
- Competition, including for drugs in the same class.
- Return on investment and fiduciary responsibilities.
- The percentage of their sales in commercial, Medicare or other government channels.

Perhaps best summing up the response to this report was a statement by Vermont State Rep. Anne Donahue, who had voted for the bill: “Some of the information is probably more synthesized than what we might have envisioned, and in that sense is perhaps a little less helpful than we might have hoped.”^{xxxvii}

Prescription drug pricing in Canada

As noted in the introduction, prescription drug pricing — and, in fact, the whole Canadian health care system — is far more complex than what might be commonly perceived. To begin with, Canada does not have a national health care system. Instead, the Canadian Constitution charges the provinces with the responsibility of establishing, maintaining and managing hospitals, asylums, charities and charitable institutions.^{xxxviii} The federal government funds half the costs for provinces' health care systems provided they meet these five criteria:

1. portability (insurance continues when people move from province to province);
2. accessibility (people cannot be charged extra for any service that is covered);
3. universality (all Canadian citizens and permanent residents are automatically covered);
4. comprehensiveness (all necessary medical services are covered); and
5. public administration (the health care system is administered on a public, not-for-profit basis).^{xxxix}

In addition, while drugs administered to patients in hospitals are fully covered in each province, those same drugs, when administered to patients in an outpatient setting, are not. Instead, they are generally covered through an employer or private insurance plan. Furthermore, although the prices for all patented drugs are subject to national price control regulations, price controls for generic drugs are the responsibility of each province. Below is a brief description of Canada's drug pricing system.

The process for newly patented drugs begins with a review by the Canadian Patented Medicine Prices Review Board's (PMPRB) Human Drug Advisory Panel to determine if the drug is a new version of an existing drug or is a new active substance (NAS), i.e., a molecule never sold in Canada before. If it is a new version of an existing drug, the PMPRB compares the proposed price to similar drug prices in Canada, and allows the drug to go to market provided that price is in keeping with those other prices.

If the drug is a NAS, the PMPRB compares the proposed price to existing products in the same therapeutic class and the median price in France, Germany, Italy, Sweden, Switzerland, United Kingdom and United States, and from that assessment establishes a maximum average potential price (MAPP). If the price of the new drug is at or below the MAPP, no further action is taken. If the price is above the MAPP, the PMPRB enters into negotiations with the manufacturer to reduce the price. At that point, consideration may be given to the cost of making and marketing the drug, as well as other factors considered relevant.^{xi}

For all patented drugs, the PMPRB limits the rate of price increase to the rate of increase in the Consumer Price Index over any three-year period.^{xii}

Figure 1
Patented Drugs
Average Foreign-to-Canadian Price Ratios
2015



Source: Protecting Canadians from Excessive Drug Prices, Health Canada, 2017

Even with this process, the prices for patented drugs in Canada remain higher than those in six of the seven countries it uses in setting its MAPP, with the United States as the clear outlier. (Consideration is currently being given to revising the list of comparison countries by adding new ones and excluding the United States.^{xlii}) See Figure 1.

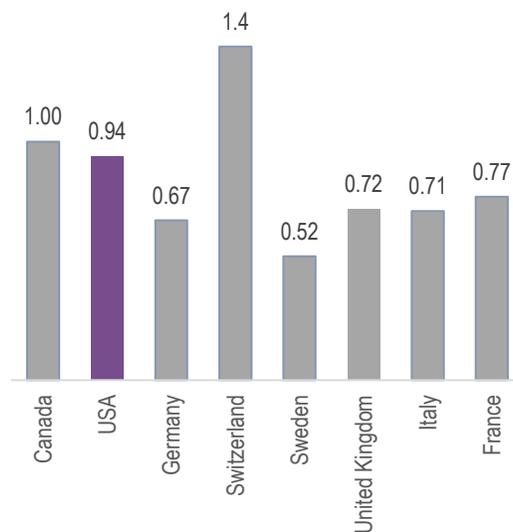
It is worth noting, though, that the prices used by PMPRB are the AWP, that is, the list (or the ain't what's paid) prices, and thus may overstate the variations shown depending upon the types of discounts and rebates built into other countries' drug pricing systems. Reforms in the PMPRB process may, therefore, also include consideration of a different metric or at least an accounting of such discounts and rebates.^{xliii}

While generic drugs accounted for more than 70 percent of the prescriptions dispensed in Canada in 2016, they accounted for only slightly more than 22 percent of the dollars spent on prescription drugs.^{xliv} This is similar to the United States, where in 2016, generics accounted for 89 percent of prescriptions dispensed but only 26 percent of the costs.^{xlv} Nevertheless, the higher prices seen for generics in Canada compared to other countries have raised concerns. See Figure 2.

Those higher prices are largely seen as a function of limited competition among pharmacy chains in combination with the capping of the formulary at a percentage of the brand name price and specifying a maximum reimbursement cost for a drug or drug group. The pharmacy chains are, in short, able to negotiate steep discounts on the AWP for generics while, concurrently, using the AWP on branded versions to set the cap. Private insurers, who cover prescription drug costs, are not incentivized to lower those costs because they are often paid as a percentage of the plan cost — hence the higher the cost, the more they profit.^{xlvi}

Each province is addressing these generic drug costs in differing ways. Perhaps the most innovative and well-established is British Columbia, which initiated a reference-based pricing (RBP) system beginning in 1995. This approach groups certain classes of drugs together that are deemed to be essentially equally safe and effective and can be interchanged, even if they are not bioequivalent. A referent price is set for each class, and the RBP will cover the cost of a prescription at or below that price. If a physician prescribes a higher-priced drug, and the patient chooses to use it, the patient pays the difference. Currently RBP is being used for five therapeutic classes of drugs in British Columbia. In 2002, the introduction of the RBP for drugs used in treating hypertension, congestive heart failure and coronary artery disease was found to have led to a 6 percent savings. Unfortunately, no more recent assessments have been published.^{xlvii}

Figure 2
Generic Drugs
Average Foreign-to-Canadian Price Ratios
2014



Source: Generics360 – Generic Drugs in Canada, 2014, Patented Medicine Prices Review Board, 2016

Washington's current drug purchasing strategy

In November 2016, the Washington State Health Care Authority (HCA), together with the Office of Financial Management, issued a report to the Washington State Legislature on prescription drug costs and potential purchasing strategies.^{xlviii}

As outlined in that report, four recommendations were issued by an inter-agency Prescription Drug Work Group convened in 2001:

1. Establish a statewide Pharmacy and Therapeutics Committee to develop, implement and maintain a Washington State Preferred Drug List. The committee will, where appropriate, seek additional expertise to address issues concerning special populations.
2. Establish a statewide Drug Utilization Review Board to develop treatment guidelines and criteria for appropriate drug use.
3. Explore the feasibility of consolidating claims processing, claims adjudication and other pharmacy management and information services.
4. For agencies and/or programs that directly purchase drugs, explore the feasibility of implementing and maintaining a consolidated rebate program.

As follow-up to those recommendations, in 2003, the Uniform Medical Plan, Department of Labor and Industries and the state's Medicaid program created the Washington Prescription Drug Consortium and contracted with a PBM for negotiating prices and rebates. During that same year, the passage of Senate Bill 6088 established a prescription drug program to create and administer the Washington Preferred Drug List and the Therapeutic Interchange Program. Preferred drug lists, in general, provide an incentive to manufacturers to negotiate prices and provide rebates so their drug will be deemed "preferred." The Therapeutic Interchange Program identifies therapeutically equivalent drugs within a class, thus allowing pharmacists to automatically exchange a nonpreferred drug with an equally safe and effective preferred drug unless the prescription specifies "dispense as written."

In 2005, the Legislature passed Senate Bill 5471, requiring all state agencies to purchase their drugs through the consortium unless they could demonstrate they received greater discounts elsewhere. One year later, Washington joined with Oregon to create the Northwest Prescription Drug Purchasing Consortium. Key characteristics and benefits of that arrangement include:

- The contract for prescription drug purchasers is fully transparent.
- Access is provided to competitive retail pharmacy discounts.
- All drug manufacturer rebates are passed through in full.
- Contracts have a guaranteed ceiling price, putting the PBM at risk for excess costs.
- Consortium drug prices have consistently proven better than commercial rates now available to other large groups in either state.
- Both the annual market price assessment and the program benefit audits are performed by a third party but are paid by the PBM.

As noted in the report, “Total consortium drug spending is currently approaching \$1 billion annually for nearly one million members in Oregon and Washington, including programs for public employee benefits, K-12 educators, worker’s compensation, uninsured discount cards, corrections, and small-employers.”

Summary and conclusions

Transparency has value. However, transparency in prescription drug prices may face significant legal barriers, many of which are now being litigated in other states. And while transparency may intuitively seem to be an effective mechanism in reducing unnecessary price increases because it has been implemented in only one state, there is little evidence to date to show that such provisions alone drive down or keep down prices.

Although Washington's drug purchasing strategy does not currently use prescription drug price transparency to mitigate price increases, its market approach as an empowered large purchaser does provide an effective mechanism for some degree of control of prescription drug prices. If federal law were changed to allow states to negotiate price directly, a broad purchaser consortium — including both public and private purchasers — could have enough market power to fully negotiate prices. Such a public/private purchasing consortium would functionally mirror the purchasing power of the Canadian system.

Alternately, a regulatory approach like Canada's, enacted perhaps under a public utility model where prices would be regulated much in the same way electricity, natural gas and water rates are, could also theoretically control costs. This seems to be the fear underlying the drug manufacturers' opposition to price transparency, as explicitly stated by those opposing (and some supporting) California's drug transparency law. Public outcry over obvious price gouging practices, such as seen with EpiPen, may not be sufficient or sustainable and could quickly fade, having only short-term impacts, if any. However, building a sustained case for unwarranted price increases — which price transparency could do — lays a foundation for regulatory action. That fear of a potential case being made for a regulatory approach may, in fact, be the true “stick” of such legislation — and the threat alone may be sufficient to affect drug manufacturers' pricing practices. But while a threat could mitigate price increases, measuring and attributing such an effect may be difficult.

If price transparency legislation were to be enacted in Washington, careful consideration should be given to the following factors:

1. Price metrics – While WAC is readily available and widely used, manufacturers are correct in pointing out that those prices do not reflect the true purchasing price. The National Average Drug Acquisition Cost, though limited in scope, more closely captures such costs. An expansion of the surveys of independent and chain retail pharmacies would, however, be necessary to acquire those data. Even still, those prices would not reflect negotiated discounts.
2. Manufacturers' costs – Nevada's comprehensive approach in requiring manufacturers' cost data elicited the strongest response from the industry, and is certainly the most probing. The details outlined in that state's statute would clearly spell out all the costs involved in every step from manufacturing to marketing. The broad legal challenge against that legislation is pending, and the court's findings will help determine if such legislation can serve as a viable model.

3. Advance notice – California’s 60-day advance public notice of a WAC increase at or above 16 percent could dampen manufacturers’ willingness to quickly raise prices. They may, however, counter by initially introducing drugs at a higher price or offer few or lower rebates. Public interest may wane in such increases, especially for lower-cost drugs for which, for instance, an \$8 increase on a \$50 prescription over the course of two years would constitute a 16 percent price increase. Moreover, as noted for both Oregon and California, such advance notice would allow wholesalers to stockpile many drugs at the lower costs and resell them later at the higher prices.
4. Public reporting – As noted with Vermont, without careful consideration of what the end-product would be, public reports may ultimately be quite limited in their impact and fundamentally call into question the utility of such transparency requirements.

While the proviso in Substitute Senate Bill 5883 asks that the WA-APCD be considered as a mechanism for establishing a prescription drug price transparency program, this does not appear to be an optimal choice. Prescription drug transparency involves detailed information from drug manufacturers — and potentially others — on why a price increase is needed. The WA-APCD is not designed for collecting such information, and instead collects claims data submitted to payers. However, Second Substitute House Bill 1541, proposed in February 2017, provides a framework for prescription drug price transparency in Washington.

From the review of other states’ transparency legislation, in addition to those reported here, OFM would neither suggest specific language nor other language that would make the WA-APCD a natural entity for collecting and reporting detailed manufacturers’ cost data justifying prescription drug price increases. Such functions have typically fallen to the state attorney general’s office, the state insurance office or the state health planning office.

In Washington, consideration could be given to these entities, but a prescription drug transparency program might best fit in the Office of Financial Management, where the health care research and planning functions are located, as well as where the WA-APCD is housed. Moreover, the WA-APCD would be useful for numerous analyses augmenting the information collected through a price transparency program such as data on consumers’ out-of-pocket expenditures, identification of the most commonly prescribed drugs, the annual charges per brand name and generic drugs and percentage increases in drug prices over time.

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EXHIBIT C

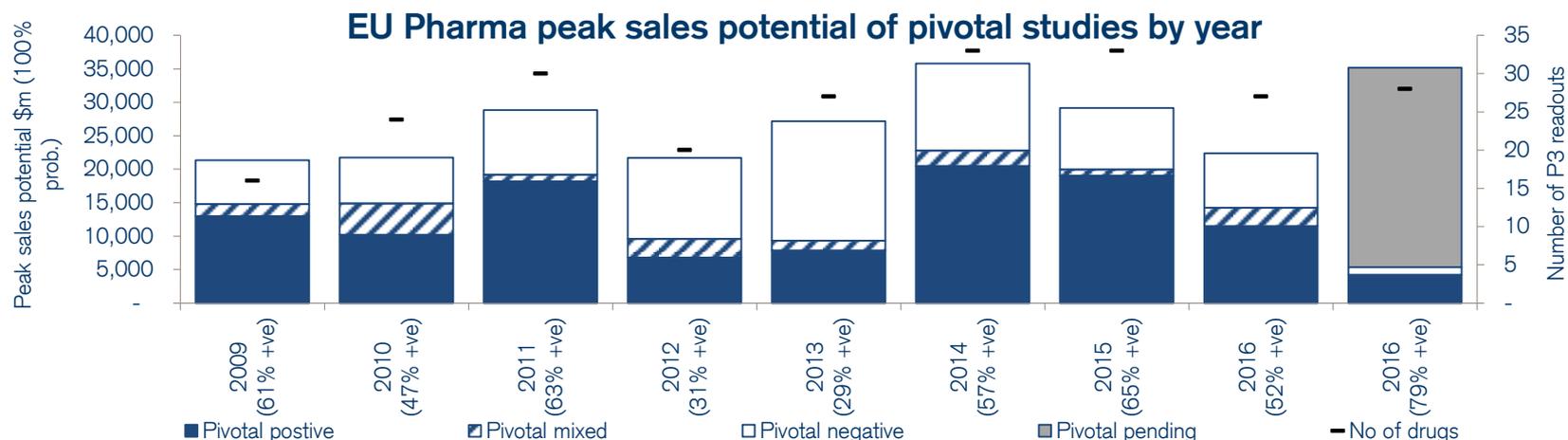
Credit Suisse Pharma Team, European Pharma 1Q17 Quarterly Prep Pack (04/18/2017)



Review of US quarterly pharma trends

Our key questions for 1Q results include:

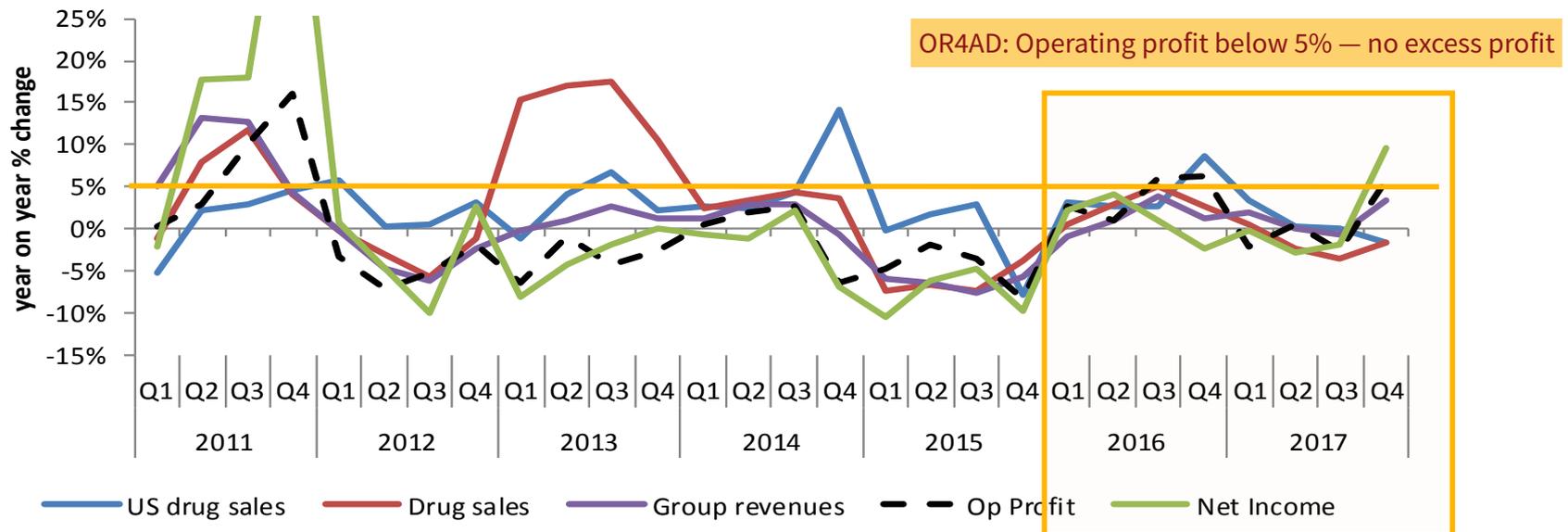
- **New products:** Update on progress for key drug launches such as Entresto, Xiidra, Ocrevus and Dupixent. Any changes to formulary positions and barriers to adoption from payers?
- **US politics:** How does the industry expect net prices to develop following President Trump's failed repeal of the ACA? Following JNJ 1Q commentary on 'higher access charges' and 'donut hole adjustments' for Xarelto, we expect a lot of discussion about US gross to net adjustments ([CS Ideas Engine US pricing](#))
- **Biosimilars:** 2017 will be the first year for many biosimilars including EU biosimilar Rituxan, Truxima, approval in the EU in Feb '17 with Herceptin expected to be approved in 1Q17. We expect discussion and questions around company assumptions of speed of adoption
- **ASCO:** We look for the announcement of key data to be presented at ASCO (IO, IO-combo, APHINITY).
- **Emerging market performance:** How has currency volatility impacted the underlying purchasing of drugs in EM and how has FX volatility impacted translation of sales/profits back to home countries?
- **R&D productivity:** In 2017 we expect total of \$35bn of peak sales of drugs to be derisked in pivotal trials for EU majors. \$5.3bn has been derisked to-date (79% positive). However, there has been a number of CRLs from the FDA – has there been a personnel change that might explain this more risk adverse approach?



What we expect for 1Q17 results

- In 1Q17 we are looking for 0.6% drug sales growth but **Operating profit decline of -2.1%.**
- We believe this is partly driven by generic erosion (Lantus, Gleevec, Crestor, Seroquel etc.), and launch investments (Ocrevus, Dupixent, Praluent, and Cosentyx)

Aggregate universe growth (underlying data in \$m)



Source: Credit Suisse estimates



US Pricing trends

US list prices and rebates

OR4AD: Average rebates paid to PBMs/
insurers across all product classes

Company	2016 US Rx sales \$m	List Price Rises									Rebates			2016 Net Price (est)*
		FY2015	FY2016	1Q	2Q	3Q	4Q	2017 1Q	2017 Apr	Avg 2017 YTD	FY13	FY14	FY15	
Abbvie	15927	23.2%	22.2%	32.7%	23.5%	16.1%	16.6%	15.5%	15.5%	15.5%	32%	35%	40%	17.3%
Alexion	118	3.3%	3.1%	0.0%	2.4%	5.0%	5.0%	5.0%	5.0%	5.0%				
Allergan	11663	14.3%	10.2%	14.0%	10.1%	8.9%	7.8%	7.5%	6.6%	7.3%				
Amgen	17923	6.2%	10.6%	6.3%	12.3%	14.1%	9.6%	13.2%	13.2%	13.2%	27%	29%	31%	9.0%
BIIB	8500	11.7%	11.0%	10.4%	14.8%	12.8%	6.0%	10.3%	10.3%	10.3%	23%	23%	25%	8.7%
Biomarin	595	0.4%	0.8%	0.3%	0.3%	0.3%	2.4%	5.6%	5.6%	4.0%		8%	9%	-0.2%
BMJ	10720	7.7%	6.2%	3.8%	6.9%	6.6%	7.3%	7.7%	6.6%	7.4%	35%	35%	35%	6.2%
Celgene	6979	4.3%	16.4%	14.3%	15.2%	18.0%	18.2%	10.6%	11.4%	16.9%	14%	15%	16%	15.2%
Gilead	19298	0.7%	5.5%	5.1%	5.1%	5.9%	5.9%	3.0%	3.0%	2.5%	21%	20%	36%	-10.8%
Incyte	853	9.3%	9.7%	10.2%	10.2%	9.2%	9.2%	3.0%	9.1%	7.6%				
JNJ	20125	9.7%	9.6%	9.3%	10.4%	9.3%	9.3%	11.5%	8.5%	11.2%	30%	32%	37%	4.1%
Lilly	9942	16.8%	13.7%	14.9%	12.1%	16.1%	11.5%	11.0%	11.0%	13.0%	26%	32%	39%	7.0%
Merck	17074	11.6%	9.4%	9.4%	10.1%	10.6%	7.5%	5.6%	5.1%	5.7%	28%	32%	34%	7.8%
Pfizer	20119	13.8%	11.4%	12.8%	11.3%	10.6%	10.9%	9.6%	9.6%	9.6%	28%	31%	34%	8.7%
Regeneron	3337	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%		6%	7%	0.0%
Teva	6724	13.8%	7.8%	7.2%	7.6%	8.3%	8.3%	7.9%	7.9%	7.9%	41%	50%	56%	1.8%
Vertex	1289	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%		9%	10%	
AZN	7474	10.8%	9.1%	9.9%	10.1%	8.8%	7.7%	7.7%	6.4%	7.3%	55%	57%	60%	
Bayer	4655	11.0%	8.8%	7.5%	9.7%	8.9%	8.9%	7.7%	7.1%	7.4%				
GSK	11431	7.1%	8.3%	9.5%	9.5%	7.1%	7.0%	5.6%	6.1%	5.7%	31%	37%	50%	4.9%
Novartis	10897	13.6%	11.8%	11.5%	14.2%	12.3%	9.3%	9.9%	9.7%	9.3%	28%	27%	25%	13.9%
Novo N	8498	18.9%	7.5%	9.5%	6.3%	9.3%	4.8%	7.9%	7.9%	7.1%	46%	47%	55%	-0.1%
Roche	18782	5.1%	5.9%	5.7%	5.7%	5.9%	6.1%	6.1%	6.3%	6.1%				5.9%
Sanofi	12777	12.4%	4.4%	5.3%	5.4%	3.4%	3.5%	4.4%	4.1%	4.4%	40%	45%	49%	0.6%
Lundbeck	1249	30.8%	22.3%	29.6%	25.7%	17.3%	16.4%	8.6%	11.4%	12.1%		11%	22%	11.3%
Merck KGaA	1783	12.9%	8.2%	9.3%	9.3%	7.1%	7.1%	9.5%	9.5%	9.5%		14%	18%	4.2%
Shire	8901	7.9%	9.2%	9.7%	9.7%	8.1%	9.5%	6.5%	6.5%	6.3%	33%	32%	33%	8.5%
UCB	1955	9.2%	4.5%	4.5%	4.5%	4.5%	4.5%	9.5%	9.5%	9.5%		24%	25%	3.5%
Universe	265327	10.5%	9.6%	10.2%	10.1%	9.6%	8.5%	8.3%	8.0%	8.4%	40%	27%	31%	4.5%
US average	176926	10.2%	10.3%	10.9%	10.8%	10.4%	9.1%	8.8%	8.4%	9.1%	28%	26%	31%	4.8%
EU average	88401	10.5%	7.9%	8.5%	8.6%	7.6%	6.9%	6.9%	6.8%	6.7%	72%	28%	32%	3.4%

Insulin
manufacturers

Source: Wolters Kluwer, Pricing database, Credit Suisse estimates. *Net price estimate based on avg. 2016 list price rise less change in rebates 2015/14, Jan price rises up to 10% Jan



The Ideas Engine series showcases Credit Suisse's unique insights and investment ideas.

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Global Pharma and Biotech

SECTOR REVIEW

KEY CONCLUSIONS

Exploring future US pricing pressure

Future pathways for US drug cost control a critical debate for bio-pharma. In this Ideas Engine Series report, we use multiple sources of proprietary and public data to analyse drug price rises and rebates in 2016 for 28 companies, and identify those most at risk from future US drug price reform.

US drug price rises contributed 100% of industry EPS growth in 2016. Arguably, this is the most important issue for a Pharma investor today. Despite public scrutiny, we estimate US net price rises contributed c\$8.7bn in 2016 to net income, 100% of sector EPS growth. US net price growth was >100% of Biogen, Lilly, and AbbVie's total net income growth. BioMarin, Gilead, Novo and Regeneron were the least reliant on US net price rises.

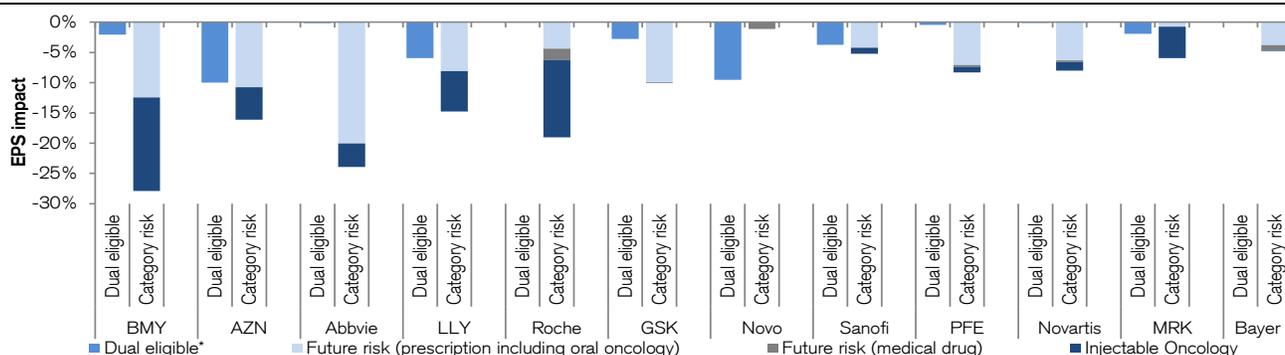
The key question: where will future pricing risk fall? We review the EPS impact of two possible new targets for incremental US price pressure: 1) Therapeutic Categories at high risk based on the greatest cost burden to payors and high Credit Suisse forecast sales growth. These include HIV, multiple sclerosis, and RA biologics; and 2) Changes in Medicare Part B cost control. Outpatient infused drugs represent a largely unmanaged cost today and are an obvious target for potential future reform. Companies with EPS most exposed to these combined drivers are Bristol-Myers and AbbVie (c25% negative impact) and in Europe, Roche and AstraZeneca (c-15%).

Changes in Dual Eligible funding: A switch of dual-eligibles from Medicare to Medicaid would result in a high one-off negative rebate charge. Based on 2016 EPS, in Europe we see AstraZeneca and Novo Nordisk (c-10%) as most at risk and in the US Eli Lilly.

Other observations: Overall Bristol-Myers scores the lowest of the Majors in our scorecard. Lilly has had the greatest negative change in portfolio outlook since 2016 (loss of Alzheimer's uniqueness). Shire's acquisition of Baxalta has brought greater risk of future pricing pressures to its portfolio.

Our full 120-page report contains further company detail, industry data, supporting analysis and a company pricing flexor.

Figure 1: EPS impact from change in dual eligible funding and identified future category risk

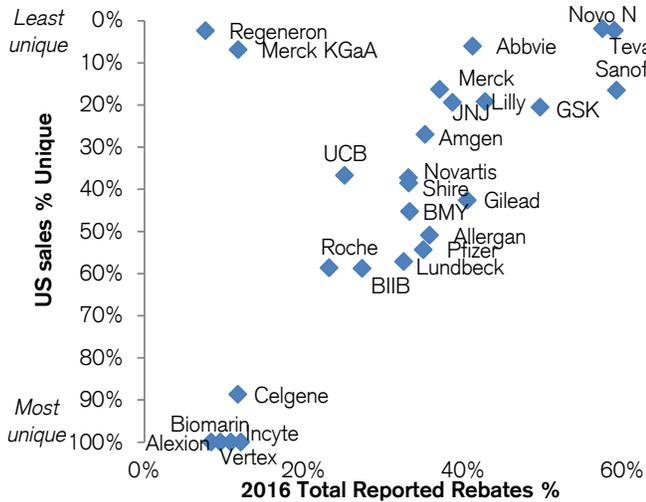


Source: Company data, Credit Suisse estimates. *Dual eligible data based on 2016 EPS, other based on 2020 CSe EPS

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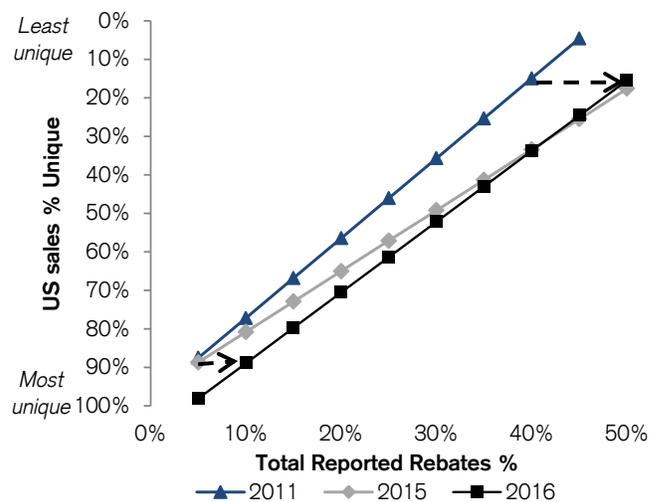
Key charts

Figure 2: Relationship between product uniqueness and rebates in 2016



Source: Company data, Credit Suisse estimates

Figure 3: Trends in relationship between product uniqueness and rebates 2011-2016



Source: Company data, Credit Suisse estimates

Figure 4: Credit Suisse US rebate Analysis 2017

Parameter	US Uniqueness 2016	Change in Uniqueness pressures	Impact on EPS of future focus on prescriptions	Impact on EPS of focus on Medical Benefit	Impact on EPS of change in dual eligibles	Overall
Weighting	10%	30%	20%	10%	30%	
Bayer	0	0	0	+	+	+
Novartis	0	0	0	+	+	+
Sanofi	0	+	0	+	0	+
AbbVie	-	+	-	0	+	0
Pfizer	+	-	0	+	+	0
MRK	0	0	+	0	0	0
GSK	0	+	-	+	0	0
Roche	+	-	0	-	+	0
Novo Nordisk	-	0	+	+	-	0
AZN	0	+	-	0	-	0
BMJ	0	-	-	-	0	-
LLY	0	-	0	0	-	-
Teva	-	+	0	+	+	+
Allergan	0	0	+	+	+	+
Merck KGaA	-	0	0	+	+	0
UCB	0	0	-	+	+	0
Shire	0	-	+	-	+	0
Lundbeck	+	-	+	+	-	0
Alexion	+	0	+	+	+	+
Biomarin	+	0	+	+	+	+
Vertex	+	0	+	+	+	+
BIIB	+	0	-	+	+	0
Incyte	+	0	-	+	+	0
Celgene	+	0	-	+	+	0
Gilead	0	+	-	+	0	0
Regeneron	-	0	+	-	+	0
Amgen	0	0	0	-	+	0

Source: Company data, Credit Suisse estimates

Company conclusions

- **Valuation premium does not capture US Majors' greater exposure vs Europe.** A key conclusion from our analysis is that US Major Pharma and US Biotech have much higher EPS exposure to potential US pricing risk. Given the larger EM footprints and more diversified portfolios of EU Pharma (generics, diagnostics, OTC, etc), this is not a surprise. However, it is in complete contrast to valuation multiples using both P/E and PharmaValues EV/NPV. On average, US Major Pharma trades on a 10% premium to EU Majors on EV/NPV. Arguably, US investors are closer to the massive complexity of the challenges around US drug pricing. One conclusion is that EU investors may simply be overreacting to the magnitude of the risks to US earnings.
- **Key catalyst – August 2017 PBM formulary season.** We expect the results of PBM rebate negotiations for the 2018 commercial health insurance season to be announced in early August 2017. This will be a critical time to understand the impact of future category risk on each company. We expect increased scrutiny on oral oncology, inflammation/RA, haemophilia and psoriasis.
- **Timing much less certain around possible political changes to the US pricing environment** around managing Medicare Part B/medical expenses and the possible shift of Medicare/Medicaid dual eligibles back to the higher discounts of Medicaid.
- **Bristol Myers (Neutral, TP \$52).** Surprisingly, BMY emerges as having the greatest risk of future pricing pressures in Major Pharma. This results from 1) our analysis of PD-1/PD-L1 as 'discountable' given the multiple players in the space; 2) the potential negative impact of greater payor focus on Eliquis and Orenicia, both in areas of high cost for PBMs; and 3) BMY's high exposure to medical benefit/Medicare Part B, which may come under increasing scrutiny as a large area of unmanaged cost today.
- **Eli Lilly (Outperform, TP \$88)** sees the greatest negative change in future pricing pressures since our analysis in 2016. Its mid-term portfolio has been negatively affected by the failure of solanezumab (Alzheimer's, unique) and our view that migraine CGRP inhibitors are discountable given multiple competitors in this category.
- **Sanofi (Outperform, TP €85) and Novo Nordisk (Neutral, TP DKK270)** both score as having modest incremental future risk. This is because our analysis is targeting *new* areas of pricing pressure. As such, diabetes is viewed as an area where investors are already familiar with the risk, which should be included in earnings forecasts. We are not saying the pressure is over. Experience from respiratory shows that PBMs extract value from a large category over multiple years. Credit Suisse forecasts continue to assume significant price pressure in US insulin and GLP-1 into 2018E.
- **AstraZeneca (Underperform, TP £40)** scores as having high exposure in both future category risk and dual eligibles. This is driven partially by its portfolio (respiratory, diabetes, discountable oral oncology, I-O), but it is exacerbated by AZN's very low level of profitability today, which amplifies the impact on earnings sensitivities.
- **Lundbeck (Outperform, TP DKK325)** has the highest exposure to risk from dual eligibles being returned to Medicaid. CNS diseases (depression/schizophrenia) are the largest area of spending for the elderly poor. Given Lundbeck's robust use of US price increases, we estimate that any move to the Medicaid pricing structure would cut EPS by c12%; however, this is exaggerated by its current low profit base.
- **Shire (Outperform, TP 5400p).** The acquisition of Baxalta has had an adverse impact on Shire's future ability to resist pricing pressure. The company's 'uniqueness' is compromised by a greater proportion of discountable sales in haemophilia and IVIG/immunology. We see haemophilia as a high-cost area which PBMs may aim to manage – albeit less aggressively than previously seen in primary care categories.

Executive summary

Introduction

In this Ideas Engine Series report, we bring together multiple sources of proprietary and public data to analyse the biopharmaceutical companies most at risk from future US drug price reform.

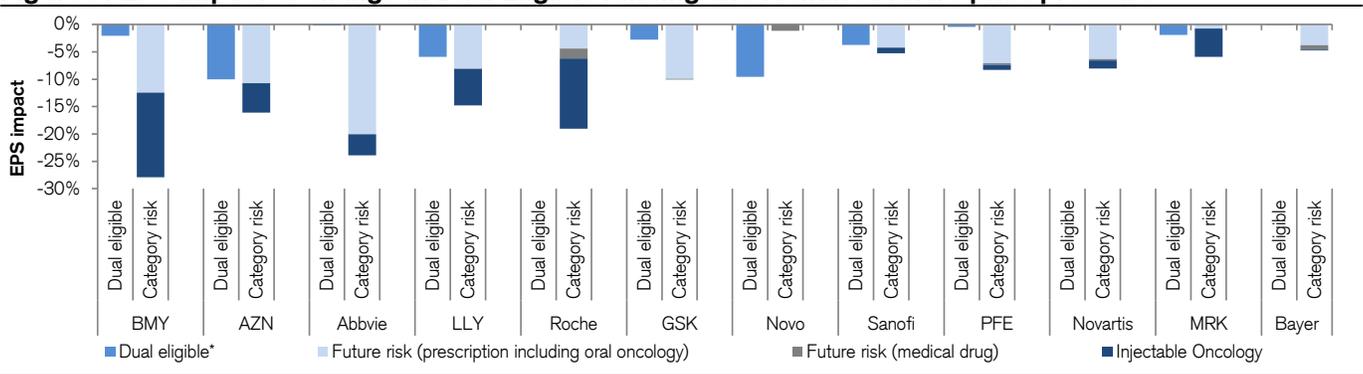
In 2015, total US healthcare spend was \$3.2trn, accounting for 17.8% of GDP (source: CMS.gov). Of this, IMS Health estimates net US drug spending reached \$318bn in 2016, up 9% YoY. Specialty drugs, including oncology and inflammation, were the key driver of spending growth, contributing over \$150bn. In addition, price increases have been a material driver of the spending increase, with net prices rising by 6.5% on average over the past five years and adding c\$70bn of cost, we estimate. With healthcare spending forecast by CMS to grow 1.2pp faster than GDP to 2025 and pharmaceuticals looking set to grow faster still, it is clear that something has to change. However, the highly complex (and often perverse) incentives that have evolved in the US healthcare system make this an exceptionally challenging task.

We summarise our key conclusions on three major topics:

- **Targets of future drug price pressure** based on areas of high-growth drug spend for health insurers and therapeutic categories where competition is increasing.
- **Earnings sensitivity to increased cost management for medical benefit** (outpatient infused drugs) in commercial plans and Medicare B. As the key driver of specialty drug cost growth, an area of relatively unmanaged spending, and an area of increasing competition (multiple PD1/PDL1s, IL17/IL23p19s, ophthalmic VEGFs), we see this as a key area of potential incremental pressure.
- **Risks of a shift in reimbursement for the elderly poor** (Medicare/Medicaid dual eligibles). In 2006, six million dual eligibles were moved from Medicaid (high discounts) to Medicare Part D (lower discounts). In 2008, the US Congress estimated that Medicare had paid prices 46% higher than Medicaid for the same drugs. With significant drug price inflation since then, this gap is likely to be much larger today. Returning dual eligibles back to Medicaid-like discounts could save c.\$15-20bn annually.

How much is at stake? For the 28 Major Pharma and Biotech stocks included in our analysis, we estimate that US drug price increases contributed 100% of 2016 earnings growth. Arguably, this is the most important issue for any pharmaceutical investor today.

Figure 5: EPS impact of change in Dual Eligible funding and identified future price pressure

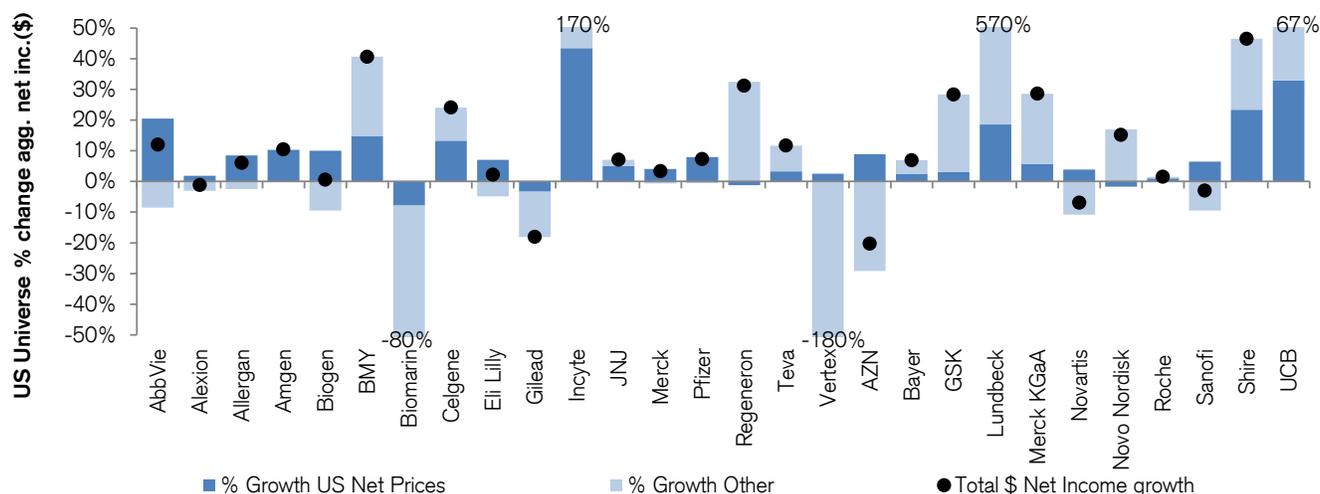


Source: Company data, Credit Suisse estimates, *Dual eligible data based on 2016 EPS, other based on 2020 CSe EPS

US Price rises contributed 100% of 2016 EPS growth

- **US List prices rose 9.8% in 2016**, broadly in line with an increase of 10.8% in 2015. Despite the negative rhetoric around list price rises in the US and commitments from the industry for change, prices still increased in 1Q2017 by >8%. Lundbeck and AbbVie had the highest list price rises in 2016; price increases at Sanofi and Novo were significantly lower in 2016 than in 2015.
- Rebates continue to rise and eat away at list price rises. **In 2016, rebates rose to 37.3% from 35.7% in 2015.** AZN had the highest rebates as a percentage of gross sales in 2016 of 61.8%, although absolute dollar rebates fell as US overall sales declined post Crestor patent expiry. The greatest rebate increases were seen by Merck and Lilly.
- After rebates, US net pricing remained a very healthy 6%. **We estimate US net prices positively affected net income by 6% in 2016, representing 100% of earnings growth.** US price rises were crucial in mitigating the impact of patent expiry losses in 2012 and 2013, but have since continued to be important drivers of growth. Our analysis suggests that US net price rises contributed at least 100% of the net income growth seen for Biogen, Eli Lilly, AbbVie, Allergan, Merck, Pfizer and Amgen.
- The aggregate of our forecasts for the 28 companies in our coverage universe for 2017 shows zero dollar net income growth, impacted partly by FX translation but with underlying local currency declines for AZN, Sanofi, Gilead and BMV and no growth for Amgen, GSK, and Merck. US pharma price rises will likely remain a driver of overall growth in 2017 and beyond.

Figure 6: Estimate of impact on 2016 net income of US price rises per company



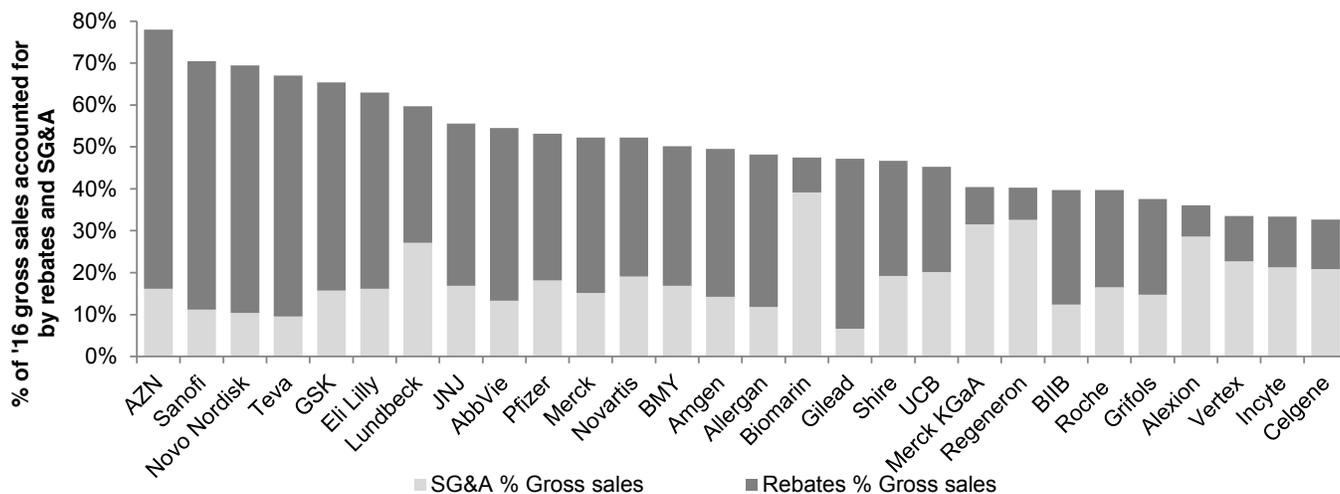
Source: Company data, Credit Suisse estimates

Overall promotional spend growing, as rising rebates offset SG&A declines

The overall promotional budget that a company has to influence doctors' prescribing and payors' formulary decisions encompasses both direct rebates and traditional SG&A. Importantly, whilst reported SG&A has fallen as a percentage of reported sales, the combination of SG&A and rebates continues to increase as a percentage of gross sales.

Companies with the highest overall promotional spend include AZN and Sanofi, despite low traditional SG&A. Companies with the lowest promotional spend are Incyte and Celgene.

Figure 7: Full promotion spend: SG&A & rebates as a % of US gross drug sales per company in 2016



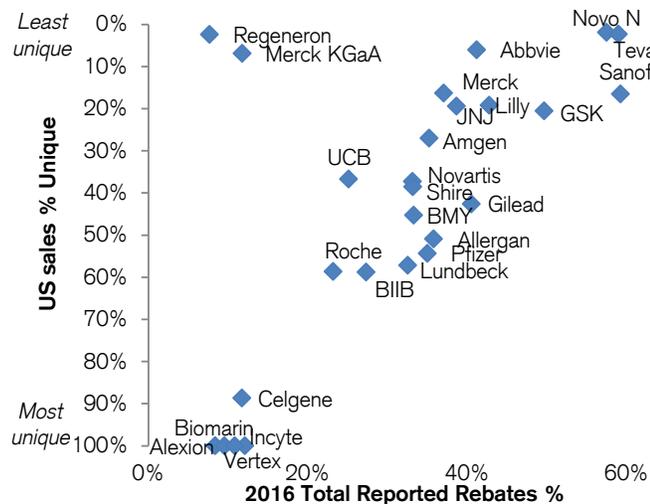
Source: Company data, Credit Suisse estimates

Portfolio uniqueness is the key protection against rebates

We find a strong correlation between the level of rebates reported and the uniqueness of a company's portfolio. Companies with more unique products typically report lower levels of rebates and we believe should be able to maintain higher long-term pricing, access to patients and, ultimately, profitability.

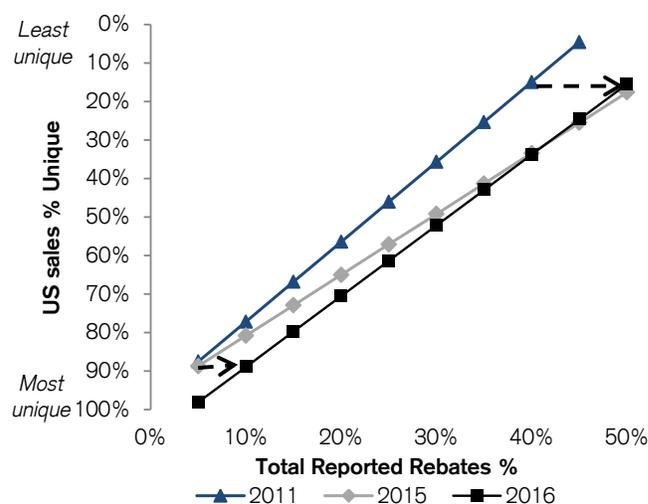
In 2016, we saw an increase in the level of rebates for more unique portfolios for the first time (Figure 9). For a US portfolio with 90% of sales from unique products, rebates increased from 5% to 10% between 2015 and 2016. The rebate levels in 2016 for the less unique portfolios remained broadly consistent with 2015.

Figure 8: Relationship between product uniqueness and rebates in 2016



Source: Company data, Credit Suisse estimates

Figure 9: Trends in relationship between product uniqueness and rebates 2011-2016



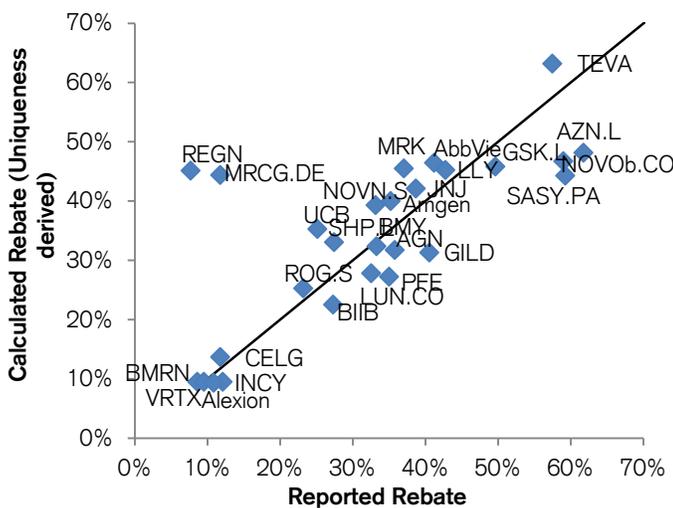
Source: Company data, Credit Suisse estimates

PharmaValues implied increase in rebates

Using our proprietary PharmaValues database, we explore how changes in portfolio uniqueness could suggest movements in rebate pressure through to 2020. Our theoretical rebates based on different levels of uniqueness correlate well with reported rebates (Figure 10). We forecast future rebates based on expected changes in portfolio uniqueness.

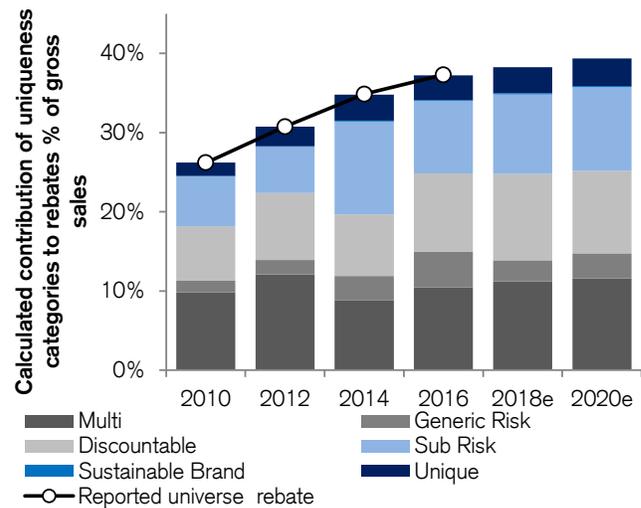
Overall, we expect rebates to grow to 40% of gross sales in 2020 from 37% in 2016. Our analysis suggests Major Pharma rebates increasing 4ppt, as uniqueness declines 5ppts while Specialty/Biotech rebates remain stable. This is despite an overall increase in the proportion that is unique from 41% in 2016 to 53% in 2020. Companies with the highest increase in expected rebate pressure are Pfizer and Roche. Companies with the biggest expected fall in rebates are AstraZeneca, GSK, Teva and Gilead (Figure 12 and Figure 13).

Figure 10: Correlation derived & reported rebates



Source: Company data, Credit Suisse estimates

Figure 11: Category contribution to universe rebate



Source: Company data, Credit Suisse estimates

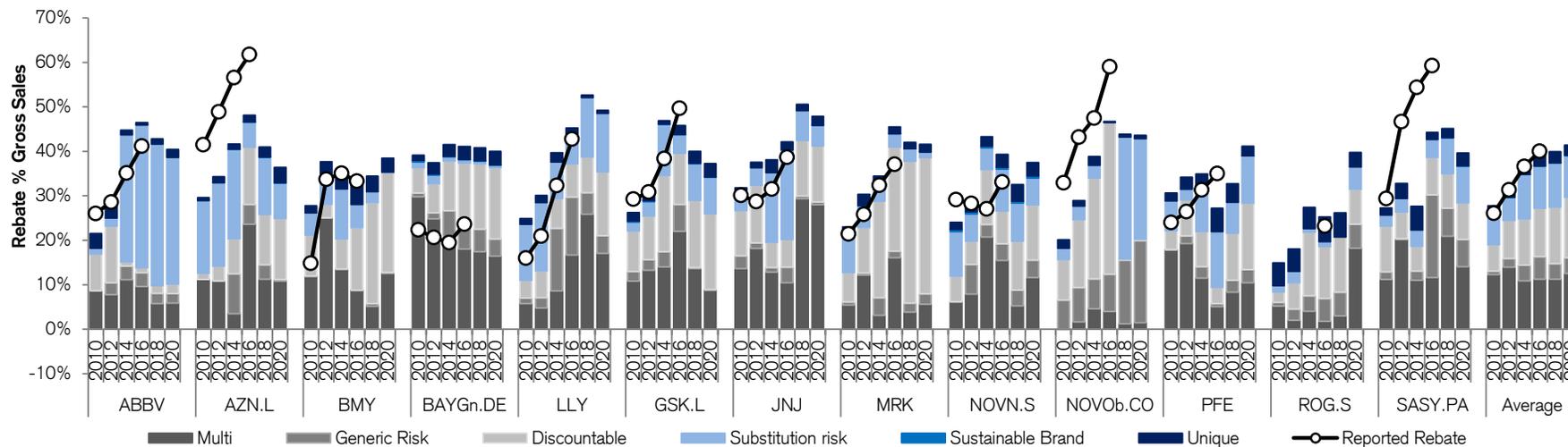
Which categories will see greater pressure from payors next?

In a new analysis for 2017, we look to identify categories of high cost burden and future growth to suggest where pressure may fall next. To identify categories at risk, we reviewed recent PBM Drug Trend reports and our PharmaValues database to isolate categories where strong growth is expected and there are broadly therapeutically equivalent offerings from multiple players. Using PharmaValues we are able to conduct a drug-by-drug analysis to identify which companies would be most affected and evaluate the related EPS impact from greater pricing pressure going forward. We separate this analysis into prescription and medical drug benefit owing to the different dynamics.

- **Prescription drugs future focus:** Here PBMs could use their purchasing power to secure substantial discounts for preferred drug access. We see potential pressures in HIV, anti-coagulants, inflammation, multiple sclerosis, migraine and psoriasis.
- **Medical drug benefit future risk:** Both specialty injectable and oncology products are areas of strong cost growth for plans. These outpatient infused drugs are a largely unmanaged cost today. Strong cost growth for payors could bring about reforms to Medicare Part B and see the medical benefit more aggressively managed in the future. We explore potential reforms and assess the impact on company earnings from greater pressure in haemophilia, ophthalmology, plasma fractions and oncology.

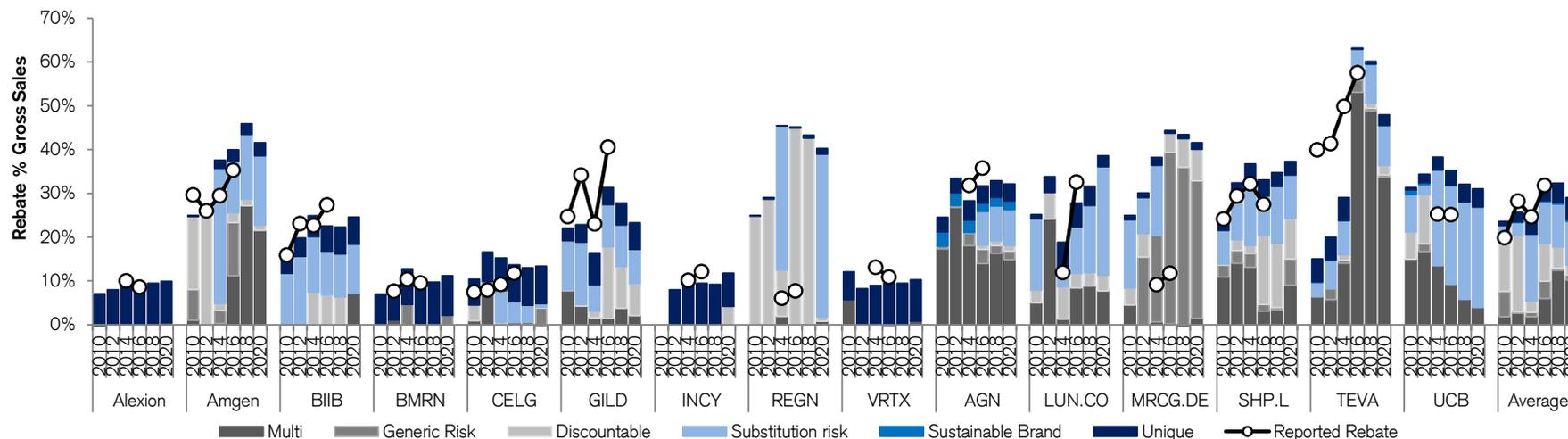
Companies with EPS most exposed to these combined drivers are BMY & AbbVie and in Europe, Roche and AstraZeneca.

Figure 12: Global Majors: Historical and derived predicted US rebates based on CS uniqueness



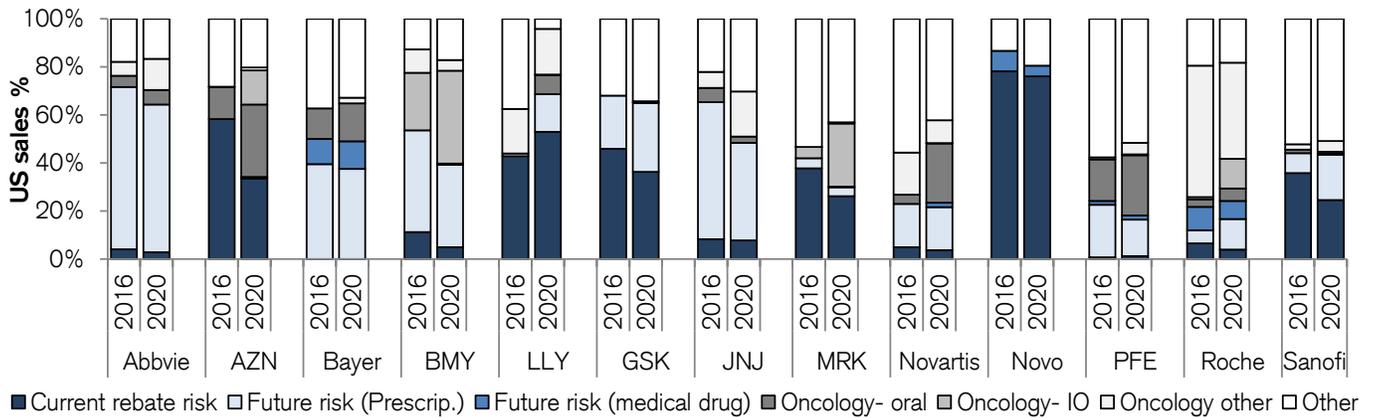
Source: Company data, Credit Suisse estimates

Figure 13: Biotech/Specialty Pharma: Historical and derived predicted US rebates based on CS uniqueness



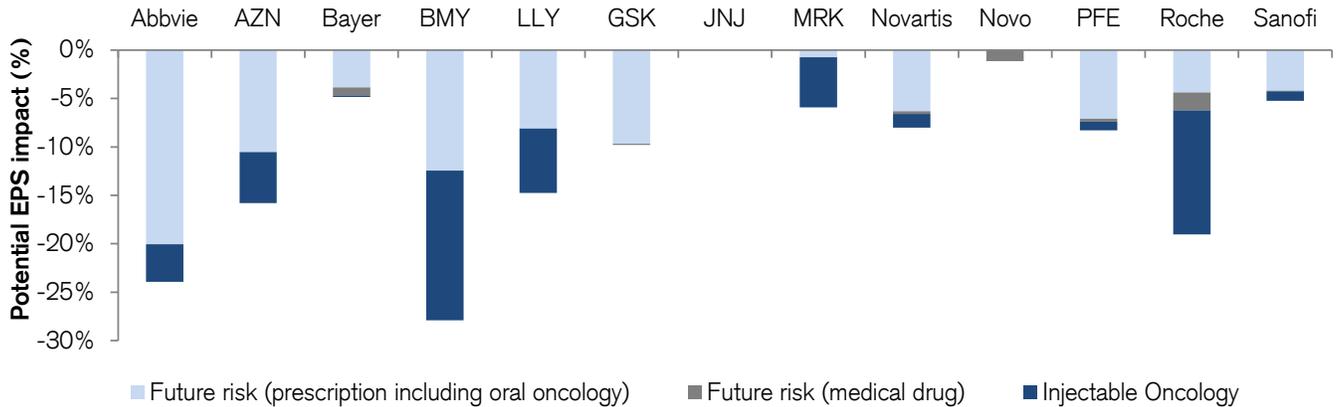
Source: Company data, Credit Suisse estimates

Figure 14: Majors: US 2016/20E Sales Exposure to Existing focus, Future focus and Oncology



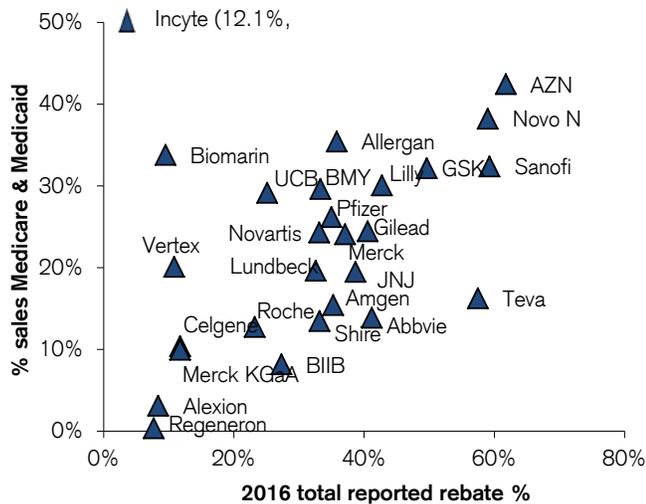
Source: Company data, Credit Suisse estimates

Figure 15: Majors: 2020 EPS impact of a 20% reduction in Future focus/Oncology sales



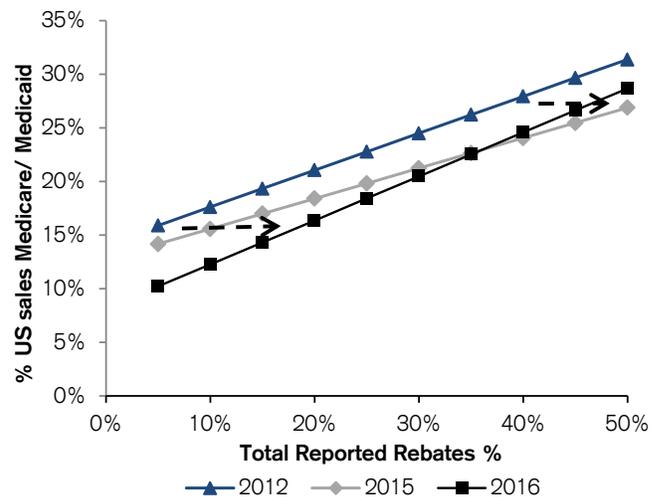
Source: Company data, Credit Suisse estimates, JNJ is excluded from this analysis

Figure 16: Exposure to Medicare Part D and Medicaid vs rebates in 2016



Source: Company data, Credit Suisse estimates

Figure 17: Exposure to Medicare and Medicaid vs rebates in 2016



Source: Company data, Credit Suisse estimates

Exposure to government-funded programmes increases rebate pressures

We find a positive correlation between companies' reported rebate levels and the level of company exposure to the US government programmes Medicaid and Medicare Part D in 2016 (Figure 16). Global Major Pharma has the most exposure to Medicare Part D currently and the Biotech names have the lowest exposure to Medicare Part D.

Among Major Pharma names, recent launches and pipeline assets at Novo Nordisk are the most exposed to Medicare Part D as they are primarily focused on diabetes. Roche, BMY and Merck are the least exposed, with growth mainly driven by new oncology products. In Specialty pharma, Shire has one of the lowest exposures to Part D as its main growth drivers rare orphan diseases and dry eye disease (commercial exposure); Lundbeck has a high exposure to Part D given its CNS portfolio.

Dual Eligibles: potential target of future pharma savings

Recent debates on strategies to reduce US healthcare spending have discussed the option of transitioning 'dual eligibles' (elderly and poor patients) back from Medicare Part D to Medicaid. Given this focus, in this year's report we provide a new assessment of the sensitivity of earnings for each company to this possible change in status based on categories historically important for dual eligibles (CNS, diabetes and respiratory).

Novo and **AZN** have the highest exposure to dual eligibles given their focus on diabetes (Novo) and diabetes/respiratory (AZN). If AZN's pipeline delivers, their exposure would decrease as the focus of the group changes. AZN's EPS exposure appears large due to the low level of current profitability. Lundbeck scores particularly poorly on this measure due to its high exposure to Medicare Part D (c30%) and the CNS franchise.

Figure 18: Major Pharma Exposure to high, medium and low risk therapeutic areas within US sales

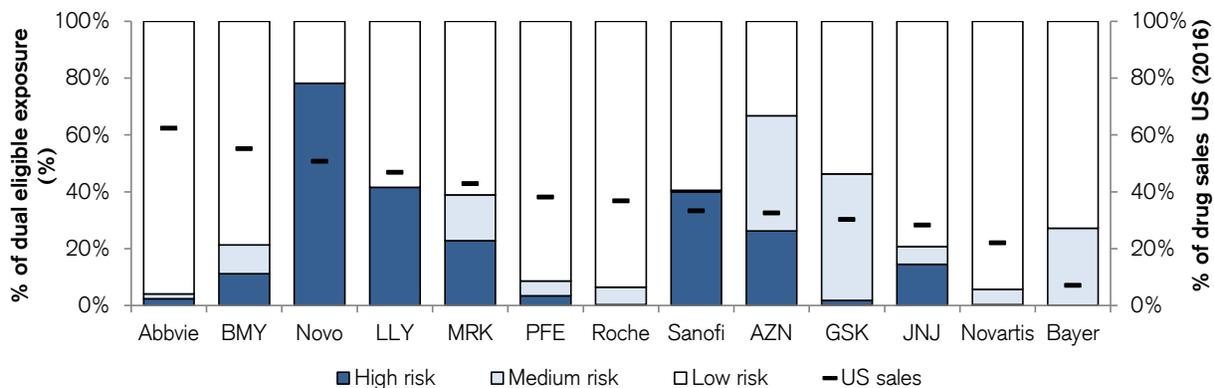
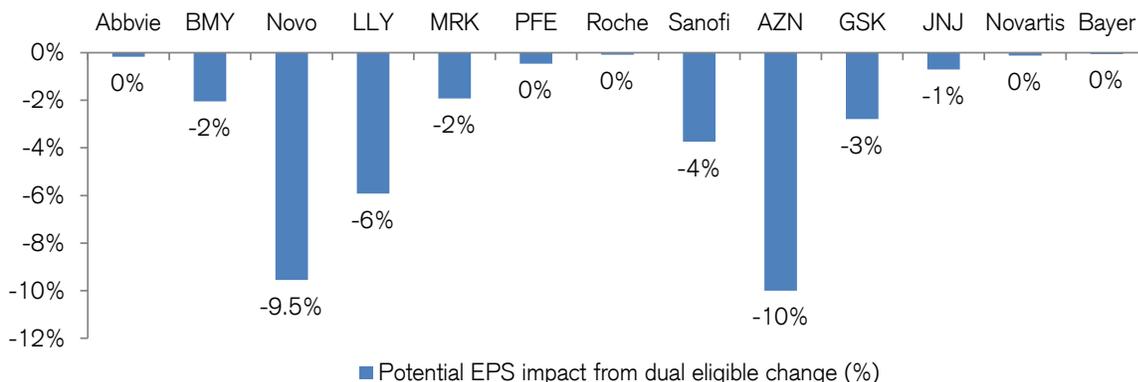


Figure 19: Major Pharma 2016 EPS sensitivity to change in dual eligible funding

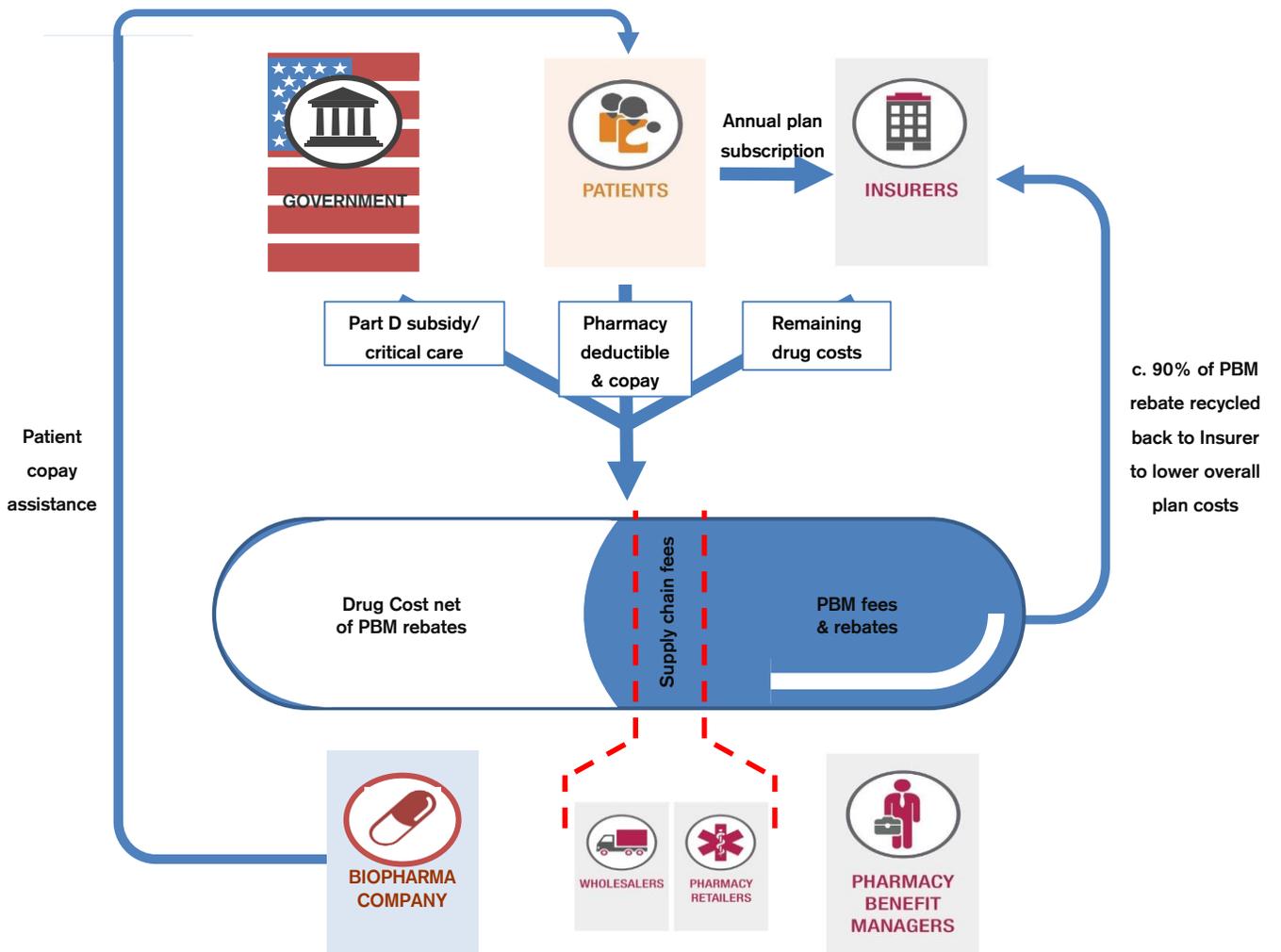


Source: Company data, Credit Suisse estimates

Understanding US Managed Care pathways

- US Rebates: How much and to whom?** An estimated \$179bn of rebates were paid from companies in our coverage universe in 2016; of these, 30% went to the government, 50% to market access, and 20% to the supply chain. Importantly, we believe that the majority of these rebates are recycled back into the system via payments to subsidise premiums. It is important to remember that this recycling already happens when looking for additional savings in the system. The purchasing of medicines in the US Healthcare system is complicated by the number of different payors involved – employers, government and insurers – and the lack of price transparency.

Figure 21: Illustration of the importance of rebate recycling



Source: Credit Suisse research

- Complex system can lead to perverse incentives.** Expensive drugs can be highly profitable for payors, rebates for older drugs can leave branded drugs much cheaper than generic alternatives, government subsidies may blunt traditional formulary restrictions and category domination is hard to break.
- Rebates are just one part of access control.** Whilst an important contributor to cost controls, we have continued to see a rise in other access controls, with data showing increased restrictions in formulary tiering with particularly strong acceleration in patient co-pays in specialty pharmacy.

- **Insights into medical benefits/Medicare Part B.** Around 50% of all specialty drug spend is billed via a medical benefit as opposed to a drug benefit programme. In both commercial and Medicare Part B plans, where the government provides funding for the elderly, there are fewer controls on this spending compared to drug benefit programmes. Prior authorisation is a key control that is utilised, and there appeared to be a notable increase in plans using 'product preferences' in 2016, which we see as nascent formulary pressure. There are still very significant differences in costs by site of delivery.
- **340B as an additional layer of hospital rebates.** In 2016, Roche disclosed the magnitude of its rebates in its annual report for the first time, with a 28% increase for 2016 over 2015. This largely relates to the US 340B and Medicaid programmes. Unlike more usual PBM rebates, it is important to note that this additional discount does not get companies any additional patient access. We see increasing numbers of institutions eligible for 340B discounts, and acquisitions of community-based practices by these entities, but trends now seem to be slowing.
- **Biosimilars potential to shake up Part B:** 2017 is expected to be a key year for biosimilars, with the number of approved products potentially tripling. Biosimilars will be an important cost saver for the US healthcare system if the mechanisms for their adoption are well implemented. We look at the uncertainties around the uptake of biosimilars including: payor reimbursement; interchangeability; CMS biosimilar payment policy and the ongoing litigation around the patent dance and 180-day stay post approval.

Industry impact from possible reforms

- **Impact on Pharma of Healthcare Reform:** We set out 13 proposals for Healthcare reform. We see Risk Sharing and Indication-Based Pricing as potentially the most beneficial to the Pharma industry and also reasonably likely to become more prevalent. Conversely, changes to the incentives in Part B, a movement towards Reference Pricing and allowing Medicare to directly negotiate drug prices would be the most detrimental, in our view.



EXHIBIT D

New Disclosures Show CVS and Express Scripts Can Survive in a World Without Rebates. Are Plan Sponsors Now the Real Barrier to Disruption? (8/24/2018)

TUESDAY, AUGUST 14, 2018

New Disclosures Show CVS and Express Scripts Can Survive in a World Without Rebates. Are Plan Sponsors Now the Real Barrier to Disruption?

Last week, the two largest pharmacy benefit managers (PBMs)—CVS Health and Express Scripts—both stated that rebates now account for a small part of their profits. The companies therefore strongly implied that they could survive in a world in which PBMs did not participate in the flow of funds from a brand-name manufacturer to a plan sponsor. Below, I unpack the new disclosures, which move us materially closer to a new model.



Hmm. The two biggest PBMs and [at least one major manufacturer \(Pfizer\)](#) have now implied a willingness to change. So what's to stop massive drug channel disruption?

CVS Health perhaps inadvertently identified the real barrier to a system without rebates: employers and health plans. As you will see below, CVS Health disclosed for the first time the massive gross-to-net bubble within its commercial book of business. The new information confirms that plan sponsors are hoarding rebates rather than sharing the savings with the employees whose prescriptions generated the rebate funds.

If we really do migrate to a system without rebates, PBMs' reportedly minimal profits from rebates mean they could escape drug channel disruption unscathed. The focus will now turn to the plan sponsors that are absorbing rebate dollars. Whether plan sponsors realize it or not, they are the next target.

THE GAME IS AFOOT

Here's a rundown of last week's unprecedented PBM disclosures.

In CVS Health's second-quarter financial reporting, it offered a spirited defense of the PBM model. The company also disclosed—for the first time—the value of commercial rebates that CVS Health's Caremark PBM business received along with the share of those rebates that the PBM retained.

CVS Health used [the following definition of "rebates"](#):

"Rebate calculation includes all rebates, including price protection, and administrative fees paid by manufacturers for commercial and MAPD clients. Excludes SilverScript."

Here's the big news: CVS Health estimates that for 2018, it will pass through 98% of rebates to plan sponsors and retain only \$300 million in commercial rebates. CVS Health disclosed that it therefore expects to negotiate \$15 billion in commercial rebates from pharmaceutical manufacturers—but will retain only 2% of those rebates.

Put another way, CVS Health has positioned its business for a system without rebates. Here's what CEO Larry Merlo said [on last week's earnings call](#):

"And while some have speculated that our retained rebates represent as much as \$2 billion, the simple fact is that over the last number of years, we have positioned the Caremark model and its broader value proposition to the point where in 2018, we expect retained rebates to be about \$300 million, or about 3% of our annual adjusted earnings per share."

Express Scripts also disclosed that rebates account for much less of its profit than many had believed. ([Click here to see the relevant slide from its SEC filing.](#)) Express Scripts said that it retains only \$400 million in rebates, which it defined to include "core PBM commercial and health plan clients but excludes value-based reimbursements and Express Scripts PDP." Express Scripts stated that it "passes 95% of all pharmaceutical purchase discounts, price reductions and rebates back to their core PBM commercial and health plan clients and their customers."

Sure, we could quibble about the fact that a mere two months ago, [CVS Health told the Department of Health and Human Services](#): "We return over 95% of rebates to commercial clients and their members." (CVS told me that the July 2018 figure was still an estimate for 2017. Um, OK.)

Or that Express Scripts' 95% figure of August 2018 seems different from May 2018, when [Express Scripts stated](#) that it "returns on average 90% of rebates we negotiate with drug manufacturers directly to our clients."

But as I see it, it's less important to know that the PBMs have accurately reported all of the rebates, fees, and other monies. Despite any financial fuzziness, both companies sent the same message: we'll be OK not handling rebate dollars. They were clearly trying to calm investors nervous about policy changes that could disrupt the drug channel.

As I see it, both PBMs are suggesting that they could thrive in [A System Without Rebates: The Drug Channels Negotiated Discounts Model](#).

THE CURIOUS INCIDENT OF THE REBATE THAT WAS NOT RETAINED

Along with its financial results, CVS Health issued the following white paper: [Current and New Approaches to Making Drugs More Affordable](#). It's a dense and complex marketing document that crams a lot into its 11 pages.

The paper provides unprecedented insight into previously unknown data about rebates and drug spending by CVS Health's plan sponsor clients. Here's my summary of the data that appear on page 6:

[\[Click to Enlarge\]](#)



Drug Channels is written by Adam J. Fein, Ph.D. Dr. Fein is CEO of Drug Channels Institute, a subsidiary of Pembroke Consulting, Inc. [Read More...](#)

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- Drug rebates aren't evil, but they should be changed to benefit consumers *St. Louis Post-Dispatch*
- Generic Drugmakers Struggle Despite U.S. Push for Copycats *Bloomberg*
- Meet the Rebate, the New Villain of High Drug Prices *The New York Times*
- Merck to Lower Prices on Some Drugs, but Not its Blockbusters *The New York Times*

Brand-Name Spending and Rebates Per Commercial Life, CVS Health Clients, 2011 vs. 2017

Item	2011	2017	Total change	% change	Compound Annual Growth Rate (CAGR)
Plan sponsor economics					
(A) • Gross spending on brand-name drugs, per commercial life	\$608.90	\$831.30	+\$222.40	+37%	+5% / year
(B) • Rebate per commercial life	\$78.00	\$254.40	+\$176.40	+226%	+22% / year
(A) - (B) • Net spending on brand-name drugs, per commercial life	\$530.90	\$576.90	+\$46.00	+9%	+1% / year
(B) / (A) • Rebate as percentage of gross spending	13%	31%	+1779 bps	+139%	+16% / year
CVS Health economics					
(C) • Rebates retained per commercial life	\$21.00	\$15.00	-\$6.00	-29%	-5% / year
(C) / (B) • Share of rebates retained	27%	6%	-2103 bps	-78%	-22% / year

Fig = Basic Prices Only
Source: Drug Channels Institute analysis of Current and New Approaches to Making Drugs More Affordable, CVS Health, August 2018. Rebate calculation includes all rebates, including price protection, and administrative fees paid by manufacturers for commercial and MPO clients. Excludes SilverScript.
Published in Drug Channels (www.DrugChannels.com) on August 14, 2018.

Observations:

- Gross spending on brand-name drugs grew by \$222 per person (+37%), from \$608.90 in 2011 to \$831.30 in 2017. But when we account for rebates, spending grew by only \$46 per person (+9%). That's an average growth rate of just 1% per year from 2011 to 2017.
- Rebates grew from 13% of gross spending in 2011 to 31% in 2017.
- Given the growth in gross spending, average rebate dollars per commercial life more than tripled, from \$78 in 2011 to \$254 in 2017. That's an average growth rate of 22% per year. The value of rebates in 2017 amounted to 44% of net drug spending.
- The share of rebates retained by CVS Health dropped sharply, from 27% in 2011 to 6% in 2017. As we note above, the rate is projected to be 2% in 2018. The rebate dollars that CVS retained per commercial life fluctuated within a fairly narrow band: \$15 to \$26 throughout this period.

BUBBLE BUDDY, I PRESUME

Ladies and gentlemen, you are looking at a classic **gross-to-net bubble**—an ever-growing pile of money between a manufacturer's list price for a drug and the net price after rebates.

In the CVS Health data, list prices—reflected by the gross spending figures—rose sharply. But the net prices after rebates—and, by extension, manufacturers' revenues—increased by just 1% per year.

This is precisely the reverse insurance problem at the core of our current rebate system:

Beneficiaries taking medicines for chronic illnesses in such highly competitive therapeutic categories as asthma and diabetes generate the majority of manufacturer rebate payments.

These funds are used primarily to offset total plan costs for the employer and plan, not to offset the costs incurred by the patients whose prescription activity generates those rebates.

Beneficiaries with prescription drug deductibles and coinsurance face higher out-of-pocket costs. That's because their coinsurance amounts and payments within the deductible phase are based on a drug's undiscounted, pre-rebate list price.

CVS Health's plan sponsor clients captured the additional rebate dollars and redirected those funds to offsetting plan costs or premiums. I highlighted this trend in **Employers Are Getting More Rebates Than Ever—But Sharing Little With Their Employees.**

In practice, rebate funds are paid long after the prescription has been dispensed, so that a big rebate check can not necessarily be attributed to the prescriptions that generated the funds. Using the data above, a plan with \$100 million in brand-name prescription spending would get a rebate check for \$31 million.

On last week's earnings call, CVS Health CEO Merlo defended this practice:

"Our clients, employers and insurers use rebates to lower the costs of providing insurance for their employees and members. And typically this means investing in insurance premiums to keep growth for all members to a minimum."

That's cold comfort for patients who need drugs for asthma, diabetes, and other chronic diseases, but have benefit designs with deductibles, coinsurance, and copay accumulators.

ELEMENTARY, MY DEAR PATRICK

Point-of-sale rebates are one possible solution to this problem. To his credit, Merlo did say that CVS Health tells plans that "at a minimum let's apply some of those rebates at the point of sale, while people are in their deductible phase."

Alas, plans very rarely use these benefit designs. In **UnitedHealthcare's Point-of-Sale Rebate Announcement: What's Next?**, I asked the following questions about rebates:

- Is it fair for an insurance company to get a rebate on a drug for which the patient paid full retail price?
- Where have the rebates been going before now?
- How much of the manufacturers' rebates is being shared with patients?
- How much is retained by PBMs and plan sponsors?
- Why don't more plans pass through drug discounts?

Thanks to CVS Health, we now have answers to questions 2 and 5: Nearly all of the rebate dollars flow to plan sponsors, not to the PBM. Now that the PBMs have come clean, it's time for employers and health plans to be much more transparent about what they do with the tens of billions collected from manufacturers. Otherwise, **as I suggested in March**, they should pass through these rebates to patients at the point of sale.

As **SpongeLock Holmes** always says: When you have eliminated the impossible, whatever remains, however improbable, must be the truth.

*P.S. For those who don't know, one of **SpongeBob SquarePants'** favorite pastimes is "blowing soap bubbles into elaborate shapes." Hence, Mr. SquarePants is the honorary mascot of the*



SpongeBob SquarePants, honorary mascot of the gross-to-net bubble

Pfizer's not the only drug company raising prices *CNN Money*

He can shame Pfizer and others, but Trump doesn't have a practical way to lower drug prices *Pharmalot/STAT*

Amazon's pharmacy strategy will take years to play out *St. Louis Post-Dispatch*

Amazon's Pharmacy Deal Threatens Retail Drugstores *The Wall Street Journal*

Five Questions About Amazon's Play for the \$300 Billion Pharmacy Market *Bloomberg*

Amazon acquires PillPack as it muscled its way into the health care industry *Marketplace*

Amazon to Buy PillPack, Jumping Into the Drug Business *The New York Times*

Amazon's attack on the pharmacy industry has begun *The Washington Post*

Amazon shakes up drugstore business with deal to buy online pharmacy PillPack *CNBC*

In May, Trump predicted the pharmaceutical industry would cut prices in two weeks. It hasn't happened yet. *The Washington Post*

Trump's health chief intensifies attack on drug middlemen, suggests getting rid of rebates *CNBC*

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- 2008 (94)
- 2007 (115)
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EMVO Admits, 'Insufficient Randomisation' Warnings Can Be Ignored

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LOG IN WITH OR SIGN UP WITH DISQUS Name

Keith Bruhnson • 7 days ago
You need an education on how plan sponsors fund health insurance and the cost sharing approaches used with their beneficiaries. You make several inflammatory statements about plan sponsors that are misleading. Their not vilans and there is no free lunch in health insurance. Its more likely eliminating rebates will drive up sponsors and beneficiaries premium cost and force more plan design changes while drug cost continue to rise annually.

Anonymous Anonymous • 7 days ago
Poor PBM's. So the plan sponsors (employers) across the country are responsible for most of the drug price increases due to rebates, not the PBM's? Yet the PBM's offer the rebate model as the 'standard' to plan sponsors them absolve themselves for associated price increases. Do you think most plan sponsors have any idea regarding the flow of money through the "Drug Channels" and the effect of rebates on drug prices? I suppose the plan sponsors are also responsible for DIR clawbacks and spread pricing??
[https://www.pharmacist.com/...](https://www.pharmacist.com/)
<http://www.pbmwatch.com/pbm...>

A Fan • 7 days ago
Another bold post, Dr. Fein. I think you will upset everyone with this posting. I don't believe the PBM numbers because they certainly make more and can play with the definitions. Your main point is very interesting. I like the data table but expect you will get a lot of negative feedback from insurers and plans.

Anonymous Anonymous → **A Fan** • 7 days ago
Agreed. Dr. Fein, I enjoy reading your articles and appreciate your expert insight (even though I don't always agree with your conclusions) but to categorically assign blame to plan sponsors and paint PBM's as innocent bystanders smacks of inflammatory journalism.

Adam J. Fein Mod → **Anonymous Anonymous** • 7 days ago
I am not saying that PBMs are "innocent bystanders." I am pointing out, however, that PBMs are trying to shift blame to plan sponsors. Whether they have been, will be, or should be successful is a different issue.

Anonymous • 7 days ago
Good piece on rebates today. Some observations:
- Not sure it's fair to say PBMs have finally come clean. Since the latter part of the 90s, contracts with clients were clear about where rebates went. I'm not so sure PBMs are obligated to come clean to parties not involved in the business arrangements except for publicly funded plans, but then the public is involved in a way

- Pharmaceutical Commerce**
Pelican BioThermal expands its container-on-demand service in Germany
- PCMA**
Visante: Reconsidering Drug Prices, Rebates, and PBMs
- Biosimilars Review & Report**
Part B to Part D and Other Questions: How CMS's Plans Could Affect Biosimilars
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Off your walker? Foray's founder Dr. Kavanagh takes a new approach to an old need (podcast)
- Pharmaceutical Executive**
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Trump Phones, And Pfizer Reverses Price Hikes. But Why?
- Bloomberg Gadfly**
Wayfair Needs to Prove This Isn't as Good as It Gets
- Drug Wonks**
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Health Affairs Web First: Choosing Wisely Campaign
- The Dose (NCPA)**
University of Pacific Team Discusses Its Path to the Business Plan Competition Finals
- Inside HSCA**
MedTech Conference Day 2 - Introducing Value Into the Supply Chain

is involved in a way.

- I've been out of the business for awhile now, but when at Medco for a long time, I saw many clients get quarterly rebates in advance of prescriptions based on estimates of future use, so not all clients have to wait a long time for rebates.

- The case for passing rebates to plan members is not as clear as it's made out to be in the mainstream media or industry press for that matter (AWP as basis for coshare amounts notwithstanding). The plan member group at large has a claim to them as well. It's a question of distributive justice made particularly difficult by the absence of distributive justice theory or principles that could be applied. Fair processes are thus needed. If you care to delve into the ethics of this issue,

^ | v · Reply · Share ›



Mel Brodsky · 7 days ago

If anyone really believes that the PBMs have come clean and their accounting is accurate - I have a bridge to sell you!!!!

PBMs are to blame
Plan sponsors are to blame
Manufacturer's are to blame
The whole system is flawed

^ | v · Reply · Share ›



Adam J. Fein Mod · 7 days ago

👏 Featured by Drug Channels

As usual, there is also a lively conversation happening on LinkedIn.

Check out those comments here: <https://drugch.nl/2BaaloU>

^ | v · Reply · Share ›



John R Borzilleri · 7 days ago

Mr. Fein...come on...how about starting with the elephant in the room? After all these years, we now find out that PBMs don't make any money off rebates. Really? So how do PBMs really make almost all their money? For instance, ESRX's annual profits have tripled to \$4.5 billion since 2013, while revenues have declined....and they are barely keeping any rebates? As they say, just follow the money...

Simple truth, PBMs now make most of their massive profits from SERVICE FEES from drug manufacturers, tied to massive brand drug "list" prices and drug price increases; % of revenue fee contracts tied to massive brand "list" drug prices...unlike rebates, PBMs don't share these fees, keep all for themselves....and of course, they are not telling their plan sponsors any of this...PBMs are now trying to blame their own clients, plan sponsors, because they are losing the PR/political battle against far more powerful pharma, their true partners...smells of desperation...

I recently served the Pharma/PBM defendants with two whistleblower cases about these "fees", regarding PART D, where it all began more than a decade ago..all public now...lots of details....you can look them up on Google..Borzilleri v. AbbVie and Borzilleri v. Bayer...or you can email me at borzillerij@gmail.com and I will send you info..please share..

Time to get to finally get to the truth in this murky drug pricing/PBM world...patients, taxpayers, plan sponsors, employers, independent pharmacists, etc. are being severely harmed.

1 ^ | v · Reply · Share ›



dankelly429 · 7 days ago

Both clearly excluded Part D business as their is no employer or plan sponsor to give a rebate to. Do we have any insights to if they are keeping 100% of those rebates and if so, how much that total adds up to be?

^ | v · Reply · Share ›



Murray · 7 days ago

Does the 2% and 5% for CVS and Express scripts include administrative fees? If not, what is the total including administrative fees?

What will be the increase in insurance premiums if rebates are passed through to patients in their entirety?

^ | v · Reply · Share ›



Murray Kay · 7 days ago

Does the 2% and 5% retained by CVS and Express Scripts, respectively, include the administrative fees? If not, what is the total retained including administrative fees?

^ | v · Reply · Share ›



drugdatahacker → Murray Kay · 5 days ago

Yeah—Adam, can you lift the veil on the trends around the growth in % of total manufacturer revenue attributable to service and admin fees over time. I would guess it's insightful. There's a bit of sleight of

hand going on with pure "rebate" (the defined term).

^ | v · Reply · Share ›



Scott · 6 days ago

You must be kidding.

To assume what PBMs call rebates is the sole source of income from manufacturers is extremely naïve or deceptive. To publish this as a factual documentation of finance in the PBM marketplace is a disservice to an already confounding environment. The reliance on rebates not only is essential for PBM profitability (triage the 10-Ks) it also compromises the effectiveness of essential clinical/fiscal management tools such as effective formularies and evidence-based PA.

The method to create competitiveness and secure PBMs that have the plan sponsor and member's interest is to establish objective metrics (eliminate AWP-discount generic pricing) and establish measurable silos for each class of money a plan sponsor pays or is paid. That is the best hope and has been proven effective. Objectiveness leads to competitiveness leads to best deal for the plan sponsor/member."

^ | v · Reply · Share ›



John Leppard IV · 5 days ago

Adam: Do you think CVS and ESRX are being completely fulsome in how they define rebates, as opposed to a broader view of DIR more generally? In other words, do you think these disclosures really paint a full picture of their revenues, particularly within government programs, and that it might be different if they defined "rebate" differently?

The reason I ask is a few observations:

- (1) CVS defined the \$300 million they retain as "all rebates, including price protection, and administrative fees paid by manufacturers for commercial and Medicare Advantage" clients. It specifically excludes Medicare Part D and makes no mention of Medicaid contracts.
- (2) Both CVS and ESRX make a big deal of the fact that they pass through 90%+ to "plans," but in Medicare Part D, they are often the plan sponsor, so they might be passing the rebate through, but it could be to themselves.
- (3) MedPAC has previously called this characterization into question, saying: "The amount of [DIR] plan sponsors receive consistently has exceeded the

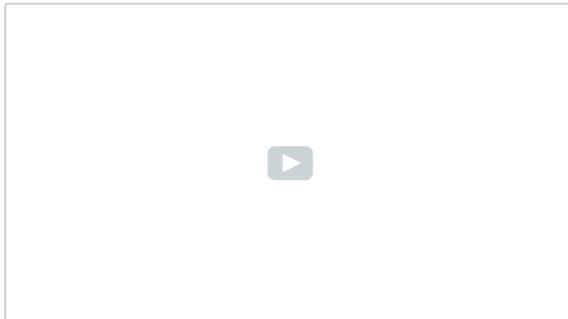
[see more](#)

^ | v · Reply · Share ›



Jeff Liberman · 4 days ago

Why doesn't anyone see where the problem is ? All these problems with the high cost of medication is ALL because of the PBM's !!!!! Watch this Utube video it's in simple english that anyone can understand .



^ | v · Reply · Share ›



Barry Carol · 4 days ago

Even if PBM's retain no drug company rebates at all, they still have three other ways to make money. They are: (1) administrative fees paid by self-funded employers or insurance companies, (2) the spread between the amount billed to the client for drugs prescribed to their members and the amount paid to pharmacies and (3) profits from filling generic prescriptions through the PBM's mail order pharmacy.

^ | v · Reply · Share ›

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EXHIBIT E

Joint Interim Task Force On the Fair Pricing of Prescription Drugs – OR4AD Calls for Resignation of AARP–UnitedHealth Lobbyist from Role as Task Force ‘Consumer Representative’ (7/18/2018)



**OREGONIANS FOR
AFFORDABLE DRUG
PRICES NOW!**

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P/F (541) 257-8878
URL www.or4ad.org
Twitter @or4ad

July 18, 2018

Gov. Kate Brown
Office of the Governor
900 Court Street NE, Suite 254
Salem, OR 97301-4047

**Re: Joint Interim Task Force On the Fair Pricing of Prescription Drugs –
OR4AD Calls for Resignation of AARP–UnitedHealth Lobbyist from Role as
Task Force ‘Consumer Representative’**

Dear Gov. Brown:

I write to you as a director of Oregonians for Affordable Drug Prices Now. I am also a named plaintiff in *Boss v. CVS Health Corporation*¹ and two other putative class actions on pharmaceutical pricing that name UnitedHealth Group (“United”) as a defendant. United sells AARP co-branded Medicare plans in the State of Oregon with benefit designs that these lawsuits, pending in federal district court in New Jersey, allege increase the prices patients pay for prescription drugs (as insurers capture manufacturer rebates) and directly cause list prices of heavily rebated pharmaceuticals like analog insulin to skyrocket—increasing in apparent parallel with United’s profit distributions to its shareholders.

An AARP lobbyist cannot act as “consumer representative” on a Task Force investigating the prices paid by Oregonians, including Oregonians on AARP–United Medicare plans, for pharmaceuticals. We now hope that Jon Bartholomew will have the decency to recuse himself and that you will finally appoint to this Task Force an actual consumer representative.

Following the resignation of OSPIRG’s Jesse O’Brien, you appointed AARP lobbyist Jon Bartholomew to serve as the “consumer representative” on the Joint Interim Task Force On the Fair Pricing of Prescription Drugs created by HB 4005. Mr. Bartholomew, also formerly with OSPIRG, and Mr. O’Brien, in close coordination with Strategies 360’s Patty Wentz² and others, drove that bill through the legislature partly via a scare campaign about a manufacturer-funded “fake patient advocacy” organization that claimed to speak for patients. If drug manufacturers cannot speak in patients’ voice, then by the same token, neither can insurers and their business associates like AARP.

¹ *Boss, et al. v. CVS Health Corporation et al.*, Case No. 3:17-cv-01823-BRM-LHG filed in the United States District Court of the District of New Jersey. This case has now been consolidated under *In re Insulin Pricing Litigation*, Case No. 3:17-cv-00699-BRM-LHG.

² An unregistered lobbyist and a vice president with PR firm Strategies 360, Ms. Wentz apparently controls the website (www.affordablerx.org), Twitter account and Facebook page that were used to entice Oregonians to “call their legislators to #voteyesonHB4005” using a Phone2Action account (now disabled). This operation, conducted under the cover of an incorporated nonprofit that failed to register with the Oregon Department of Justice’s Charitable Activities Section and to file annual reports with the Corporation Division, should be investigated for breach of nonprofit, corporation, lobbying and possibly political campaign laws—disclosure and compliance breaches of which, as AARP’s chief lobbyist and point man for HB 4005, Mr. Bartholomew was or should have been aware.



As the new Oregonians for Affordable Drug Prices Now, we have reclaimed a patient and consumer voice previously appropriated by payers' own astroturfing operation—an operation apparently intended to persuade patients that a genuine consumer nonprofit existed to advocate on their behalf. Oregonians for Affordable Drug Prices Now is committed to bringing a genuine patient and consumer voice to Oregon's conversation on drug pricing in general and to this Joint Interim Task Force On the Fair Pricing of Prescription Drugs.

As Governor, you have the power under HB 4005 to appoint Task Force members; it is now your responsibility to allow Oregonians to reclaim their place and their voice in this process.

If Mr. Bartholomew were to remain on this Task Force, he would serve as an additional representative of “Insurance companies offering health insurance in this state,”³ along with Moda Health’s Robert Judge and BlueCross Blue Shield’s Abigail Stoddard.⁴ Your administration would thus remain in breach of its duty to name to the Task Force individual(s) representing consumers per HB 4005’s Section 11(2)(D)(v).

The consumer representative on this Task Force can't have a duty of loyalty to an insurance company. This Task Force is concerned with the “prices paid by Oregonians for pharmaceutical products.”⁵ These prices include the prices health insurers ask health plan members to pay in the form of premiums, copays, and coinsurance payments. In 2017, payers' benefit design⁶ controlled the prices paid for prescription drugs by 93.8% of Oregonians under ACA, Medicare, and other plans.⁷ The pharmaceutical prices paid by the other 6.2% of Oregonians who are uninsured are also controlled by an insurance company—Moda Health, OPDP's third party administrator. The Oregon Prescription Drug Program (OPDP), a public program, was supposed to give under- and uninsured Oregonians access to the low net prices paid by commercial insurers. As recently acknowledged by the co-chair of this Task Force, Dr. Hargunani, OPDP, under Moda Health's management, has failed to deliver the benefit of manufacturer rebates to its individual discount card holders. Again, point-of-sale pricing to OPDP individual discount card holders is jointly controlled by a private insurer.

As the chief lobbyist for AARP in Oregon, Jon Bartholomew is bound to advance the interests of AARP/United's Medicare-related insurance business against legal liabilities, regulatory oversight and public scrutiny. United is a named defendant in multiple putative class action lawsuits brought by the Type 1 Diabetes Defense Foundation (pending in New Jersey federal court) relating to payer benefit design that bases patient payment and premium rates actuarial assessment on unrebated pharmacy claims expenses or list prices. Mr. Bartholomew's duty of loyalty to the AARP-United Medicare joint venture—which is now adverse to consumers in pending litigation—

³ HB 4005, Section 11(2)(D)(ii).

⁴ Ms. Stoddard joins the Task Force as an employee of PBM Prime Therapeutics. Prime Therapeutics is fully owned by 20 Blue Cross Blue Shield “owner-client” organizations—including Regence, which operates BSBC plans in Oregon and Blue Shield plans in Washington. Prime does not represent independent pharmacy benefit managers. To avoid over-representation of insurance companies on the Task Force, PBM representation would more appropriately have been entrusted to a representative of an independent PBM such as Express Scripts, MedImpact, Navitus Health Solutions or Ventegra, Inc. (a California Benefit Corporation).

⁵ HB 4005, Section 11(10).

⁶ Insurer benefit designs that base patient payments on inflated list prices for drugs on which payers obtain very large rebates are directly responsible for the high prices currently paid by many Oregonians. Oregon insurance commissioner and co-chair of this Task Force Andrew Stolfi has oversight responsibility over these issues.

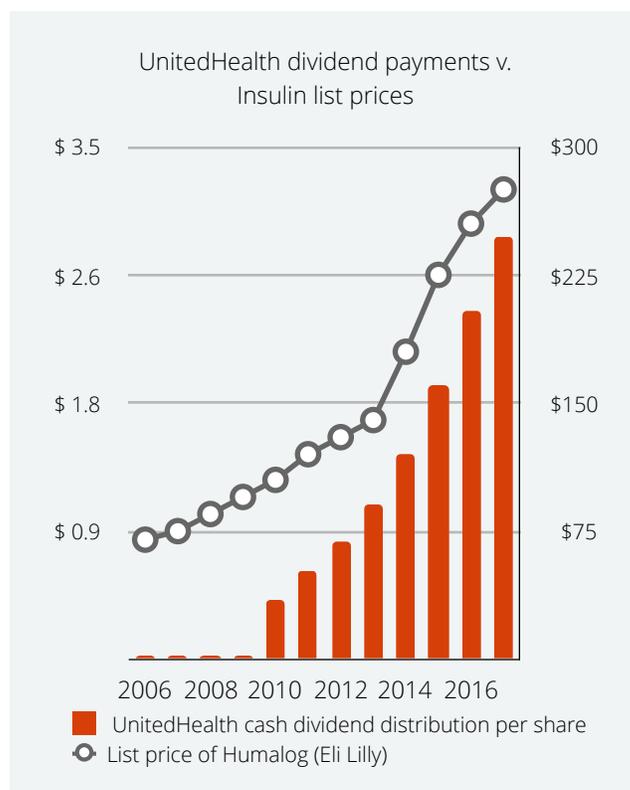
⁷ 2017 Oregon Health Insurance Survey, V7 (6/8/2018).

precludes him from serving as a “consumer representative” in any government body that is dedicated to investigating drug pricing and hence the role of payer benefit design in inflating point-of-sale prices and encouraging list price inflation.⁸

Mr. Bartholomew’s conflict is intrinsic to his position with AARP and thus his duty of loyalty to a health insurance joint venture. Health insurers (including AARP/ASI business partner United) appear to have capitalized on high list prices via benefit design and thus increased insurer profits at patients’ expense. Any serious investigation of factors influencing drug prices paid by Oregonians would be adverse to the business interests of Mr. Bartholomew’s employer.

Health insurance companies have, in recent years, become increasingly profitable. Profits have risen on a trajectory that tracks closely with—not against—rising list prices for prescription drugs like Eli Lilly’s Humalog analog insulin (see graph):

- **Cigna** had an exceptionally strong 2017 performance, with total revenues for 2017 of \$41.6 billion, an increase of 5% over 2016 supported by strong margins in its commercial healthcare business.⁹
- **Aetna**’s adjusted earnings increased by 13%, supported by “moderate medical cost trend” that resulted in better than projected total company results.¹⁰ Aetna made \$1.21 billion and beat Wall Street earnings expectations in 2018 first quarter, as the health insurer moved closer to sealing its roughly \$69 billion combination with CVS Health.¹¹
- **Anthem**’s profit soared by 234% to \$1.2 billion in its 2017 fourth quarter, compared to \$368 million for the same period in the prior year. Full-year 2017 financial results were also strong. Anthem reported a 55% increase in net profits year-over-year of \$3.84 billion, compared to \$2.47 billion in 2016.¹²
- **UnitedHealth Group**’s full year 2017 revenues of \$201.2 billion grew 8.8% or \$16.3 billion year-over-year—driven by fourth-quarter profit that more than doubled over 2016. United’s adjusted net earnings grew 25.1%. In 2017, Optum Rx, United’s PBM, saw its revenues grow by \$7.6



⁸ See, e.g., Lawrence W. Abrams, “Pharmacy Benefit Managers As Conflicted Countervailing Powers,” blog post December 24, 2007. Available at: <http://www.nu-retail.com/PBM-Countervailing-Power.pdf>

⁹ <https://www.cigna.com/newsroom/news-releases/2018/cigna-delivers-strong-2017-results-expects-continued-revenue-and-earnings-growth-in-2018>

¹⁰ <https://news.aetna.com/news-releases/aetna-reports-fourth-quarter-and-full-year-2017-results/>

¹¹ <https://wtop.com/business-finance/2018/05/aetna-swings-to-a-first-quarter-profit/>

¹² <https://www.healthcarefinancenews.com/news/anthem-profits-skyrocket-234>

billion or 9.1% to \$91.2 billion.¹³ If 2017 was a good earnings year for United, 2018 second quarter results are expected to be even more profitable.¹⁴

There is increasing evidence that private insurers, other third-party payers, and their regulators have played a contributory role in the unfair pricing of prescription drugs to Oregonian consumers. While the scope of insurers' contributory role to the current crisis is still being debated, there is no longer any doubt that insurers are not victims similarly situated with individual consumers. In fact, health insurers seem to derive increasingly larger profit as brand drugs' list prices—and rebates paid by manufacturers to insurers—skyrocket.

As a whole, the health insurance industry posted improved earnings for 2016, with net income rising by 46% to \$13.1 billion compared with \$9.0 billion in 2015.¹⁵ 2017 proved even more lucrative for health insurance companies,¹⁶ and 2018 has seen health insurers reporting even stronger financial results—attributed in part to improving profits from individual HDHP products offered under the Affordable Care Act.¹⁷ ACA policies, as a group, have high deductibles and employ benefit designs that calculate many health plan members' payments for prescription drugs on the basis of unrebated list price (not the payers' much lower net cost). Insurers have thus found a way to profit from high drug list prices.¹⁸

Individual consumers, on the one hand, and commercial payers with their government regulators, on the other hand, have adverse interests and must therefore receive separate representation on a Task Force responsible for “expos[ing] the cost factors that negatively impact prices paid by Oregonians for pharmaceutical products” as required under HB 4005's Section 11(10).

Consideration of benefit design aside, AARP's/ASI's control over and revenue from co-branded United insurance products means any AARP lobbyist would serve on this Task Force as an additional representative of “Insurance companies offering health insurance in this state,” rather than as a representative of consumers.

¹³ <https://finance.yahoo.com/news/unitedhealth-group-reports-2017-results-105500521.html>

¹⁴ “Earnings from Operations Increased 13% to \$4.2 Billion in Second Quarter and Second Quarter Adjusted Net Earnings of \$3.14 Per Share Grew 28% Year-Over-Year.” <https://research.tdameritrade.com/grid/public/research/stocks/news/article?dockey=100-198b1957-1>. See also “UnitedHealth tops earnings estimates, raises forecast”: https://www.compuserve.com/pf/story/0002/20180717/KBN1K7114_4.

¹⁵ “A.M. Best Special Report: U.S. Health Insurance Industry Earnings Up 46% in 2016,” June 15, 2017: <http://www3.ambest.com/ambv/bestnews/presscontent.aspx?refnum=25374&altsrc=23>.

¹⁶ “Profits are booming at health insurance companies,” May 24, 2017: <https://www.axios.com/profits-are-booming-at-health-insurance-companies-1513302495-18f3710a-c0b4-4ce3-8b7f-894a755e6679.html>.

¹⁷ Bruce Japsen, “Rising Insurer Profits Boost Obamacare's Long-Term Prospects,” November 12, 2017: <https://www.forbes.com/sites/brucejapsen/2017/11/12/rising-insurer-profits-boost-obamacare/#4001f9fc7b9a>

¹⁸ “Dr. Marc Siegel: Health insurers earn billions, while patients and doctors suffer under ObamaCare,” October 27, 2017: <http://www.foxnews.com/opinion/2017/10/27/dr-marc-siegel-health-insurers-earn-billions-while-patients-and-doctor-suffer-under-obamacare.html>,” and Chris Larson, “Humana has billions in cash on hand — did Obamacare really hurt that much?” *Louisville Business First*, July 25, 2017: <https://www.bizjournals.com/louisville/news/2017/07/25/humana-has-billions-in-cash-on-hand-did-obamacare.html>.

AARP's contractual relationship with United indicates AARP may share responsibility for United benefit designs that have directly impacted the prices some Oregonians pay for brand drugs. As of the end of December 2016, the number of Americans on AARP/United Medicare Supplement Insurance Plans exceeded 4 million.¹⁹ The scope of AARP's involvement in the Medicare program and the substantial financial benefits AARP derives from its health insurance ventures (see graph) create in itself an insurmountable conflict of interest between AARP and Oregonian consumers.

AARP Services, Inc. ("ASI"),²⁰ a wholly-owned for profit subsidiary of AARP, is primarily an insurance business that derives a substantial share of its \$880 million in revenue from its business partnerships with United²¹ and The Hartford.²² For the year ended December 31, 2016, AARP processed \$10.3 billion of premium payments paid by member participants for group health insurance and other health-related products and services available to AARP, Inc. members.²³

The service provider United accounted for approximately 68% of total royalties earned in 2016 (\$880.15 million)— or about \$598.5 million.²⁴ In 2016, AARP also derived \$46



¹⁹ https://www.aarpsupplementalhealth.com/content/dam/uhcmedsupstats/claim-substantiation-reports/WB26166ST_ORC_report_2017.pdf.

²⁰ AARP created ASI in 1999 pursuant to a settlement agreement with the U.S. Internal Revenue Service ("IRS") resulting from an investigation by the IRS into the large amount of income that AARP, Inc., a "non-profit" tax exempt organization, earned through its business deals with for-profit businesses.

²¹ AARP markets three types of United Medicare-related insurance: Part D prescription drug insurance, Medicare Advantage, and Medigap. United Medicare premiums are collected by AARP Insurance Plan ("AARP Trust"), a grantor trust organized by AARP, Inc. AARP Trust is the vehicle through which AARP, Inc. collects, invests and remits premium payments for AARP United Medicare policies. The AARP Trust also collects a 4.95% commission.

²² The AARP Automobile & Homeowners Insurance Program has been underwritten since 1984 by Hartford Fire Insurance Company and its affiliates. In 2017, The Hartford derived \$3.1 billion in underwritten premiums from AARP policies—or 86% of its Personal Line and 33% of its combined Personal and Commercial Lines.

²³ "Consolidated Financial Statements Together with Report of Independent Certified Public Accountants: December 31, 2016 and 2015," Note 3, p.14.

²⁴ See "Consolidated Financial Statements Together with Report of Independent Certified Public Accountants: December 31, 2016 and 2015," Note 2, p.11: https://www.aarp.org/content/dam/aarp/about_aarp/about_us/2017/2016-financial-statements-AARP.pdf. Insurance products are offered through AARP Services, a wholly-owned taxable subsidiary of AARP. See also Charles Elmore, "AARP gets \$762M from royalties. Do seniors get best insurance deal?" *Palm Beach Post*, November 30, 2015: <https://www.palmbeachpost.com/business/personal-finance/aarp-gets-762m-from-royalties-seniors-get-best-insurance-deal/BT6vDwMx2khlP2Klp06u4O/>.

million from investment income generated by health insurance premiums collected by AARP.²⁵ AARP revenue from the health insurance and other health-related products and services consumed by its members for 2016 thus amounts in total to \$644.5 million—40.2% of AARP total operating revenues (\$1.604 billion in 2016) are thus generated by AARP insurance business with United.

*AARP's choice to partner with United, which has been frequently criticized for anti-consumer behaviors, further undermines any claim an AARP lobbyist might make to represent consumers.*²⁶

United has been accused of using its association with AARP to increase premiums on products aimed at seniors, even when these products are no better than their cheaper counterparts. The AARP reputation gives seniors a false sense of value and quality, even when there is little difference in services and AARP co-branded products have higher premiums.²⁷ Consumers are currently suing AARP for misleading business practices in California,²⁸ Connecticut²⁹ and Florida,³⁰ alleging AARP has breached insurance laws by calling brokerage revenues 'marketing royalties.'

Significantly, AARP/ASI's involvement with United Medicare plans extends to control over plan management and benefit design, which may thus directly involve AARP in any lawsuit filed by consumers against United regarding drug pricing.

Benefit design directly involves AARP in increasing the prices consumers pay for prescription drugs when United Medicare plans' benefit designs link patient obligations to rising list prices, not commercial payers' much lower cost net of manufacturer rebates. This rebate capture enterprise is at the core of the RICO scheme alleged in T1DF's lawsuits.

AARP's relationship with United is not limited to collecting royalties. United's obligations under the three contracts governing United's marketing and sale of AARP branded Medigap, Medicare Advantage, and Medicare Part D policies detail AARP and ASI's extensive influence over United's involvement in for-profit business

²⁵ Medicare premiums collected by AARP are subsequently remitted to the third-party insurance carriers, but United gives AARP the right to retain any gains on those investments. In 2016, net investment income amounted to \$45,766,000. See "Consolidated Financial Statements Together with Report of Independent Certified Public Accountants: December 31, 2016 and 2015," Note 3, p.14.

²⁶ See, e.g., American Association for Justice, "The Ten Worst Insurance Companies in America" (2008), and Mary Williams Walsh, "United Health Overbilled Medicare by Billions, US Says in Suit," *The New York Times*, May 19, 2017.

²⁷ American Association for Justice, "The Ten Worst Insurance Companies in America" (2008), p. 19

²⁸ Robert Kahn, "Class Accuses AARP of Elder Financial Abuse," *Courthouse News*, November 20, 2017: <https://www.courthousenews.com/class-accuses-aarp-elder-financial-abuse/>

²⁹ Mike Stankiewicz, "UnitedHealth, AARP sued for diverting \$400M a year to illegal rebates," *FierceHealthcare*, May 10, 2018: <https://www.fiercehealthcare.com/payer/unitedhealth-aarp-sued-diverting-400m-a-year-to-illegal-rebates>.

³⁰ *Sacco v. AARP et al.*, Case 2:18-cv-14041-JEM (Feb. 8, 2018).

activities, most notably in the Medigap business, and several instances in which United is required to take specific actions, beyond making “royalty” payments, to the benefit of AARP.³¹

AARP also acts in the role of quality control contractor and overseer of United’s operations, as those relate to Medigap, Medicare Advantage, and Medicare Part D. ASI must approve United’s appointments to the joint “Senior Leaders” team that oversees all aspects of performance under the contracts. No decision can be taken by the joint “Senior Leaders” team without AARP’s approval.

More critically, AARP, via ASI, has “consultation, review, and consent rights related to any proposed plan design changes” (emphasis added) including, but not limited to, premium levels and rates.³²

In Lane County, AARP, through its partnership with United, markets 17 co-branded Medicare plans.³³ At least some of these AARP/United Medicare plans currently overcharge AARP members by using inflated list prices (not payers’ net rebated cost) as the basis for beneficiary cost-sharing in Medicare Part D—e.g. \$275.20 to \$293.80 as the basis of consumer cost-sharing for a 10 ml vial of Humalog.³⁴ Payers’ net price for the same 10 ml vial of Humalog insulin may be as low as \$47.20 per vial (based on Veterans’ Administration schedules and manufacturer-reported average net prices).³⁵

United is named as a defendant in three putative class action lawsuits on the pricing of insulin, glucagon, and test strips filed by the Type 1 Diabetes Defense Foundation in early 2017 and currently pending in New Jersey

³¹ December 21, 2011, Letter from the Ways and Means Committee to the IRS, available at: https://waysandmeans.house.gov/UploadedFiles/Letter_to_IRS-Shulman_12-15-11.pdf. The letter concludes that “AARP has extensive decision making authority and is deeply involved in United’s business operations.”

³² See, e.g., *Sacco v. AARP et al.*, Case 2:18-cv-14041-JEM (Feb. 8, 2018), p. 12. Available at: <https://www.truthinadvertising.org/wp-content/uploads/2018/02/Sacco-v-AARP-complaint.pdf>. On October 15, 2013, AARP and United announced that they were extending the Agreement to run through December 2020. See statement at: <https://www.optum.com/about/news/unitedhealth-group-to-extend-broaden-its-relationship-with-aarp-to-focus-on.html>

³³ Part D prescription drug insurance and Medicare Advantage plans. See: <https://www.aarpmedicareplans.com/health-plans.html#plan-summary>. AARP Medigap is the dominant player in the Medigap market. Nationwide, over 32% of beneficiaries enrolled in a Medigap insurance plan were enrolled in AARP Medigap and the only Medigap plans insured by United, again the largest health insurer in the country, are AARP Medigap plans.

³⁴ 2018 Medicare Advantage copay guidelines provided for United’s “Oregon AARP® MedicareComplete® Plans” inform consumers that “Insulin and insulin syringes are covered under the Medicare Part D prescription drug benefit.” OR4AD spot checks of AARP/United’s Part D Drug Cost Estimator for Humalog in the “donut hole” and catastrophic phase: \$293.80 per 10 ml vial. A Lane County–specific spot check of AARP/United’s Part D costs for 10ml vial of Humalog yielded \$275.20. See <https://www.uhcprovider.com/content/provider/en/viewer.html?file=%2Fcontent%2Fdam%2Fprovider%2Fdocs%2Fpublic%2Fhealth-plans%2Fmedicare%2FMA-Copayment-Guidelines.pdf> and <https://www.uhcprovider.com/en/health-plans-by-state/oregon-health-plans/or-medicare-plans/or-aarp-medicarecomplete-plans.html>. That same vial is currently priced in Oregon by OPDP at \$271 (before rebates but including pharmacy dispensing fee).

³⁵ See T. Joseph Mattingly et al, “How do Manufacturer Net Prices Compare with Other Common US Price References?” *PharmacoEconomics* <https://doi.org/10.1007/s40273-018-0667-9> (May 12, 2018): <https://link.springer.com/content/pdf/10.1007/s40273-018-0667-9.pdf>.

federal court.³⁶ Medicare Part D beneficiaries are among these lawsuits' named plaintiffs, potentially implicating AARP in liability for the injuries alleged against United in these consumer actions. The T1DF lawsuits focus on payers' (with their PBM agents') failure to pass through to consumers in the form of reduced point-of-sale prices the rebates and other price concessions that insurers receive from manufacturers. With AARP partner United and consumers as adverse parties in pending actions in federal district court, an AARP lobbyist would be required to advocate for his employer's interests in any evaluation of factors affecting drug pricing; any statement from Mr. Bartholomew to this Task Force that advanced patients' interests against payers' could potentially be used against United and/or AARP in current or future legal action.

Mr. Bartholomew's professional relationship to AARP, and thus to United, is an insurmountable conflict of interest and he should immediately resign from this Task Force. You must, in any event, recognize that Mr. Bartholomew cannot serve in the role of "consumer representative" and name an independent consumer representative to replace him in this role.

Naming as "consumer representative" a lobbyist from an organization that derives 37.3% of its total operating revenues from an insurance company currently sued for inflating prices on insulin and other pharmaceuticals is an insult to hundreds of thousands of Oregonians who desperately need relief from the high list prices they now pay for prescription drugs—including the many who now pay those prices solely due to their health insurers' discretionary benefit design.

Using this Task Force and the state's regulatory authority to hold insurers and OPDP responsible for basing patient cost-sharing on commercial payers' actual net cost—as state and federal laws likely already require them to do—would immediately save lives and right a wrong that has been ignored for far too long. Instead, you are making the problem worse by skirting HB 4005's statutory requirements to balance representation on this Task Force and, yet again, giving more power to the overwhelmingly profitable health insurance companies, their executives,³⁷ and business partners like AARP.

You have failed to comply with HB 4005's statutory requirement in Section 11(2)(D)(v) to name an individual representing consumers to the Joint Interim Task Force On Fair Pricing of Prescription Drugs. Nominating as "consumer representative" to this Task Force on fair pricing the chief lobbyist from AARP, an entity that currently directly benefits from price gouging of retired Oregonians via United adds insult to the injury already sustained by under- and uninsured Oregonians who are forced to compromise their health thanks to high drug prices sustained in part by decisions made by AARP and its partner United.

³⁶ The T1DF class actions against United, among other defendants, include: (1) *Boss, et al. v. CVS Health Corp. et al.* (analog insulin), filed in United States District Court, District of New Jersey, No. 3:17-cv-01823-BRM-LHG and consolidated under *In re Insulin Pricing Litigation*, No. 3:17-cv-00699-BRM-LHG, in December 2017. A motion for reconsideration of the consolidation order was filed in March 2018 to initiate a parallel litigation track against insurers and their PBM agents (pending). See <https://www.t1df.org/projects/> and Mary Caffrey, "Out-of-Pocket Costs for Insulin Are a Problem. Litigants in Case Disagree on Who Is at Fault," AJMC March 22, 2018: <https://www.ajmc.com/newsroom/out-of-pocket-costs-for-insulin-are-a-problem-litigants-in-case-disagree-on-who-is-at-fault>. (2) *Bewley, et al. v. CVS Health Corporation, et al.* (glucagon), United States District Court, District of New Jersey, No. 3:2017-cv-12031-BRM-LHG. ON test strips; and (3) *Prescott, et al. v. CVS Health Corporation, et al.* (test strips) United States District Court, District of New Jersey, No. 3:2017-cv-13066-BRM-LHG.

³⁷ United former CEO William McGuire, who orchestrated the lucrative deal with AARP in 1998, left United with \$800 million in stock options and \$530 million in compensation. American Association for Justice, "The Ten Worst Insurance Companies in America" (2008), p. 18.

This appointment is not only a breach of the letter of HB 4005, it once again privileges powerful corporate interests over the lives of the most vulnerable Oregonians, including retirees, people on high-deductible and high cost-sharing plans, the uninsured, and the undocumented immigrants for whom OPDP might be the only available prescription drug program.

Oregon is facing simultaneous crises over education, housing, PERS, a lack of living-wage jobs and access to affordable pharmaceuticals. Under- and uninsured rates are going back up, especially in rural counties. Uninsurance was highest in traditionally Republican frontier areas at 11.0%, nearly double the uninsurance rate in Democrats' urban stronghold (5.8%). Oregon Health Authority and Moda Health were supposed to offer these uninsured Oregonians access to the same net low prices for prescription drugs that commercial insurers negotiate for themselves—they are instead overcharging individual discount card holders while exclusively passing the manufacturer rebates Moda and OPDP obtain to Moda's plans offered to public employees and union members.

To make this rigged healthcare system work for under- and uninsured Oregonians, we need principled leadership from politicians who will put Oregonians' needs first. A vague constitutional amendment³⁸ mandating that Oregon ensures access to “cost-effective... and affordable health care as a fundamental right” will remain totally ineffective if your administration continues to let health insurers and OPDP/Moda Health define “cost-effectiveness” and “affordability” on their own terms. Far too many Oregonians remain uninsured, or insured but unable actually to afford health services and the inflated, unrebated list prices for prescription drugs that insurers now incorporate into many health plan designs.

What the Poor People's Campaign has defined as “the attention violence that refuses to see these injustices and acknowledge the human and economic costs of inequality”³⁹ is nowhere more troubling than in this wholly preventable prescription drug pricing crisis. Here the imperative health needs of individuals, and the longterm economic interests of society, are both served by making prescription drugs affordable at the point of sale, particularly when those drugs are already available to commercial insurers at very low net cost. And that “attention violence” can be expressed in no more troubling way than by denying patients who are dying for lack of access to medicine even their statutory right to representation on a Task Force dedicated to the fair pricing of prescription drugs.

Your appointment of a lobbyist for the “market leader in Medicare” as a ‘consumer representative’ is an issue that strikes to the core of Oregon's deepening social crisis. Mr. Bartholomew should now recuse himself as consumer representative and resign his position on the Task Force. And you should now finally bring a genuine patient and consumer voice to Oregon's conversation on drug pricing.

Regards,



Julia Boss
Director

Oregonians for Affordable Drug Prices Now

³⁸ Oregon House Joint Resolution 203.

³⁹ <https://www.poorpeoplescampaign.org/demands/>